Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 3490

Corresponding Measures:

Measure Title: Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

Measure Steward: Centers for Medicare & Medicaid Services

sp.02. Brief Description of Measure:

The Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure, hereafter referred to as the chemotherapy measure, was developed to assess the quality of care provided to cancer patients receiving outpatient chemotherapy and inform quality improvement efforts to reduce potentially preventable inpatient hospital admissions and ED visits for this population.

The target population for this measure is Medicare Fee-for-Service (FFS) patients aged 18 years or older with a diagnosis of cancer who received chemotherapy treatment in a hospital outpatient setting. The measure evaluates two outcomes: inpatient admissions and ED visits (including observation stays) occurring within 30 days of any chemotherapy treatment. The measure calculates the two rates separately because the severity and cost of an inpatient admission differs from those of an ED visit or stand-alone observation stay, but both adverse events are important signals of quality and represent outcomes of care that are important to patients.

The measure score is calculated for all HOPDs and reported for HOPDs with at least 25 cases and is calculated separately for PPS-exempt Cancer Hospitals (PCH-HOPDs) (11 in total) (hereafter referred to as PCH-HOPDs), and for HOPDs that are not PPS-exempt (hereafter referred to as non-PCH HOPDs).

1b.01. Developer Rationale:

Previous Submission

The primary purpose of this measure is to assess the extent to which cancer patients receiving outpatient chemotherapy treatment experience complications resulting in a hospital visit (either an inpatient admission or ED visit). By identifying these events, the measure seeks to encourage quality improvement across facilities to reduce the number of potentially avoidable inpatient admissions and ED visits and increase transparency in the quality of care patients receive. The measure is envisioned to promote effective communication and coordination of care, which is both a Meaningful Measures quality category and a National Quality Strategy priority. It also meets an additional National Quality Strategy priority of promoting the most effective prevention and treatment practices for the leading causes of mortality.

Chemotherapy treatment can have severe, predictable side effects, which, if inappropriately managed, can reduce patients' quality of life and increase healthcare utilization and costs. On average, cancer patients receiving

chemotherapy have one hospital admission and two ED visits per year; approximately 40 percent of these admissions, and 50 percent of these ED visits stem from complications of chemotherapy, respectively [1]. The literature suggests that ten symptoms in particular –anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis –are primary reasons for hospital visits among cancer patients receiving chemotherapy, and are potentially avoidable with proper outpatient management [3 - 5]. Improved management of these symptoms, through improved adherence to clinical treatment guidelines and enhanced care coordination, has been shown to reduce admissions and ED visits and increase patients' quality of care and quality of life [2] [3] [4].

Admissions and ED visits are costly to payers, with one study estimating that, on average, those experiencing chemotherapy-related adverse events incurred $12,907 in additional hospitalization expenditures per person per year [6]. In addition to increased cost to payers, unplanned admissions and ED visits related to chemotherapy treatment reduce cancer patients' quality of life. Measuring potentially avoidable admissions and ED visits for cancer patients receiving outpatient chemotherapy will provide hospitals with an incentive to improve the quality of care for these patients, by taking steps to prevent and better manage side effects and complications from treatment. Hospitals that provide outpatient chemotherapy should implement appropriate care to minimize the incidence of these adverse events and the subsequent need for acute hospital care.

Evidence suggests that coordination of care and better management of these symptoms in the outpatient setting can decrease hospital visits among patients receiving chemotherapy. Studies have indicated that in outpatient settings, where established guidelines are not properly followed and structured protocols are not put into place, there is a higher likelihood for adverse events [7] [8] [9]. This measure will encourage hospitals to use guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies with evidence-based interventions to prevent and treat common side effects and complications of chemotherapy [10]. This risk-standardized measure seeks to increase transparency in the quality of care patients receive, and to provide information to help physicians and hospitals mitigate patients' need for acute care, which can be a burden on patients, and increase patients' quality of life [11 – 12].

Citations

1. Vandervelde A, Miller H, Younts J. Impact on Medicare payments of shift in site of care for chemotherapy administration. Washington, DC: Berkeley Research Group; June 2014. http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf. Accessed September 16, 2015

2. Burke, T.A., Wisniewski, T., and Ernst, F.R. "Resource utilization and costs associated with chemotherapy-induced nausea and vomiting (CINV) following highly or moderately emetogenic chemotherapy administered in the US outpatient hospital setting." Supportive Care in Cancer, vol. 19, 2011, pp. 131-141.

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12. Wu, H.S., T. Natavio, J.E. Davis, and H.N. Yarandi. "Pain in Outpatients Treated for Breast Cancer: Prevalence, Pharmacological Treatment, and Impact on Quality of Life." Cancer Nursing, vol. 36, no. 3, 2013, pp. 229–235. Available at http://www.cancernursingonline.com/. Accessed September 24, 2012.

Current submission

The information provided in the prior submission remains applicable. Below we provide an update to the literature on the relevance and need for this measure.

The global prevalence of cancer is rapidly increasing and will increase the acute care needs of cancer patients. Recent population-based estimates suggest that 4% of all ED visits are cancer-related, and about two-thirds result in hospitalization [1]. Approximately 44% of cancer patients visit the ED within one year of diagnosis, and most have repeat ED visits within a short time. In a 2019 study, more than 50% of cancer patients who visited the ED experienced an inpatient admission or observation stay [2].

Oncology patients disproportionately utilize the ED for symptom management. A 2019 multicenter study also found a high prevalence of pain (about 60% of patients with cancer who visited the ED) and nausea (about 30% of patients) and noted opportunities for improving outpatient care among these patients. A 2021 study in older patients and a small single-center study found similar results in terms of prevalence [3, 4] and preventability of symptoms.

Taken together, the updated literature supports the continued relevance and rationale for this measure.

References:

1. Lash, R.S., Hong, A.S., Bell, J.F. et al. Recognizing the emergency department's role in oncologic care: a review of the literature on unplanned acute care. Emerg Cancer Care 1, 6 (2022). https://doi.org/10.1186/s44201-022-00007-4
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3. Loerzel VW, Hines RB, Deatrick CW, Geddie PI, Clochesy JM. Unplanned emergency department visits and hospital admissions of older adults under treatment for cancer in the ambulatory/community setting. Support Care Cancer. 2021 Dec;29(12):7525-7533. doi: 10.1007/s00520-021-06338-y. Epub 2021 Jun 9. PMID: 34105026.
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sp.12. Numerator Statement: The Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure provides facilities with information to improve the quality of care delivered for patients undergoing outpatient chemotherapy treatment. The measure calculates two mutually exclusive

outcomes: (1) one or more inpatient admissions for anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis within 30 days of chemotherapy treatment and (2) one or more ED visits or stand-alone observation stays for any of the same 10 diagnoses within 30 days of chemotherapy treatment. These 10 listed conditions are potentially preventable through appropriately managed outpatient care. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

sp.14. Denominator Statement: The target population for this measure is Medicare Fee-for-Service (FFS) patients aged 18 years or older at the start of the performance period with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting.

sp.16. Denominator Exclusions:

The measure excludes:

1. Patients with a diagnosis of leukemia at any time during the performance period.

   Rationale: We exclude patients with leukemia from the measure cohort because the high toxicity of treatment and recurrence of disease leads to admissions among this population that do not reflect the quality of outpatient care. Patients with leukemia have a higher expected admission rate due to frequent relapse, which is not the type of admission the measure intends to capture.

2. Patients who were not enrolled in Medicare FFS Parts A and B in the year before any outpatient chemotherapy treatment during the performance period.

   Rationale: The measure excludes these patients to ensure that complete patient diagnosis data will be available for the risk-adjustment model, which uses the year before the first chemotherapy treatment during the period to identify comorbidities.

3. Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the treatment.

   Rationale: The measure excludes these patients to ensure that full data will be available for outcome assessment.

4. Cases in which patients receive chemotherapy to treat conditions other than cancer such as treatment of auto-immune diseases.

   Rationale: The measure is intended to assess the quality of care provided to cancer patients receiving outpatient chemotherapy.

Measure Type: Outcome

sp.28. Data Source:

Claims

Enrollment Data

Other (specify)

Enrollment Data

sp.07. Level of Analysis:

Facility

IF Endorsement Maintenance – Original Endorsement Date: 2019-06-10 02:11 PM

Most Recent Endorsement Date: 6/10/2019 2:11:51 PM

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

sp.03. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?:

1. Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria

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1ma.01. Indicate whether there is new evidence about the measure since the most recent maintenance evaluation. If yes, please briefly summarize the new evidence, and ensure you have updated entries in the Evidence section as needed.

[Response Begins]

Yes

[Yes Please Explain]

We have updated the Evidence section to include additional studies that examine the preventability of hospital visits for patients with cancer, as well as updates to the literature showing opportunities for reducing ED visits through better outpatient management. In addition, we provide literature on quality improvement efforts that have been put in place to reduce both inpatient visits and ED visits for cancer patients. Finally, we refer readers to the validity and improvement sections of this submission, which describe improvement in facility-level measure scores between 2019 and 2021, for both PCH and non-PCH-HOPDs.

[Response Ends]

Please separate added or updated information from the most recent measure evaluation within each question response in the Importance to Measure and Report: Evidence section. For example:

Current Submission:

Updated evidence information here.

Previous (Year) Submission:

Evidence from the previous submission here.

1a.01. Provide a logic model.

Briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

[Response Begins]

Previous Submission

Figure A: Logic model for the chemotherapy measure.

Current Submission

Please see the flowchart above.

[Response Ends]

1a.02. Provide evidence that the target population values the measured outcome, process, or structure and finds it meaningful.

Describe how and from whom input was obtained.

[Response Begins]

Previous Submission

This was not a question in the previous submission.

Current Submission

Evidence from patient activists on the original measure developer's Technical Expert Panel (TEP), as well as evidence from the literature, support that patients value the measured outcome and find it meaningful. During measure development, the measure developer convened a 12-person TEP that included patient advocates who provided input on key methodological decisions, including the outcome. In addition, surveys of patients have shown that chemotherapy-induced adverse effects impact health-related quality of life [1, 2, 3], and patients substantially weight side effects of chemotherapy in their own decisions of whether to undergo chemotherapy treatment [4,5].

References:

1. Wagland R, Richardson A, Ewings S, Armes J, Lennan E, Hankins M, Griffiths P. Prevalence of cancer chemotherapy-related problems, their relation to health-related quality of life and associated supportive care: a cross-sectional survey. Support Care Cancer. 2016 Dec;24(12):4901-4911.

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[Response Ends]

1a.03. Provide empirical data demonstrating the relationship between the outcome (or PRO) and at least one healthcare structure, process, intervention, or service.

[Response Begins]

Previous Submission

To demonstrate the relationship between the measure outcome and current healthcare processes/services as they relate to chemotherapy care, we provide evidence that: (1) better management of these symptoms and enhanced coordination of care reduces outcome rates among patients receiving chemotherapy; (2) chemotherapy patients frequently seek emergency department (ED) care or experience inpatient hospital admissions due to the ten diagnoses/symptoms comprising the measure outcome; and (3) all ten symptoms can be managed in the outpatient setting using national clinical guidelines and established best care practices.

Improved Symptom Management and Coordination of Care Reduces Hospital Visits

Chemotherapy treatment can have severe, predictable side effects, and hospital admissions and ED visits among patients receiving treatment in a hospital outpatient setting are often caused by manageable side effects and complications. Improved management of these symptoms and coordination of care in the outpatient setting can decrease hospital visits among patients receiving chemotherapy.

Divergence from established guidelines for the use of antiemetic medications to manage chemotherapy-related nausea can result in adverse outcomes. A 2011 study identified great variability in the use of antiemetic medications to manage chemotherapy-related nausea. Most medications prescribed in this study did not follow the American Society of Clinical Oncology Guidelines, and researchers suggested that the low level of agreement between actual clinical practice and evidence-based consensus guidelines may be contributing significantly to the incidence of chemotherapy-related nausea and vomiting [1]. In another study, nonadherence to established, evidence-based guidelines for antiemetic medications were associated with increased occurrence of chemotherapy-induced nausea, and patients who received proper medications were much less likely to experience vomiting (6.6% v 21.9%; P < .001), emergency department visits (2.6% v 5.8%; P = .006), and hospitalization for emesis (0.9% v 4.9%; P < .001)[2]

Enhanced care coordination can also decrease hospital visits and ED visits among cancer patients receiving chemotherapy. According to a 2017 study, the implementation of a hospital-based, dedicated, supportive care service to monitor and assist outpatient chemotherapy patients with treatment-related symptoms showed decreases of 18.5% in unplanned hospital admissions (from 17.3% to 14.1%) and 7.6% in ED visits (from 66.0% to 61.0%), relative to the pre-implementation period [3]. The authors note that these decreases occurred even though outpatient chemotherapy volume increased by approximately 6.5% (from 1,275 to 1,358) during the study period. In a second study, routine symptom screening of breast cancer patients undergoing adjuvant outpatient chemotherapy was associated with a 43% decrease in ED visits relative to those who were not screened. For each additional prior symptom screening assessment, there was a further 17% decrease in the rate of ED visits [4].

Chemotherapy patients with access to enhanced electronic care monitoring systems also experience fewer hospital visits relative to those without access. According to a 2016 random control trial, patients who were able to report symptoms using tablet computers, which triggered an email alert to the clinical nurse and were summarized for review during clinic visits with the treating oncologist, had 17% fewer ED visits (from 41% to 34%; P = .02) and 8% fewer hospitalizations (from 49% to 45%; P = .08) relative to patients receiving usual symptom monitoring [5].

The introduction of additional hospital-based coordination and monitoring systems have also been associated with declines in adverse events among chemotherapy patients. At the University of Alabama at Birmingham Health System Cancer Community Network, patient navigators were assigned to high-risk cancer patients to improve their access to care, enhance coordination, and overcome barriers to obtaining timely, high-quality care [6]. The study authors found that relative to matched, non-navigated patients, those with a navigator had fewer emergency department visits (6.0% decrease), hospitalizations (7.9% decrease), and intensive care unit admissions (10.6% decrease). According to another study, utilization of an oncology management program that prioritizes survival, minimizing toxicity, and avoiding unnecessary healthcare, along with a telephonic nursing intervention – wherein oncology-certified nurses contacted, assessed, and educated patients in between treatments – resulted in decreases of 28.6% in ED visits (from 14% to 10%) and 25.0% in inpatient admissions (from 24% to 18%), relative to the control group [7].

Facility-wide, alternative delivery models focused on coordinating care can also improve the management of chemotherapy-related adverse events. According to a 2013 study examining breast cancer patients, patients who were treated at a facility using a patient-centered medical home delivery model were significantly less likely to experience an inpatient admission with chemotherapy-related adverse events compared to patients who were provided with usual care [8]. According to a second study, patients in an oncology medical home demonstration project had 68% fewer ED visits (0.07 relative to 0.22) and 47% fewer inpatient admissions (0.18 relative to 0.34) per patient relative to historical control data. The study's authors concluded that in addition to reducing hospital visits and reducing costs, the model encouraged adherence to national guidelines, advanced care planning, and standardized symptom management [9].

Reasons for Admissions and ED Visits among Cancer and Chemotherapy Patients

Admissions and ED visits for the ten diagnoses captured in the measure—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—are among the most common reasons that cancer patients receiving chemotherapy visit the hospital [10] [11-19].

The frequency of and reasons for hospital admissions and ED visits among cancer patients overall and among specific subpopulations of cancer patients receiving chemotherapy are well documented in the literature. An analysis by Rivera et al. of Nationwide Emergency Department Sample (NEDS) data from 2006 – 2012 determined that 4.2% of all ED visits (n = 29.5 million) were made by patients with cancer, and the most common primary reasons for these visits were pneumonia (4.5%), nonspecific chest pain (3.7%), and urinary tract infection (3.2%) [16]. Among visits where maintenance chemotherapy or radiotherapy was reported, the primary reasons for the visit were deficiency and other anemia (5.7%), fluid and electrolyte disorders (4.7%), nausea and vomiting (4.3%), diseases of white blood cells (3.3%), and fever of unknown origin (3.1%). A smaller assessment of ED visits among cancer patients living in North Carolina similarly found that the top 3 most frequent complaints were: (1) pain (chest pain, abdominal pain, back pain, extremity pain, other), (2) respiratory (respiratory distress/shortness of breath, cough, hemoptysis, fever/pneumonia, chronic obstructive pulmonary disease, or other), and (3) gastro-intestinal (nausea/vomiting, diarrhea, constipation, bowel obstruction, other) [13].

Additional studies focusing on specific populations of cancer patients receiving chemotherapy show similar results. Among breast cancer patients receiving chemotherapy, one study reported the most common reasons for hospital visits were fever or infection (8.4%), neutropenia or thrombocytopenia (5.5%), dehydration or electrolyte disorders (2.5%), nausea, emesis, or diarrhea (2.4%), and anemia (2.2%) [12], while a second study found that fever (23.3%), pain (12.8%), and febrile neutropenia (9%) were the most frequent reasons for hospital visits [15]. For colorectal cancer patients receiving chemotherapy, the majority of unplanned visits occurred within 30 days of treatment, and the most frequent complaints were pain, fatigue, and anorexia [10]. In another study of 233 cancer patients receiving chemotherapy who visited the hospital, the authors reported the most frequent symptoms were: nausea and/or vomiting (45.2%), pain (27%), fever and/or febrile neutropenia (23.4%), shortness of breath (19.3%), dehydration (12.1%), anemia (8.8%), fatigue (8.8%), diarrhea (8.8%), and anxiety and/or depression (5.5%) [14].

Furthermore, 70% of all hospital visits occurred within four weeks of receiving chemotherapy, and the majority (87.6%) resulted in hospital admission.

Guidelines to Support Outpatient Management of Measure Outcome Conditions/Symptoms

Treatment plans and guidelines exist to support the outpatient management of the ten conditions captured in the outcome. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies recommend evidence-based interventions to improve the quality of disease and symptom management [20] [21]. Proper management of symptoms associated with outpatient chemotherapy reduces the risk of admissions and ED visits for side effects and complications such as nausea and vomiting, anemia, and neutropenic fever [22] [23] [24]. Below we provide more detail on clinically proven treatment plans used to prevent and manage the side effects and symptoms of cancer and outpatient chemotherapy treatment that decrease the risk of admissions and ED visits.

Anemia: There are many therapeutic agents (e.g., epoetin beta) available to treat anemia, as well as clinical guidelines on how to prevent and manage anemia in patients receiving chemotherapy treatment [25] [26] [27].

Dehydration: Dehydration can be prevented by educating patients on the importance of fluid intake and monitoring patients that have reduced oral intake or appetite loss. Healthcare professionals should also closely monitor patients at risk for chemotherapy-induced diarrhea and vomiting for signs of dehydration [28].

Diarrhea: Providers can often treat chemotherapy-induced diarrhea on an outpatient basis, and effective treatment of diarrhea can prevent dehydration [28]. Existing evidence enables the management of diarrhea, and evidence about prevention continues to evolve as research focuses on identifying predictive factors of chemotherapy-induced diarrhea [29].

Nausea/emesis: Chemotherapy-induced nausea and emesis can be prevented and effectively managed in the outpatient setting [30]. Studies and reviews have shown the effectiveness of specific drugs (e.g., serotonin receptor antagonists, dexamethasone, and aprepitant) for the prevention and management of nausea and emesis resulting from particular chemotherapy regimens and their effects on quality of life [31] [30] [32] [33] [34] [35] [36].

Neutropenic fever: A systematic review and meta-analysis of randomized controlled trials concluded that prophylactic granulocyte colony-stimulating factors significantly reduce neutropenic fever [37]. Additionally, a 2017 update to the standard treatment guidelines published by the American Society of Clinical Oncology and Infectious Diseases Society of America Clinical Practice recommends the use of validated tools such as the Multinational Association of Support Care in Cancer Risk Index when determining candidacy for outpatient management of neutropenic fever [20].

Pain: A number of pharmacological treatments for pain exist, including opioids. However, many patients receive inadequate analgesia [38] [39]. Optimal pain control can be achieved by combining pharmacological and non-pharmacological approaches, in addition to assessing and reassessing patients' pain [40].

Pneumonia/Sepsis: The relationship between neutrophil count and the risk of infection is well established, and studies have shown that risk factors can be identified and appropriate prophylactic measures, such as the use of colony-stimulating factor, implemented to prevent neutropenia and associated complications [41]. Because of this relationship and the need for lab results to confirm neutropenia, neutropenia is often captured on the claim as a related infection, such as pneumonia and sepsis. The measure includes pneumonia and sepsis as outcomes to capture this population [37] [41].

Conclusion

We have shown that specific healthcare structures, processes, and services have a demonstrated relationship with the measure outcome. There is clear evidence that better management of the ten diagnoses/symptoms captured by this measure and enhanced coordination of care reduces the rate of inpatient admissions and ED visits among patients receiving chemotherapy. In addition, there is strong evidence that these ten symptoms are primary factors in chemotherapy patients seeking emergency department care or experiencing inpatient hospital admissions, indicating that the measure focus is appropriate and important for cancer patients receiving outpatient chemotherapy. Finally, established national clinical guidelines and best practices on appropriate care

underlying effective symptom management in the outpatient setting suggests that there are specific evidence-based interventions that will reduce hospital visits. This evidence supports the relevance and need for this measure.

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Current Submission

The previous submission section is still applicable. Below we provide an update to the literature that supports the relationship between the outcome and processes/structures.

Since the prior submission, several studies have examined the preventability of hospital visits in patients with cancer. For example, a 2018 study in a single state in a commercially insured population found that between 41% and 64% of ED visits due to cancer-related conditions could be considered preventable [1]. A small single-site study found about 44% of ED visits among cancer patients were preventable and that ED visits without a clinic appointment or phone call to the clinic on the day of ED presentation were more likely to be preventable [2]. A 2019 multicenter study found opportunities for better outpatient management of ED visits for pain and nausea, symptoms that were present in 62% and about 30% of their patient population, respectively [3].

Quality improvement efforts aimed at improving rates of hospital visits after chemotherapy underscore the link between processes and the outcome for this measure. For example, as described earlier, quality improvement programs have been put in place to improve patient care and reduce inpatient admissions following chemotherapy [4]; strategies that have been put in place include a screening algorithm to identify high-risk patients, providing actionable data back to clinicians providing patient care (including infusion nurses), standardizing symptom management and use of a 24/7 nurse on-call virtual center. Additional quality improvement projects have been launched that address the emergency room visit outcome [5]. In addition, in 2016, CMS's Center for Innovation (CMMI) launched the voluntary Oncology Care Model that requires participants to provide 24/7 access to a clinician with real-time access to patients' medical records [6]. Finally, as presented earlier, we found that facility-level performance on this measure between 2019 and 2021 substantially improved for both PCH and non-PCH-HOPDs.

Conclusion

Available evidence shows that there are specific processes that facilities can put in place to reduce hospital visits following chemotherapy treatment.

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[Response Ends]

1b.01. Briefly explain the rationale for this measure.

Explain how the measure will improve the quality of care, and list the benefits or improvements in quality envisioned by use of this measure.

[Response Begins]

Previous Submission

The primary purpose of this measure is to assess the extent to which cancer patients receiving outpatient chemotherapy treatment experience complications resulting in a hospital visit (either an inpatient admission or ED visit). By identifying these events, the measure seeks to encourage quality improvement across facilities to reduce the number of potentially avoidable inpatient admissions and ED visits and increase transparency in the quality of care patients receive. The measure is envisioned to promote effective communication and coordination of care, which is both a Meaningful Measures quality category and a National Quality Strategy priority. It also meets an additional National Quality Strategy priority of promoting the most effective prevention and treatment practices for the leading causes of mortality.

Chemotherapy treatment can have severe, predictable side effects, which, if inappropriately managed, can reduce patients' quality of life and increase healthcare utilization and costs. On average, cancer patients receiving chemotherapy have one hospital admission and two ED visits per year; approximately 40 percent of these admissions, and 50 percent of these ED visits stem from complications of chemotherapy, respectively [1]. The literature suggests that ten symptoms in particular –anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis –are primary reasons for hospital visits among cancer patients receiving

chemotherapy, and are potentially avoidable with proper outpatient management [3 - 5]. Improved management of these symptoms, through improved adherence to clinical treatment guidelines and enhanced care coordination, has been shown to reduce admissions and ED visits and increase patients' quality of care and quality of life [2] [3] [4].

Admissions and ED visits are costly to payers, with one study estimating that, on average, those experiencing chemotherapy-related adverse events incurred $12,907 in additional hospitalization expenditures per person per year [6]. In addition to increased cost to payers, unplanned admissions and ED visits related to chemotherapy treatment reduce cancer patients' quality of life. Measuring potentially avoidable admissions and ED visits for cancer patients receiving outpatient chemotherapy will provide hospitals with an incentive to improve the quality of care for these patients, by taking steps to prevent and better manage side effects and complications from treatment. Hospitals that provide outpatient chemotherapy should implement appropriate care to minimize the incidence of these adverse events and the subsequent need for acute hospital care.

Evidence suggests that coordination of care and better management of these symptoms in the outpatient setting can decrease hospital visits among patients receiving chemotherapy. Studies have indicated that in outpatient settings, where established guidelines are not properly followed and structured protocols are not put into place, there is a higher likelihood for adverse events [7] [8] [9]. This measure will encourage hospitals to use guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network, Oncology Nursing Society, Infectious Diseases Society of America, and other professional societies with evidence-based interventions to prevent and treat common side effects and complications of chemotherapy [10]. This risk-standardized measure seeks to increase transparency in the quality of care patients receive, and to provide information to help physicians and hospitals mitigate patients' need for acute care, which can be a burden on patients, and increase patients' quality of life [11 – 12].

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Current submission

The information provided in the prior submission remains applicable. Below we provide an update to the literature on the relevance and need for this measure.

The global prevalence of cancer is rapidly increasing and will increase the acute care needs of cancer patients. Recent population-based estimates suggest that 4% of all ED visits are cancer-related, and about two-thirds result in hospitalization [1]. Approximately 44% of cancer patients visit the ED within one year of diagnosis, and most have repeat ED visits within a short time. In a 2019 study, more than 50% of cancer patients who visited the ED experienced an inpatient admission or observation stay [2].

Oncology patients disproportionately utilize the ED for symptom management. A 2019 multicenter study also found a high prevalence of pain (about 60% of patients with cancer who visited the ED) and nausea (about 30% of patients) and noted opportunities for improving outpatient care among these patients. A 2021 study in older patients and a small single-center study found similar results in terms of prevalence [3, 4] and preventability of symptoms.

Taken together, the updated literature supports the continued relevance and rationale for this measure.

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[Response Ends]

1b.02. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.

Include mean, std dev, min, max, interquartile range, and scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Previous Submission

We assessed hospital-level performance scores using 100% national Medicare Fee-for-Service (FFS) claims and enrollment data for short-term acute hospitals (please see Measure Testing Attachment Section 1.2 and 1.7 for full description of the datasets used).

We estimated the measure score for hospitals using Medicare FFS claims with a performance period of October 1, 2015 to September 30, 2016. We estimated separate scores for qualifying patients receiving outpatient chemotherapy treatment at two facility types: (1) non-cancer hospitals included in calculations for the Outpatient Quality Reporting (OQR) program and (2) Prospective Payment System-Exempt Cancer hospitals (PCHs) participating in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) program. The total number of hospitals with at least one attributed patient was 3,562 in non-cancer hospitals and 11 in PCHs. The total number of patients meeting inclusion and exclusion criteria across these hospitals was 266,066 non-cancer hospital patients and 23,477 PCH patients.

The risk-standardized inpatient admission rate (RSAR) for non-cancer hospitals ranged from 8.9% to 18.5 % (median 12.5%, 25th and 75th percentiles are 12.2% and 13.0%, respectively) while the risk-standardized inpatient admission rate for PCHs ranged from 12.3% to 15.2% (median 13.7%, 25th and 75th percentiles are 13.4% and 14.8%, respectively).

The risk-standardized ED visit rate (RSEDR) for non-cancer hospitals ranged from 2.9% to 15.2% (median 5.6%, 25th and 75th percentiles are 5.6% and 6.2%, respectively) while the risk-standardized ED visit rate for PCHs ranged from 3.6% to 9.1% (median 6.7%, 25th and 75th percentiles are 4.4% and 8.9%, respectively).

The distributions of facility scores (RSARs for non-cancer and cancer hospitals, RSEDRs for cancer and non-cancer hospitals) are provided below.

Distribution of RSARs and RSEDRs for Non-Cancer and Cancer Hospitals

Non-Cancer RSAR (%)

Minimum: 8.9

1st: 10.2

5th: 11.1

10th: 11.6

25th: 12.2

50th (Median): 12.5

75th: 13.0

90th: 13.9

95th: 14.8

99th: 16.4

Maximum: 18.5

PCHs: RSAR (%)

Minimum: 12.3

1st: 12.3

5th: 12.3

10th: 13.4

25th: 13.4

50th (Median): 13.7

75th: 14.8

90th: 14.8

95th: 15.2

99th: 15.2

Maximum: 15.2

Non-Cancer RSEDR (%)

Minimum: 2.9

1st: 4.2

5th: 4.8

10th: 5.2

25th: 5.6

50th (Median): 5.6

75th: 6.2

90th: 6.8

95th: 7.4

99th: 8.6

Maximum: 15.2

PCHs: RSEDR (%)

Minimum: 3.6

1st: 3.6

5th: 3.6

10th: 4.1

25th: 4.4

50th (Median): 6.7

75th: 8.9

90th: 9.1

95th: 9.1

99th: 9.1

Maximum: 9.1

Current submission

Measure scores for each facility type and outcome are shown in the table below. These results use data from the 2022 EM Dataset, which includes performance data from Jan 1, 2021 – November 30, 2021. The distribution of measure scores shows a clear quality gap for both PCH and non-PCH HOPDs; see section 2b.06 for a detailed interpretation of the variation in measure scores.

*	PCH-HOPDs	PCH-HOPDs	Non-PCH HOPDs	Non-PCH HOPDs
Percentile	**RSARs (%)**	**RSEDRs (%)**	**RSARs (%)**	**RSEDRs (%)**
Minimum	**9.2**	**3.8**	**6.3**	**3**
1st	**9.2**	**3.8**	**7.2**	**3.9**
5th	**9.2**	**3.8**	**8.1**	**4.5**

*	PCH-HOPDs	PCH-HOPDs	Non-PCH HOPDs	Non-PCH HOPDs
10th	**10.5**	**4.2**	**8.5**	**4.7**
25th	**10.7**	**4.4**	**9**	**5**
50th (median)	**11.8**	**4.7**	**9.3**	**5.2**
75th	**13.2**	**5.6**	**9.7**	**5.4**
90th	**13.5**	**6.5**	**10.6**	**5.8**
95th	**14.1**	**6.9**	**11.4**	**6.3**
99th	**14.1**	**6.9**	**12.8**	**7.1**
Maximum	**14.1**	**6.9**	**18.6**	**9.1**

Table A: Distribution of RSARs and RSEDRs for PCH- and Non-PCH HOPDs

*cell intentionally left empty

[Response Ends]

1b.03. If no or limited performance data on the measure as specified is reported above, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement. Include citations.

[Response Begins]

Not applicable, performance data provided above demonstrating gap.

[Response Ends]

1b.04. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.

Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included. Include mean, std dev, min, max, interquartile range, and scores by decile. For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b) under Usability and Use.

[Response Begins]

Previous Submission

Please note that the following describes disparities analyses performed in 2018 using updated measure specifications. For a description of methods and results of the original disparities analyses performed in 2016 please see the testing attachment.

Our analysis of disparities examined the impact of social risk factors on the measure score. We evaluated two indicators of social risk: 1) race, specifically African-American or not and 2) the Agency for Healthcare Research and Quality (AHRQ) Socio-Economic Status (SES) Composite index, which was derived from January 2009 – December 2013 American Community Survey (ACS) data. The AHRQ SES Composite index score is calculated using 7 different variables which generally represent the socio-economic well-being of populations within each zip code in the ACS data. These variables are: (1) median household income, (2) percentage of persons living below the federal poverty level, (3) percentage of persons who are aged >16 years and in the labor force but not employed, (4) median value of owner-occupied homes, (5) percentage of persons aged >25 years who completed at least a 12th grade education, (6) percentage of persons aged >25 years who completed at least four years of college, and (7)

percentage of households that average one or more persons per room. SES composite scores range from 0 to 100 with higher scores indicating higher socio-economic well-being and lower scores indicating lower socio-economic well-being. An SES score of below 42.7 is considered "low" socio-economic well-being for the purpose of this analysis. Dual status was evaluated at the time of initial measure development as described in Section 2b3.4b of the Testing Attachment, but was not re-examined for the current measure specification (2018 reevaluation).

These data included 3,562 OPD facilities, 11 PCH facilities, and 289,543 unique patients. Our goal for these analyses were twofold: 1) to examine whether these factors were associated with increased risk in inpatient admissions and ED visits after adjusting for other risk factors and 2) to evaluate the impact of social risk factors on facility-level measure scores. Key findings are detailed below. We examined associations between outcomes and sociodemographic status (SDS) factors using both bivariate and multivariate analyses. At the patient-level, our analysis shows that "low SDS" patients (as characterized by two individual indicators: race as black and low AHRQ SES Composite Index) receiving hospital-based outpatient chemotherapy are more likely to have an inpatient admission and emergency department (ED) visit within 30 days than "non-low SDS" patients.

- Black patients are more likely to have an inpatient admission or ED visit than non-black patients (14.2 percent of black patients versus 12.6 percent of non-black for inpatient admission, and 7.6 percent of black patients versus 5.8 percent of non-black for ED visits)

- Low AHRQ SES Composite Index patients are more likely to have an inpatient admission or ED visit than higher SES Composite Index patients (14.4 percent of patients with low AHRQ SES Composite Index compared to 12.4 percent of patients with higher AHRQ SES Composite Index for inpatient admission, and 7.1 percent of patients with low AHRQ SES Composite Index versus 5.7 percent of patients with high AHRQ SES Composite Index for ED visits).

When evaluating the hospital-level, there was no significant impact of disparities on hospital-level measure scores. No clear relationship between the median risk-standardized rates and hospitals' case mix by these two SDS factors was observed. Additionally, the distributions of risk-standardized rates overlapped significantly across hospitals grouping by these two SDS factors, suggesting that hospitals caring for a greater percentage of low SDS patients have similar rates of inpatient admission and ED visits within 30 days of hospital-based outpatient chemotherapy. See Section 2b4.4b of the Testing Attachment, Section 2b4.4b and in the separate appendix titled "ChemoMeasure_NQF Appendix_SDS" for more information on the analysis and results.

Current submission

As described in section 2b.25, to explore the relationship between the hospitals' proportion of patients with social risk factors and measure scores, we compared measure score distributions for both outcomes across the four social risk factors (Tables B and C) stratified into quartiles of the proportion of patients with each social risk factor. For the RSAR, measure scores are slightly higher for Low AHRQ SES, DE, and Race, Black variables, but the distributions overlap. For the rural indicator, RSARs are slightly lower for the fourth quartile compared with the first quartile (Table B). For the RSER, measure scores are similar between the first and fourth quartiles for all except the rural variable; for the rural variable, RSERs are higher for the fourth quartile across the entire distribution (Table C).

Furthermore, as described previously in section 4a.01, in the Calendar Year (CY) 2022 OPPS Proposed Rule, CMS described a plan to perform stratified reporting of two disparity methods for this measure. The details of those methods are described in section sp.18, the results are described in section 2b.30, and additional information is provided in the attachment entitled "Disparity Methodology Report."

Social risk factor	Low AHRQ SES	Low AHRQ SES	DE	DE	Race, Black	Race, Black	Rural	Rural
Quartile for proportion of patients with social risk factor	Q1	Q4	Q1	Q4	Q1	Q4	Q1	Q4

Social risk factor	Low AHRQ SES	Low AHRQ SES	DE	DE	Race, Black	Race, Black	Rural	Rural
Number of facilities	370	368	370	369	394	368	368	368
Number of patients	52,054	45,626	58,686	52,408	28,934	80,497	67,528	41,037
RSAR	*	*	*	*	*	*	*	*
100% Max	14.7	18.6	15.5	18.6	15.2	14.1	14.7	16.1
90%	11.6	11.3	11.3	11.6	10.8	11.5	11.8	11.1
75% Q3	10.3	10.3	10.1	10.5	9.8	10.6	10.8	10.1
50% Median	9.3	9.5	9.2	9.6	9.1	9.6	9.7	9.3
25% Q1	8.6	8.7	8.5	8.8	8.6	8.7	8.8	8.6
10%	8.1	8.1	8.0	8.1	8.1	8.1	8.1	8.1
0% Min	6.7	7.0	6.3	6.3	6.8	7.0	6.4	6.6

Table B: Inpatient Admission (RSAR): Facility proportion of patients with SRFs comparing the 1st and 4th quartiles of patients with social risk factors

*cells intentionally left empty

Social risk factor	Low AHRQ SES	Low AHRQ SES	DE	DE	Race, Black	Race, Black	Rural	Rural
Quartile for proportion of patients with the social risk factor	Q1	Q4	Q1	Q4	Q1	Q4	Q1	Q4
Number of facilities	370	368	370	369	394	368	368	368
Number of patients	52,054	45,626	58,686	52,408	28,934	80,497	67,528	41,037
RSEDR	*	*	*	*	*	*	*	*
100% Max	7.7	9.0	7.7	9.0	9.0	7.7	7.2	9.1
90%	6.3	6.3	6.1	6.3	6.5	6.1	5.8	6.6
75% Q3	5.6	5.7	5.5	5.7	5.8	5.5	5.3	6.0
50% Median	5.2	5.2	5.1	5.2	5.4	5.0	4.9	5.5
25% Q1	4.8	4.8	4.7	4.8	5.0	4.7	4.6	5.1
10%	4.5	4.5	4.5	4.5	4.7	4.3	4.1	4.8
0% Min	3.0	3.5	3.0	3.2	3.7	3.2	3.0	4.1

Table C: ED Visit (RSEDR): Facility proportion of patients with SRFs comparing the 1st and 4th quartiles for proportion of patients with social risk factors

*cells intentionally left empty

[Response Ends]

1b.05. If no or limited data on disparities from the measure as specified is reported above, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in above.

[Response Begins]

Not applicable; performance data provided in above.

[Response Ends]

2. Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.

---

spma.01. Indicate whether there are changes to the specifications since the last updates/submission. If yes, update the specifications in the Measure Specifications section of the Measure Submission Form, and explain your reasoning for the changes below.

[Response Begins]

Yes

[Yes Please Explain]

Please see section spma.02 for the reasoning for the changes since the last submission, as well as additional information.

[Response Ends]

spma.02. Briefly describe any important changes to the measure specifications since the last measure update and provide a rationale.

For annual updates, please explain how the change in specifications affects the measure results. If a material change in specification is identified, data from re-testing of the measure with the new specifications is required for early maintenance review.

For example, specifications may have been updated based on suggestions from a previous NQF CDP review.

[Response Begins]

2021 Measure Updates:

- Removal of 11 codes from the denominator (cohort), addition of 1 code to the numerator (outcome), the addition of 19 codes to the denominator (cohort), and the addition of 81 codes to the Concurrent Radiotherapy risk variable.

  Rationale: Each year, as part of reevaluation of the measure, CMS reviews the measure's existing code set as well as updates to ICD-10, CPT®, and HCPCS coding guidelines to ensure that the measure's code set is up to date.

2020 Measure Updates:

- Update to code the measure at the procedure-level, not the claim-level.

  Rationale: Facilities do not necessarily bill every day, they bill monthly, or longer. This update ensures all individual chemotherapy treatments that are billed on the claim are adjusted for.

- Update to exclusion criteria to exclude all cases where chemotherapy was administered on the same date as hospital admission and during inpatient stays.

  Rationale: It would be uncommon for a patient to receive outpatient chemotherapy and then be admitted to the ER.

- Update to coding of number of chemotherapy treatments risk variable to include only chemotherapy treatments that meet inclusion criteria.

  Rationale: This better reflects the probability of experience in outcome in the 30 days following the event.

2019 Measure Updates:

- Addition of stand-alone observation stays to the ED-visit measure outcome.

  Rationale: It has become increasingly common for observation stays to be used in place of hospital admissions or ED visits. This rate already captured observation stays billed with an ED 2021 Measure Updates: Surgery, Chemotherapy, Colonoscopy 64 visit, so this update adds in a small portion billed separately. This update improved the measure's ability to capture all hospital visits that may indicate gaps in quality of care.
- Addition of four new four new cancer risk variables (anal cancer, bladder cancer, ovarian cancer, and pancreatic cancer) from existing, broader risk factor categories in both risk models.

  Rationale: Adding more specificity to cancer type in the risk models will account for patients with cancer types that may be more likely to experience an outcome and ensure that both models more accurately discriminate and predict facility performance.

[Response Ends]

sp.01. Provide the measure title.

Measure titles should be concise yet convey who and what is being measured (see What Good Looks Like).

[Response Begins]

Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

[Response Ends]

sp.02. Provide a brief description of the measure.

Including type of score, measure focus, target population, timeframe, (e.g., Percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year).

[Response Begins]

The Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure, hereafter referred to as the chemotherapy measure, was developed to assess the quality of care provided to cancer patients receiving outpatient chemotherapy and inform quality improvement efforts to reduce potentially preventable inpatient hospital admissions and ED visits for this population.

The target population for this measure is Medicare Fee-for-Service (FFS) patients aged 18 years or older with a diagnosis of cancer who received chemotherapy treatment in a hospital outpatient setting. The measure evaluates two outcomes: inpatient admissions and ED visits (including observation stays) occurring within 30 days of any chemotherapy treatment. The measure calculates the two rates separately because the severity and cost of an inpatient admission differs from those of an ED visit or stand-alone observation stay, but both adverse events are important signals of quality and represent outcomes of care that are important to patients.

The measure score is calculated for all HOPDs and reported for HOPDs with at least 25 cases and is calculated separately for PPS-exempt Cancer Hospitals (PCH-HOPDs) (11 in total) (hereafter referred to as PCH-HOPDs), and for HOPDs that are not PPS-exempt (hereafter referred to as non-PCH HOPDs).

[Response Ends]

sp.04. Check all the clinical condition/topic areas that apply to your measure, below.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Surgery: General*

[Response Begins]

Cancer

[Response Ends]

sp.05. Check all the non-condition specific measure domain areas that apply to your measure, below.

[Response Begins]

Care Coordination

Safety: Complications

[Response Ends]

sp.06. Select one or more target population categories.

Select only those target populations which can be stratified in the reporting of the measure's result.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Populations at Risk: Populations at Risk*

[Response Begins]

Adults (Age >= 18)

[Response Ends]

sp.07. Select the levels of analysis that apply to your measure.

Check ONLY the levels of analysis for which the measure is SPECIFIED and TESTED.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

sp.08. Indicate the care settings that apply to your measure.

Check ONLY the settings for which the measure is SPECIFIED and TESTED.

[Response Begins]

Outpatient Services

[Response Ends]

sp.09. Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials.

Do not enter a URL linking to a home page or to general information. If no URL is available, indicate "none available".

[Response Begins]

https://qualitynet.cms.gov/outpatient/measures/chemotherapy/methodology

[Response Ends]

sp.12. Attach the data dictionary, code table, or value sets (and risk model codes and coefficients when applicable). Excel formats (.xlsx or .csv) are preferred.

Attach an excel or csv file; if this poses an issue, contact staff. Provide descriptors for any codes. Use one file with multiple worksheets, if needed.

[Response Begins]

Available in attached Excel or csv file

[Response Ends]

Attachment: 3490_3490_3490_NQF3490_Chemotherapy_DataDictionary_Fall2022-508.xlsx

For the question below: state the outcome being measured. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.13. State the numerator.

Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome).

DO NOT include the rationale for the measure.

[Response Begins]

The Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy measure provides facilities with information to improve the quality of care delivered for patients undergoing outpatient chemotherapy treatment. The measure calculates two mutually exclusive outcomes: (1) one or more inpatient admissions for anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis within 30 days of chemotherapy treatment and (2) one or more ED visits or stand-alone observation stays for any of the same 10 diagnoses within 30 days of chemotherapy treatment. These 10 listed conditions are potentially preventable through appropriately managed outpatient care. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

[Response Ends]

For the question below: describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.14. Provide details needed to calculate the numerator.

All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

The chemotherapy measure is a risk-adjusted outcome measure and does not have a traditional numerator like a process measure; thus, we define here the measured outcomes of interest as this measure separately reports hospital rates of two outcomes: (1) inpatient admissions and (2) ED visits occurring within 30 days of any chemotherapy treatment. The measure calculates the two rates separately because the severity and cost of an inpatient admission differs from those of an ED visit or stand-alone observation stay, but both adverse events are important signals of quality and represent outcomes of care that are important to patients.

Inpatient Admissions

The first outcome is one or more inpatient admissions, including those that began with an observation stay, within 30 days of any chemotherapy treatment in an HOPD with either a:

1. Principal discharge diagnosis of any of 10 conditions – anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis; or
2. Principal discharge diagnosis of cancer and a secondary diagnosis of one of the same 10 conditions, on the same claim.

These 10 conditions are potentially preventable through appropriately managed outpatient care. The 2021 Chemotherapy Measure Data Dictionary shows the qualifying diagnosis codes for each of these conditions in the "Chemo Numerator" tab.

Inpatient admissions that are considered "always planned" do not qualify as outcomes for this measure. Planned admissions are defined as those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. CMS seeks to count only unplanned admissions in the measure outcome because variation in planned admissions does not reflect quality differences. For the chemotherapy measure, inpatient hospital admissions with the following Agency for Healthcare Research and Quality (AHRQ) Clinical Classification Software (CCS) procedures or diagnoses are considered always planned and do not qualify for the measure outcome.

Procedure CCS Categories Considered Always Planned

- AHRQ CCS 64 – Bone marrow transplant
- AHRQ CCS 105 – Kidney transplant
- AHRQ CCS 176 – Other organ transplantation (other than bone marrow corneal or kidney)

Diagnosis CCS Categories Considered Always Planned

- AHRQ CCS 45 – Maintenance chemotherapy; radiotherapy
- AHRQ CCS 254 – Rehabilitation care; fitting of prostheses; and adjustment of devices

ED Visits

The second outcome is any ED visit within 30 days of any chemotherapy treatment with the same ten qualifying diagnoses listed for the inpatient admissions outcome (anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis) either in the principal diagnosis position or as a secondary diagnosis with cancer as principal diagnosis.

The ED visits outcome includes ED visits that were billed alone, with observation stays, or as stand-alone observation stays. Stand-alone observation stays are defined as observation stays in which either the patient (1) was discharged without being admitted as an inpatient or (2) did not have an ED visit on the same claim. The measure groups ED visits with or without observation stays and stand-alone observation stays into a single ED Visit outcome. The measure only assesses ED visit outcomes for patients who did not experience a qualifying inpatient admission.

Multiple Events

A patient can experience only one qualifying outcome event. If the patient experiences a qualifying inpatient admission following the first treatment and a qualifying ED visit following the second treatment, the patient qualifies only for the inpatient admission outcome. As a result, the rates provide a comprehensive performance estimate of patients' quality of care following hospital-based outpatient chemotherapy treatment.

Outcome Time Frame

The measure limits the outcome time frame to the 30 days (including the day of treatment) following the date of each chemotherapy treatment in an outpatient setting for four reasons:

1. Existing literature suggests that most adverse events occur within 30 days after treatment, indicating that a 30-day period is a reasonable time frame to observe the side effects of treatment.
2. We observed that the highest rates of hospital visits occur within 30 days after chemotherapy treatment.
3. Restricting the time frame links patients' experiences more closely to the hospitals that provided their recent treatment while accounting for variations in duration between outpatient treatments.
4. Relating the timeframe to a specific chemotherapy administration supports the idea that the admission stems from the management of side effects of treatment and ongoing care, rather than the progression of disease or other unrelated events.

Outcome Identification and Counting

Outcomes are identified using Medicare Part A Inpatient and Part B Outpatient hospital claims. The qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer. The ICD-10-CM codes that identify these diagnoses are in the Data Dictionary on sheets "S.6 Numerator-Anemia," "S.6 Numerator-Dehydration," "S.6 Numerator-Diarrhea," "S.6 Numerator-Emesis," "S.6 Numerator-Fever," "S.6 Numerator-Nausea," "S.6 Numerator-Neutropenia," "S.6 Numerator-Pain," "S.6 Numerator-Pneumonia," and "S.6 Numerator-Sepsis." The ICD-9 codes were used during development and testing of the measure; the Data Dictionary also includes the mapping from these ICD-9 codes to ICD-10 codes.

References

Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study. Supportive Care in Cancer, vol. 21, no. 2, 2013, pp. 397–404.

Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case- Crossover Study. Supportive Care in Cancer, vol. 22, no. 9, 2014, pp. 2527–2533.

McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study. Supportive Care in Cancer, vol. 19, no. 7, 2011, pp. 963–969.

Oatley, M., M. Fry, and L. Mullen. A Cross-Sectional Study of the Clinical Characteristics of Cancer Patients Presenting to One Tertiary Referral Emergency Department. International Emergency Nursing, vol. 24, 2016, pp. 35 – 38.

Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE). Centers for Medicare & Medicaid Services (CMS), 2021, pp. 1–70, 2021 Measure Updates and Specifications Report Hospital Outpatient Quality Reporting Program.

[Response Ends]

For the question below: state the target population for the outcome. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.15. State the denominator.

Brief, narrative description of the target population being measured.

[Response Begins]

The target population for this measure is Medicare Fee-for-Service (FFS) patients aged 18 years or older at the start of the performance period with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting.

[Response Ends]

For the question below: describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in sp.22.

sp.16. Provide details needed to calculate the denominator.

All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets.

Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Chemotherapy Measure Inclusion Criteria

The target population for this measure is Medicare FFS patients aged 18 years or older at the start of the performance period with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting.

The measure includes patients meeting the following criteria:

- Patients who are aged 18 years or older at the start of the performance period;
- Patients with a cancer diagnosis; and
- Patients receiving chemotherapy in an outpatient setting.

Cancer diagnoses are identified using International Classification of Disease, Tenth Revision diagnosis (ICD-10-CM) codes from inpatient, outpatient, or Part B claims during the performance period (see the 2021 Measure Updates:

Surgery, Chemotherapy, Colonoscopy 13 "Chemo Denominator" tab in the Data Dictionary for codes). These codes identify a clinically coherent group of patients with cancer using diagnoses from all available Medicare Part A and B claims during the performance period. We identify chemotherapy treatment using Healthcare Common Procedure Coding System (HCPCS)/Common Procedural Terminology® (CPT®) procedure and medication procedure codes, ICD-10-CM chemotherapy encounter diagnosis codes, and ICD-10-PCS codes, or revenue center codes for chemotherapy administration (see 2021 Chemotherapy Measure Data Dictionary for codes). In addition, we use specific ICD-10-CM procedure codes on inpatient claims to identify chemotherapy services subject to the CMS 3-day billing rule.

We do not include oral chemotherapy because it is challenging to identify oral chemotherapy administrations without using pharmacy claims data, which is not available for all Medicare recipients; furthermore, most oral chemotherapies are associated with fewer adverse reactions that result in acute care use.

[Response Ends]

sp.17. Describe the denominator exclusions.

Brief narrative description of exclusions from the target population.

[Response Begins]

The measure excludes:

1. Patients with a diagnosis of leukemia at any time during the performance period.

   Rationale: We exclude patients with leukemia from the measure cohort because the high toxicity of treatment and recurrence of disease leads to admissions among this population that do not reflect the quality of outpatient care. Patients with leukemia have a higher expected admission rate due to frequent relapse, which is not the type of admission the measure intends to capture.

2. Patients who were not enrolled in Medicare FFS Parts A and B in the year before any outpatient chemotherapy treatment during the performance period.

   Rationale: The measure excludes these patients to ensure that complete patient diagnosis data will be available for the risk-adjustment model, which uses the year before the first chemotherapy treatment during the period to identify comorbidities.

3. Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the treatment.

   Rationale: The measure excludes these patients to ensure that full data will be available for outcome assessment.

4. Cases in which patients receive chemotherapy to treat conditions other than cancer such as treatment of auto-immune diseases.

   Rationale: The measure is intended to assess the quality of care provided to cancer patients receiving outpatient chemotherapy.

[Response Ends]

sp.18. Provide details needed to calculate the denominator exclusions.

All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at sp.11.

[Response Begins]

Denominator exclusions are identified as follows:

1. Patients with a diagnosis of leukemia at any time during the performance period:
    a. ICD-10 codes for leukemia diagnoses from inpatient or outpatient claims during the performance period are shown in the "Chemo Denom Exclusions" tab in the Data Dictionary.
2. Patients who were not enrolled in Medicare FFS Parts A and B in the year before any outpatient chemotherapy treatment during the performance period.
    a. Medicare enrollment database information is used to identify enrollment status.
    b. Outpatient claims are used to identify chemotherapy treatment as described earlier.
3. Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the treatment.
    a. Medicare enrollment database information is used to identify enrollment status.
4. Cases in which patients receive chemotherapy to treat conditions other than cancer such as treatment of auto-immune diseases.
    a. We identify these cases using ICD-10, HCPCS, and CPT® chemotherapy codes and ICD-10 diagnoses for auto immune diseases (see "Chemo Denom Exclusions" tab in the Data Dictionary for full list).

[Response Ends]

sp.19. Provide all information required to stratify the measure results, if necessary.

Include the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate. Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format in the Data Dictionary field.

[Response Begins]

In the Calendar Year (CY) 2022 OPPS Proposed Rule, CMS described a plan to perform stratified reporting of two disparity methods, described below, in the HOPD setting, and have identified the chemotherapy measure as one of six priority measures included in the Hospital Outpatient Quality Reporting (OQR) program for confidential disparity reporting stratified by patient dual eligibility.

The two stratification methods are:

1. **The Within-Facility Disparity Method**, which highlights differences in outcomes for patient groups based on social risk factors within an HOPD; and
2. **The Across-Facility Disparity Method**, which illuminates variation in healthcare quality for patients with social risk factors across facilities.

The two methods are described in more detail below, and visually shown in Figure 1. Details of the methodology can be found here: https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology

- The Within-Facility Disparity Method reports differences in health outcomes between patient populations in the same facility. The goal of this method is to assess the difference in outcomes for two patients with the same condition and medical history, but with different social risks. This method can answer the question: "Does a patient with a social risk factor experience similar health outcomes as a patient without that social risk factor when cared for at the same facility?"
- The Across-Facility Disparity Method reports facility outcome rates for one patient population with a particular social risk factor across facilities. This method can answer the question: "How does the

outcome rate for patients with a social risk factor at a specific facility compare to the outcome rate for patients with that social risk factor at an average facility?"

Figure 1: Within- and Across-Facility Disparity Methods

[Response Ends]

sp.20. Is this measure adjusted for socioeconomic status (SES)?

[Response Begins]

No

[Response Ends]

sp.21. Select the risk adjustment type.

Select type. Provide specifications for risk stratification and/or risk models in the Scientific Acceptability section.

[Response Begins]

Stratification by risk category/subgroup (specify number of risk factors)

[Stratification by risk category/subgroup (specify number of risk factors) Please Explain]

This measure is risk-adjusted two ways:

1. Statistical risk model
2. Stratification by risk category/subgroup (21 risk factors)

[Response Ends]

sp.22. Select the most relevant type of score.

Attachment: If available, please provide a sample report.

[Response Begins]

Rate/proportion

[Response Ends]

Attachment: 3490_3490_3490_2020 FSR-508.xlsx

sp.23. Select the appropriate interpretation of the measure score.

Classifies interpretation of score according to whether better quality or resource use is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score

[Response Begins]

Better quality = Lower score

[Response Ends]

sp.24. Diagram or describe the calculation of the measure score as an ordered sequence of steps.

Identify the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period of data, aggregating data; risk adjustment; etc.

[Response Begins]

Figure 2: Creation of the Chemotherapy Cohort

Denominator

Steps to Identify Cohort (see Figure 2)

Step 1: Identify all Medicare Fee-for-Service (FFS) patients age 18 and older with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting during the performance period.

Step 2: Remove all patients with a diagnosis of leukemia at any time during the performance period.

Step 3: Remove all patients who were not enrolled in Medicare FFS Parts A and B in the year before any outpatient chemotherapy treatment during the performance period.

Step 4: Remove all patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the treatment.

Step 5: Remove all cases in which patients receive chemotherapy to treat conditions other than cancer such as treatment of auto-immune diseases. Note that this is a case-level exclusion; if the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

Step 6: Identify the unique number of patient-level provider ID/Facility ID combinations for the remaining cases.

Step 7: The remaining unique patients the measure denominator (cohort) at each facility.

Numerator

Steps to Identify Qualifying Inpatient Hospital Admissions and ED Visits

Step 1: Identify the first qualifying outpatient chemotherapy administration for each patient in each facility. [Note: a patient may be included at multiple facilities.]

Step 2: Determine whether that outpatient chemotherapy treatment was followed by either an inpatient hospital admission or ED visit within 30 days with either:

- A principal diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis, or
- A principal diagnosis of cancer and a secondary diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis.

Step 3: Remove any qualifying inpatient admissions with an “always planned" diagnosis or procedure.

Step 4: If a patient had both a qualifying inpatient admission and an ED visit within 30 days, select the inpatient admission.

Step 5. If a patient multiple qualifying inpatient admissions, select the first one.

Step 6. Sum the number of patients in the cohort with an inpatient admission. This is the numerator for the inpatient admissions outcome.

Step 7. Sum the number of patients in the cohort who had an ED visit, but no inpatient admission. This is the numerator for the ED visit outcome.

Calculation of the Observed Performance Rate

The measure’s two-level hierarchical logistic regression model accounts for the clustering of patients within hospitals and variation in sample size. The measure calculates the hospital-specific risk-adjusted rate as the ratio of a hospital’s “predicted” number of outcomes to “expected” number of outcomes multiplied by the national observed outcome rate.

- Predicted Rate: The measure estimates the predicted number of outcomes for each hospital using the same patient mix, but an estimated hospital-specific intercept. It calculates the predicted number of outcomes for each hospital by summing the predicted probabilities for all patients in the hospital. The measure calculates the predicted probability for each patient through the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the hospital-specific intercept.
- Expected Rate: This rate estimates the expected number of outcomes for each hospital using the hospital’s patient mix and the average hospital-specific intercept (that is, the average intercept among all hospitals in the sample). Operationally, the measure obtains the expected number of outcomes for each hospital by summing the expected probabilities of outcomes for all patients treated at the hospital. It calculates the expected probability of outcomes for each patient via the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the average hospital-specific intercept.

If a hospital’s ratio of predicted to expected outcomes is less than 1, it indicates that the hospital is performing better than expected given its case mix. If a hospital’s ratio of predicted to expected outcomes is greater than 1, it indicates that the hospital is performing worse than expected given its case mix. The risk factors included in the Inpatient Admission and ED Visit models are listed in section 2b.24 and in tabs “Chemo IP Risk Factor CCs” and “Chemo ED Risk Factor CCs” in the Data Dictionary.

Calculation of the Risk-Adjusted Rates

The risk-standardized admission rate (RSAR) is calculated as the ratio of the number of “predicted” qualifying inpatient admissions to the number of “expected” qualifying inpatient admissions multiplied by the national

observed qualifying inpatient admission rate. Similarly, the risk-standardized ED visits rate (RSEDR) is calculated as the ratio of the number of "predicted" qualifying ED visits to the number of "expected" qualifying ED visits multiplied by the national observed qualifying ED visit rate.

For each rate, this approach is analogous to a ratio of "observed" to "expected" outcomes used in other types of statistical analyses. It conceptually allows for a comparison of a particular facility's performance given its case mix to an average facility's performance with the same case mix. Thus, a predicted/expected ratio of less than one indicates a lower-than-expected visit rate (or better quality), and a ratio of greater than one indicates a higher-than-expected visit rate (or worse quality).

[Response Ends]

sp.27. If measure testing is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.

Examples of samples used for testing:

• Testing may be conducted on a sample of the accountable entities (e.g., hospital, physician). The analytic unit specified for the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing.

• The sample should represent the variety of entities whose performance will be measured. The 2010 Measure Testing Task Force recognized that the samples used for reliability and validity testing often have limited generalizability because measured entities volunteer to participate. Ideally, however, all types of entities whose performance will be measured should be included in reliability and validity testing.

• The sample should include adequate numbers of units of measurement and adequate numbers of patients to answer the specific reliability or validity question with the chosen statistical method.

• When possible, units of measurement and patients within units should be randomly selected.

[Response Begins]

This measure is not based on a sample or survey.

[Response Ends]

sp.30. Select only the data sources for which the measure is specified.

[Response Begins]

Claims

Other (specify)

[Other (specify) Please Explain]

Enrollment Data

[Response Ends]

sp.31. Identify the specific data source or data collection instrument.

For example, provide the name of the database, clinical registry, collection instrument, etc., and describe how data are collected.

[Response Begins]

The numerator (outcome), denominator (cohort), and risk factors for this measure are based on Medicare administrative claims and enrollment data.

Medicare Part A Inpatient and Part B Outpatient Claims: This data source contains claims data for FFS inpatient and outpatient services including Medicare inpatient hospital care, outpatient hospital services, as well as inpatient and outpatient physician claims for the 12 months prior to the outpatient chemotherapy treatment.

Medicare Enrollment Database (EDB): This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This data source was used to obtain information on several inclusion/exclusion indicators such as Medicare status on admission as well as vital status. These data have previously been shown to accurately reflect patient vital status (Fleming et al., 1992). The Master Beneficiary Summary File (MBSF) is an annually created file derived the EDB that contains enrollment information for all Medicare beneficiaries including dual eligible status.

References

Fleming C., Fisher ES, Chang CH, Bubolz D, Malenda J. Studying outcomes and hospital utilization in the elderly: The advantages of a merged data base for Medicare and Veterans Affairs Hospitals. Medical Care. 1992; 30(5): 377-91.

[Response Ends]

sp.32. Provide the data collection instrument.

[Response Begins]

No data collection instrument provided

[Response Ends]

2ma.01. Indicate whether additional empirical reliability testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Reliability - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

[Response Begins]

Yes

[Response Ends]

2ma.02. Indicate whether additional empirical validity testing at the accountable entity level has been conducted. If yes, please provide results in the following section, Scientific Acceptability: Validity - Testing. Include information on all testing conducted (prior testing as well as any new testing).

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous Submission:

Testing from the previous submission here.

[Response Begins]

Yes

[Response Ends]

2ma.03. For outcome, patient-reported outcome, resource use, cost, and some process measures, risk adjustment/stratification may be conducted. Did you perform a risk adjustment or stratification analysis?

[Response Begins]

Yes

[Response Ends]

2ma.04. For maintenance measures in which risk adjustment/stratification has been performed, indicate whether additional risk adjustment testing has been conducted since the most recent maintenance evaluation. This may include updates to the risk adjustment analysis with additional clinical, demographic, and social risk factors.

Please update the Scientific Acceptability: Validity - Other Threats to Validity section.

Note: This section must be updated even if social risk factors are not included in the risk adjustment strategy.

[Response Begins]

Yes - Additional risk adjustment analysis is included

[Response Ends]

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate fields in the Scientific Acceptability sections of the Measure Submission Form.

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.
- All required sections must be completed.
- For composites with outcome and resource use measures, Questions 2b.23-2b.37 (Risk Adjustment) also must be completed.
- If specified for multiple data sources/sets of specifications (e.g., claims and EHRs), Questions 2b.11-2b.13 also must be completed.
- An appendix for supplemental materials may be submitted (see Question 1 in the Additional section), but there is no guarantee it will be reviewed.
- Contact NQF staff with any questions. Check for resources at the Submitting Standards webpage.

- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for the 2021 Measure Evaluation Criteria and Guidance.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a. Reliability testing demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For instrument based measures (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure;

AND

If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

2b3. For outcome measures and other measures when indicated (e.g., resource use):

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; 14,15 and has demonstrated adequate discrimination and calibration
- rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful 16 differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias.

2c. For composite performance measures, empirical analyses support the composite construction approach and demonstrate that:

2c1. the component measures fit the quality construct and add value to the overall composite while achieving the related objective of parsimony to the extent possible; and

2c2. the aggregation and weighting rules are consistent with the quality construct and rationale while achieving the related objective of simplicity to the extent possible.

(if not conducted or results not adequate, justification must be submitted and accepted)

Definitions

Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

Risk factors that influence outcomes should not be specified as exclusions.

With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v.$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

Please separate added or updated information from the most recent measure evaluation within each question response in the Scientific Acceptability sections. For example:

Current Submission:

Updated testing information here.

Previous (Year) Submission:

Testing from the previous submission here.

2a.01. Select only the data sources for which the measure is tested.

[Response Begins]

Claims

Other (specify)

[Other (specify) Please Explain]

Enrollment database files

[Response Ends]

2a.02. If an existing dataset was used, identify the specific dataset.

The dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

[Response Begins]

The measure requires a data source that allows us to link patient data across care settings in order to identify qualifying patients receiving chemotherapy in hospital outpatient departments (HOPDs) for inclusion, comorbidities for risk adjustment, and the outcomes of inpatient hospital admissions and emergency department (ED) visits. Therefore, we used Medicare Fee-for-Service (FFS) claims and enrollment data, as they support these linkages and were available for the population of interest.

1. The primary dataset used to support updated measure testing included Medicare Outpatient, Inpatient, and Part B Physician claims and enrollment data from the Medicare Enrollment Database (see Table 1 for details on dates of data).
    A. Datasets used to define the cohort:
        a. Outpatient chemotherapy procedures performed at qualifying PPS-Exempt Cancer Hospitals (PCH-HOPDs) and non-PCH hospital outpatient departments were identified using outpatient and Inpatient hospital claims data. Inpatient hospital claims data are used to capture outpatient chemotherapy treatment that may be bundled on an inpatient claim due to the CMS 3-day payment window policy; only chemotherapy procedures occurring within the 3-day window prior to an inpatient admission are included.
        b. Outpatient hospital, Inpatient hospital, and Part B Physician claims were also used to identify cancer diagnoses.
        c. Medicare Enrollment Database data was used to determine Medicare Fee-For-Service (FFS) enrollment status, demographic, and death information.
    B. Datasets used to capture the outcome (inpatient hospital admissions and ED visits)
        a. Inpatient and outpatient hospital claims data were used to identify qualifying hospital admissions and ED visits, respectively.
        b. Qualifying inpatient hospital admissions and ED visits are those that occur within 30 days of a qualifying chemotherapy procedure with either: (1) a primary discharge diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis, or (2) a primary discharge diagnosis of cancer and a secondary diagnosis of one of those 10 diagnoses on the same claim.
    C. Datasets used to identify comorbidities for risk adjustment and social risk factor testing for dual eligibility and race (Black) variables:
        a. Inpatient hospital, Outpatient hospital, and Part B Physician claims were used to identify comorbidities during the prior 365 days for risk adjustment for these patients.
        b. The Medicare Enrollment Database was used to identify patients with two of the social risk factors used in testing: dual eligibility, and race (Black).
2. We also utilized datasets from other performance periods to support other aspects of measure development and testing, as follows:
    A. July 2012 – June 2013 data were used to support the development and testing of the initial risk-adjustment models, as described in Section 2b.20 Risk-Adjustment/Stratification. These data were derived from the Medicare Standard Analytic Files, rather than HAJI, but were otherwise identical in terms of identifying the measure cohort, outcomes, and comorbidities for risk adjustment.

To evaluate the inclusion of additional social risk factors in our risk-adjustment algorithms, we used the following dataset (additional details about these datasets are provided in section 2b.20):

3. American Community Survey (ACS) data from the United States Census Bureau, used to derive the Agency for Healthcare Research and Quality (AHRQ) Socio-economic status (SES) index for each patient ZIP code. See Table 1 for dates of data.

New for the 2022 Fall Cycle, we have added an evaluation of the impact of rurality. To evaluate the impact of rurality on the measure, we used the following dataset:

4. The Rural-Urban Commuting Area Codes 2019 dataset, used to assign a patients' admission as rural vs. not rural, using pre-established coding categories.

[Response Ends]

2a.03. Provide the dates of the data used in testing.

Use the following format: "MM-DD-YYYY - MM-DD-YYYY"

[Response Begins]

Dates of data vary depending on the type of testing. See Table 1 in section 2a.07 for details.

[Response Ends]

2a.04. Select the levels of analysis for which the measure is tested.

Testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan.

Please refrain from selecting the following answer option(s). We are in the process of phasing out these answer options and request that you instead select one of the other answer options as they apply to your measure.

Please do not select:

- *Clinician: Clinician*
- *Population: Population*

[Response Begins]

Facility

[Response Ends]

2a.05. List the measured entities included in the testing and analysis (by level of analysis and data source).

Identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample.

[Response Begins]

The number of measured entities (hospital outpatient departments at PCH-HOPDs and non-PCH HOPDs) varies by testing type; see Section 2a.07 for details.

[Response Ends]

2a.06. Identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis), separated by level of analysis and data source; if a sample was used, describe how patients were selected for inclusion in the sample.

If there is a minimum case count used for testing, that minimum must be reflected in the specifications.

[Response Begins]

The number of patients varies by testing type; see Section 2a.07 for details.

[Response Ends]

2a.07. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing.

[Response Begins]

The datasets, number of measured entities, and demographic profiles for the patients used in each type of testing are shown in Table 1.

Dataset	Applicable Section	Description of Dataset
Full Sample, and Development and Validation Datasets (Medicare Fee-For-Service Administrative Claims Data)	Development and testing of the initial risk-adjustment models	Dates of Data: July 1, 2012 - June 30, 2013 See Table 2 and Table 3 for demographic descriptions and numbers of facilities.
2016 Initial Endorsement Data	Section 2a.10 Facility-level reliability Section 2b.06 Analyses to address potential threats to validity Section 2b.02 Face validity review Section 2b. 17 Testing the exclusion criteria Section 2b.20 Re-evaluation of risk-adjustment algorithm Section 2b.05 Demonstrating meaningful differences in performance	Dates of Data: October 1, 2015 - September 30, 2016 See Table 4 for demographic descriptions and numbers of facilities.
2022 Endorsement Maintenance (EM) Testing Dataset (Medicare Fee-For-Service Administrative Claims Data)	Section 2a.04 Reliability Testing Section 2b.02 Validity Testing Section 2b.17 Testing of Measure Exclusions Section 2b.20 Risk Adjustment/Stratification Section 2b.20 Statistical Risk Model Discrimination Statistics Section 2b.05 Meaningful Differences	Dates of Data: Jan 1, 2021 – November 30, 2021 See Table 5 for demographic descriptions and numbers of facilities.

Dataset	Applicable Section	Description of Dataset
The American Community Survey (ACS)	Section 2b.20: Risk adjustment/Stratification for Outcome or Resource Use Measures	Dates of Data: 2013-2017 for the current submission Prior dates of ACS data include: January 2008 – December 2012 for initial development; January 2009 – December 2013 for the 2018 re-evaluation cycle We used the AHRQ SES index score derived from the American Community Survey (2013-2017) to study the association between the 30-day EDAC outcome and SRFs. The AHRQ SES index score is based on beneficiary 9-digit zip code level of residence and incorporates 7 census variables found in the American Community Survey.
Master Beneficiary Summary File (MBSF)	Section 2b.20: Risk adjustment/Stratification for Outcome or Resource Use Measures	Dates of Data: July 2016 – June 2019 We used dual eligible status (for Medicare and Medicaid) derived from the MBSF, and race variables to study the association between these social risk factors and 30-day measure outcomes.
Rural Urban Commuting Area Codes (new for 2022 submission)	Section 2b.20: Risk adjustment/Stratification for Outcome or Resource Use Measures	Dates of Data: 2010 We used information on patients' rurality to study the association between rural geographic location and 30-day measure outcomes.

Table 1: Dataset Descriptions

Previous submission:

*	Overall	PCH-HOPDs	Non-PCH HOPDs
Hospitals (n)	3,765	11	3,754
Patients (n)	240,446	18,400	223,719
Age (average)	72.2	71.6	72.2
Male (%)	50.2	54.6	49.8
Chemotherapy Exposure: Number of Treatments during Performance Period	*	*	*
25th Percentile	2	2	1
Median	3	4	3
75th Percentile	7	8	7
Most Frequent Cancer Diagnoses (%)	*	*	*
Solid Tumors	42.2	60.4	40.9

*	Overall	PCH-HOPDs	Non-PCH HOPDs
Other Cancer	39.8	45.5	39.4
Digestive Cancer	24.2	27.8	23.9
Respiratory Cancer	21.8	21.6	21.8

Table 2: Number of patients and patient characteristics for 2012-2013 full sample

**Cells intentionally left empty.*

See attached Data Dictionary for Cancer category definitions.

*	Development	Validation
Hospitals (n)	**3,483**	**3,469**
Patients (n)	**123,149**	**123,115**
Age (average)	**72.2**	**72.1**
Male (%)	**50.1**	**50.0**
Chemotherapy Exposure: Number of Treatments during Performance Period	*	*
25th Percentile	**1**	**1**
Median	**3**	**3**
75th Percentile	**7**	**7**
Most Frequent Cancer Diagnoses (%)	*	*
Solid Tumors	**42.4**	**42.5**
Other Cancer	**28.2**	**28.3**
Digestive Cancer	**24.3**	**24.1**
Respiratory Cancer	**21.8**	**21.7**

Table 3: Number of patients and patient characteristics for 2012-2013 development and validation split samples

**Cells intentionally left empty.*

See attached Data Dictionary for Cancer category definitions.

*	Overall	PCH-HOPDs	Non-PCH HOPDs
Hospitals (n)	3,573	11	3,562
Patients (n)	289,543	23,477	266,066
Age (average)	72.1	71.6	72.1
Male (%)	51.5	54.6	51.3
Chemotherapy Exposure: Number of Treatments during Performance Period	*	*	*
25th Percentile	2	2	1
Median	4	4	3
75th Percentile	7	9	7
Most Frequent Cancer Diagnoses (%)	*	*	*
Solid Tumor	44.2	58.7	42.9

*	Overall	PCH-HOPDs	Non-PCH HOPDs
Other Cancers	28.0	33.9	27.4
Digestive Cancer	20.7	22.3	20.5
Lymph Node	19.9	37.2	18.4

Table 4: Number of patients and patient characteristics; 2016 initial endorsement database

**Cell intentionally let empty.*

See attached Data Dictionary for Cancer category definitions

Current submission:

*	Overall	PCH-HOPDs	Non-PCH HOPDs
Hospitals (n)	3,289	11	3,278
Hospitals with >=25 cases (n)	1,485	11	1,474
Patients (n)	298,516	25,763	272,753
Age (average)	73.7	73.3	73.8
Male (%)	54.1	56.6	53.8
Chemotherapy Exposure: Number of Treatments during Performance period	*	*	*
25th percentile	2	2	2
Median	4	5	4
75th percentile	10	10	10
Most frequent cancer diagnoses (%)	*	*	*
Solid tumor	48.2	61.3	47.0
Other cancers	25.5	29.5	25.1
Prostate cancer	21.7	25.5	21.4
Lymph node	21.2	35.3	19.9

Table 5: Number of patients and patient characteristics

*Cell intentionally left empty.

See attached Data Dictionary for Cancer category definitions.

[Response Ends]

2a.08. List the social risk factors that were available and analyzed.

For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

[Response Begins]

Please see Section 2a.11 for the conceptual model for social risk factors' potential impact on the outcome. For testing, we were limited to social risk factors that that are available and can be linked to claims data. The NQF-

convened Technical Expert Panel that considered risk-adjustment for social risk factors recognized that testing and risk adjustment for social risk may be constrained by data limitations and data collection burden [NQF, 2014].

Below we list the variables that are available within, or that can be linked directly, to Medicare administrative claims data used for this measure. In selecting variables for analysis, our intent was to be responsive to the National Quality Forum (NQF) guidelines for measure developers and the findings of work funded by the IMPACT Act [HHS, 2016; NASEM, 2016; NQF, 2021]. Our approach was to examine patient-level indicators that are reliably available for all Medicare beneficiaries and linkable to claims data and to select those that have established validity.

Potential pathways for SES and race variables' effects are described in Section 2a.11. This section is limited to a description of the variables.

The SES and race variable that we examined, further described below, are:

- Black race (updated analyses provided for endorsement maintenance)
- Dual-eligible status (updated analyses provided for endorsement maintenance)
- AHRQ-validated SES Index score
- Rurality (new for Fall 2022 submission)

Black race (black, other)

Data source: Medicare enrollment database

We used the Medicare enrollment database to identify the patient-level race variable (Black) that we used in these analyses. The Black variable has been shown to be reliable for use in this dataset (Waldo, 2004).

Medicaid dual-eligible status (Medicaid-Medicare dual, Medicare only)

Data source: Medicare enrollment database

The dual-status patient-level variable provides a reliably-obtained indication of patients with low income/assets and high health care spending. Following guidance from ASPE and a body of literature demonstrating differential health care and health outcomes among dual eligible patients, we identified dual eligibility as a key variable (ASPE 2016, ASPE 2020). We recognize that Medicare-Medicaid dual eligibility has limitations as a proxy for patients' income or assets because it does not provide a range of results and is only a dichotomous outcome. However, the threshold for over 65-year-old Medicare patients is valuable, as it considers both income and assets and is consistently applied across states for the older population. We acknowledge that it is important to test a wider variety of SRFs including key variables such as education and poverty level; therefore, we also tested a validated composite (AHRQ SES Index – see below) based on census data linked to as small a geographic unit as possible.

AHRQ-validated SES Index score: neighborhood SES factors as proxies for patient-level SES

Data source: Enrollment database and Census data (American Community Survey)

The American Community Survey (ACS) provides several social risk indicators that are available at the ZIP code level and can be linked directly to Medicare claims at the 9-digit ZIP code level. We used the Agency for Healthcare Research and Quality (AHRQ)-validated composite index of SES which has been used and tested among Medicare beneficiaries [NQF, 2014]. This index is a composite of seven different variables found in the Census data which may capture social risk better than any single variable. The variables are: (1) median household income, (2) percentage of persons living below the federal poverty level, (3) percentage of persons who are aged >16 years and in the labor force but not employed, (4) median value of owner-occupied homes, (5) percentage of persons aged >25 years who completed at least a 12th grade education, (6) percentage of persons aged >25 years who completed at least four years of college, and (7) percentage of households that average one or more persons per room.

Rurality

Data Source: Rural-Urban Commuting Area Codes, 2019

The rural-urban commuting area (RUCA) codes classify U.S. census tracts using measures of population density, urbanization, and daily commuting. A second dataset applies 2010 RUCA classifications to ZIP code areas by

transferring RUCA values from the census tracts that comprise them. The most recent RUCA codes are based on data from the 2010 decennial census and the 2006-10 American Community Survey.

References

Creation of New Race-Ethnicity Codes and Socioeconomic Status (SES) Indicators for Medicare Beneficiaries: Final Report. August 2012. Agency for Healthcare Research and Quality, Rockville, MD. http://archive.ahrq.gov/research/findings/final-reports/medicareindicators/index.html. Accessed August 24, 2015.

Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (HHS). Report to Congress: Social Risk factors and Performance Under Medicare's Value-based Payment Programs. 2016; https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs. Accessed November 10, 2017.

National Academies of Sciences, Engineering, and Medicine (NASEM); Accounting for Social Risk Factors in Medicare Payment: Data. Washington DC: National Academies Press; 2016.

National Quality Forum (NQF). Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk within Healthcare Performance Measurement.; 2021. https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=96087

National Quality Forum (NQF). Risk Adjustment for Socioeconomic Status or Other Sociodemographic Factors: Technical Report. August 15, 2014. http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx

Waldo DR. Accuracy and Bias of Race/Ethnicity Codes in the Medicare Enrollment Database. Health Care Financing Review. 2004;26(2). Accessed July 14, 2022.

[Response Ends]

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a.09 check patient or encounter-level data; in 2a.010 enter "see validity testing section of data elements"; and enter "N/A" for 2a.11 and 2a.12.

2a.09. Select the level of reliability testing conducted.

Choose one or both levels.

[Response Begins]

Accountable Entity Level (e.g., signal-to-noise analysis)

[Response Ends]

2a.10. For each level of reliability testing checked above, describe the method of reliability testing and what it tests.

Describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used.

[Response Begins]

Previous submission

Split-Sample Reliability. We tested the reliability of the facility measure score by calculating the intra-class correlation coefficient (ICC) of the measure score using a split-sample (i.e., test-retest) approach. To calculate the ICC, we used the Medicare FFS FY 2015-2017 Dataset. The two years of data from the Medicare FFS FY 2015-2017

Dataset were then randomly split into two samples (1 year of combined data for each sample). We calculated ICC (2,1) described by Shrout and Fleiss, which evaluates the agreement between the risk-standardized admissions rates (RSARs) and risk-standardized emergency department rates (RSEDR) calculated in the two randomly selected samples assuming that all patients are rated by the same raters who are assumed to be a random subset of all possible raters [Adams et al., 2010]. The formula for ICC (2,1) described in Shrout & Fleiss (1979) utilizes a two-way ANOVA to calculate the ICC as a measure of absolute agreement. The formula is implemented as follows:

$$ICC(2,1) = \frac{MS_R - MS_E}{MS_R + (k-1)MS_E + k(MS_C - MS_E)/N}$$

where MS_R = Between Measure Mean Square Error, MS_C = Between Sample Mean Square Error, MS_E = Average Error Variance, k = # of samples =2, and N = # of facilities

The split-sample reliability testing methods were aligned with the specifications used for measure implementation in CMS's PCHQR and OQR programs. All patients meeting the measure inclusion and exclusion criteria were included in the split-sample measure score calculations to ensure that the measure cohort was as comprehensive as possible. However, because CMS has determined that measure scores cannot be reliably determined for facilities with fewer than 25 patients, the ICC analysis was limited to hospitals with at least 25 patients in each of the split samples. This approach is consistent with CMS's current public reporting strategy for the PCHQR and OQR programs that includes smaller hospitals in the measure calculation, but does not publicly release the measure score for hospitals with fewer than 25 patients (i.e., labels them in public reporting as having "too few cases" to support a reliable estimate). We note that the minimum sample size for public reporting is a policy choice that balances competing considerations such as the reliability of the measure score and transparency for consumers.

Prior and Current Submission

Facility-Level Reliability. We estimated the facility-level reliability using the formula presented by Adams and colleagues (2010):

$$Reliability = \frac{\sigma^2{}_{facility-to-facility}}{\sigma^2{}_{facility-to-facility} + \frac{\sigma^2{}_{facilityerrorvariance}}{n}}$$

Where facility-to-facility variance is estimated from the model, *n* is equal to each facilities observed case size, and the facility error variance is estimated using the variance of the logistic distribution. The facility-level reliability testing methods were also aligned with the specifications used in CMS's PCHQR and HOQR programs, with the analysis limited to facilities with at least 25 patients.

Reference

Adams J, Mehrota, A, Thoman J, McGlynn, E. (2010). Physician cost profiling – reliability and risk of misclassification. NEJM, 362(11): 1014-1021.

[Response Ends]

2a.11. For each level of reliability testing checked above, what were the statistical results from reliability testing?

For example, provide the percent agreement and kappa for the critical data elements, or distribution of reliability statistics from a signal-to-noise analysis. For score-level reliability testing, when using a signal-to-noise analysis, more than just one overall statistic should be reported (i.e., to demonstrate variation in reliability across providers). If a particular method yields only one statistic, this should be explained. In addition, reporting of results stratified by sample size is preferred (pg. 18, NQF Measure Evaluation Criteria).

[Response Begins]

Previous submission

Split-Sample Reliability. There were 1,450 hospitals (11 PCHs and 1,439 non-PCH hospitals) with ≥ 25 patients in their cohorts in each half of the two-year, FY 2015 – 2017 sample. This sample was randomly split and the key characteristics were compared to ensure the patients in each sample were similar, as shown in Table 2, in Section 2a.07. For the 11 PCHs, the ICC score was 0.6704 for the Risk-Standardized Admissions Rate (RSAR), and 0.8904 for the Risk-Standardized Emergency Department Visit Rate (RSEDR). Among the 1,099 non-PCH hospitals with at least 50 patients in the combined sample, the ICC score was 0.4314 for the RSAR and 0.3585 for the RSEDR.

Signal-to-noise reliability: PCH-HOPDs had a median reliability of 0.7848 for the RSAR, and 0.9808 for the RSEDR. All 11 PCH-HOPDs had 25 or more patients in the FFY 2016 (October 1, 2015 – September 30, 2016) dataset. Among the 1,524 non-PCH HOPDs with at least 25 patients, the median reliability was 0.6027 for the RSAR, and 0.7326 for the RSEDR. The reliability estimates for the 25th and 75th percentile denominator values (number of patients) are also shown in Table 6 below.

*	**RSAR**		**RSEDR**	
ICC Score for Volume Percentile	PCH-HOPDs (N=11)	Non-PCH HOPDs (N=1,524)	PCH-HOPDs (N=11)	Non-PCH HOPDs (N=1,524)
25th Percentile	0.749	0.437	0.977	0.583
Median	0.785	0.603	0.981	0.733
75th Percentile	0.892	0.763	0.991	0.853

Table 6. Signal-to-Noise Reliability

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Current submission

Signal-to-noise reliability: PCH-HOPDs had a median reliability of 0.933 for the RSAR, and 0.958 for the RSEDR. All 11 PCH-HOPDs had 25 or more patients in the EM Dataset. Among the 1,474 non-PCH HOPDs with at least 25 patients, the median reliability was 0.667 for the RSAR, and 0.683 for the RSEDR. The reliability estimates for the 25th and 75th percentile denominator values (number of patients) are also shown in Table 7 below.

Percentile	**RSAR: PCH-HOPDs (N=11)**	**RSEDR: PCH-HOPDs (N=11)**	**RSAR: Non-PCH HOPDs (N=1,474)**	**RSEDR: Non-PCH HOPDs (N=1,474)**
100% Max	**0.985**	**0.990**	**0.979**	**0.981**
99%	**0.985**	**0.990**	**0.966**	**0.968**
95%	**0.985**	**0.990**	**0.931**	**0.935**
90%	**0.976**	**0.985**	**0.901**	**0.907**
75% Q3	**0.972**	**0.983**	**0.808**	**0.818**
50% Median	**0.933**	**0.958**	**0.667**	**0.683**
25% Q1	**0.909**	**0.942**	**0.504**	**0.522**
10%	**0.870**	**0.916**	**0.401**	**0.419**
5%	**0.739**	**0.822**	**0.377**	**0.394**
1%	**0.739**	**0.822**	**0.351**	**0.367**
0% Min	**0.739**	**0.822**	**0.351**	**0.367**

Table 7: Signal-to-noise reliability (current submission) for hospitals with at least 25 cases

[Response Ends]

2a.12. Interpret the results, in terms of how they demonstrate reliability.

(In other words, what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Previous submission

For the facility-level reliability, the median ICC values for PCH-HOPDs were 0.7848 for the RSAR, and 0.9808 for the RSEDR, showing substantial and almost perfect agreement, respectively. Among the non-PCH HOPDs, the median ICC values were 0.6027 for the RSAR and 0.7326 for the RSEDR, indicating substantial agreement.

Current submission

Updated reliability testing results demonstrate that facility-level reliability remains sufficiently high for both outcomes for both PCH HOPDs (RSAR, 0.933; RSEDR, 0.958) and non-PCH HOPDs (RSAR, 0.667; RSEDR, 0.683) for facilities with at least 25 admissions during the performance year.

References

Adams J, Mehrotra, A, Thoman J, McGlynn, E. (2010). Physician cost profiling – reliability and risk of misclassification. NEJM, 362(11): 1014-1021.

Yu H, Mehrotra A, Adams J. (2013). Reliability of utilization measures for primary care physician profiling. Healthcare, Jun; 1(1-2):22-9.

[Response Ends]

2b.01. Select the level of validity testing that was conducted.

[Response Begins]

Empirical validity testing

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

[Response Ends]

2b.02. For each level of testing checked above, describe the method of validity testing and what it tests.

Describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used.

[Response Begins]

Below we provide information from the previous submission on face validity, and for the current submission add information for empiric validity testing.

Previous Submission

We demonstrated measure validity through assessment by external groups. Specifically, our Technical Expert Panel (TEP) and PPS-Exempt Cancer Hospital Measure Development Workgroup (Cancer Workgroup) provided input on the measure's initial development, while subsequent Expert Workgroups (EWGs) convened from 2015 – 2018 advised on revisions to the measure specifications during annual measure reevaluation. In addition, we received measure feedback through a formal public comment process in 2015. Also, the 11 PCH-HOPDs and all hospitals participating in CMS's OQR program had the opportunity to review draft, non-public results, and provide comments on the measure specifications during August/September 2017 during the measure dry run CMS hosted

to educate and receive input from facilities on the measure results and data used for measure calculation. Finally, the measure's face validity was systematically assessed by the 2018 EWG members.

Validity as Assessed by External Groups:

Throughout the initial measure development and reevaluation processes, we obtained expert and stakeholder input by holding regular discussions with external clinical consultants, consulting our TEP, PPS-Exempt Cancer Hospital Workgroup, and subsequent EWGs convened from 2015 – 2018 (see below and Measure Submission Form, Section 2b.02 for full membership lists). We also held a 46-day public comment period during measure development in 2013 and a subsequent, 45-day public comment period during the measure's national Dry Run for the PCHQR and OQR programs (August 15 – September 29, 2017). Additional details about these activities are provided below.

Technical Expert Panel:

TEP. In alignment with the CMS Measures Management System (MMS) Blueprint, we convened a TEP to provide input and feedback during measure development. To convene the TEP, we released a public call for nominations and selected individuals to represent a range of perspectives, including clinicians, patients, and individuals with experience in quality improvement, performance measurement, and healthcare disparities. The TEP had 12 members, including physicians, nurses and patient advocates (see below and the Measure Submission Form, Section 2b.02 for full membership list). We held thirteen structured TEP conference calls consisting of presentation of key issues, our proposed approach, and relevant data, followed by open discussion among TEP members. The TEP's role was to provide advice and feedback through all phases of the initial measure development process, including review and comment on evidence provided in an environmental scan, input to and reviews of measure specifications, and review and guidance relating to public comment on and testing of the measure.

Workgroups:

2014 PPS-Exempt Cancer Hospital Workgroup. The Cancer Workgroup consisted of representatives from each of the 11 PPS-exempt cancer hospitals (see below and the Measure Submission Form, Section 2b.02 for full membership list). The purpose of engaging with the workgroup was to understand quality measurement and improvement activities taking place at the PPS-exempt cancer hospitals and to obtain their perspectives on the importance and usefulness of the measure during its initial development.

2015 – 2018 EWGs

Following the initial measure development phase and during measure reevaluation, we convened a series of EWGs to provide input and feedback on potential revisions to the measure specifications during annual reevaluation. While the membership fluctuated over time, these EWGs generally included 2-3 members from the original TEP and Cancer Workgroups, and then additional experts who were added over time to ensure representation from key stakeholders (see below and the Measure Submission Form, Section 2b.02 for full membership lists). We held 2-3 structured EWG conference calls per year, where we presented key reevaluation issues, discussed our proposed approach and relevant data, and then held open discussion among EWG members.

Public Comment Periods:

2013 Public Comment During Initial Measure Development. During development, we solicited public comment on the measure from June 1 through July 19, 2013 using the standard CMS, MMS Blueprint process. The measure specifications were posted for 45 calendar days to allow time for interested stakeholders to review and comment. 13 measure-specific comments were received, including comments from the American Hospital Association and the Alliance of Dedicated Cancer Centers.

Measures' Application Partnership Review & Public Comment. In addition, in December 2015 and January 2016 as part of the NQF Measure Applications Partnership process, the measure underwent a second public comment period. Throughout the MAP process stakeholders submitted a total of 11 unique comments.

CMS Federal Regulation Public Comment Period. Additionally, as part of CMS' Federal rulemaking process, the measure's final rule language for the Inpatient Prospective Payment System (IPPS) and the Outpatient Prospective Payment System (OPPS) was released for review and public comment. Each program's final rule language was made public for 45 calendar days with the IPPS public comment period occurring May 15 – June 30, 2016, and the OPPS public comment period occurring August 1 – September 15, 2016. CMS received 33 measure specific

comments were received during the IPPS public comment period and 75 comments were received during the OPPS public comment period. Commenters included the Alliance of Dedicated Cancer Centers and the American Society of Hematology.

2017 Measure Dry Run and Public Comment. Additionally, during the measure's national Dry Run CMS held a 45-day public comment period from August 15 through September 29, 2017. During this period, facilities participating in the PCHQR and OQR programs had the opportunity to ask questions about the measure specifications, and their non-public, facility-level results for the FY 2016 data period. We received 216 questions during this period, 3 from PCH-HOPDs and 213 from non-PCH HOPDs.

CMS used feedback from all these sources – TEP, Workgroups (Cancer Workgroup, EWGs), public comment periods, and measure Dry Run – to refine the measure specifications during the initial development phase and then during reevaluation. They served as a source of ongoing face validity review on key aspects of the measure, including the codes and logic used to define the cohort, outcomes, exclusions, and risk-adjustment model. In addition, CMS conducted a formal, face validity assessment of the measure with the 2018 EWG, the group most recently convened to provide input on and evaluate the measure, as described below.

Face Validity as Determined by the 2018 EWG:

The 2018 EWG includes an interdisciplinary team of clinicians, medical coders, and measurement experts from cancer and non-PCH HOPDs. Three of the EWG members have been involved with the measure since the initial development stages, while the remaining five members were added in 2018 to ensure representation from a diverse set of stakeholders with relevant clinical, coding, and quality measurement expertise. The group met twice in May 2018 to review the current measure specifications and provide input on changes under consideration during the 2018 reevaluation cycle.

The measure score as an indicator of quality was systematically assessed for face validity by confidentially soliciting the EWG members' agreement with the following statement via an online survey: "The risk-standardized admissions rates and risk standardized emergency department rates obtained from the chemotherapy measure as specified can be used to distinguish between better and worse quality facilities." The survey offered participants six response options ranging from "strongly disagree" to "strongly agree." EWG members were asked to complete this survey after reviewing the revised measure specifications and distribution of measure performance among PCH-HOPDs and non-PCH HOPDs in the FFY 2016 dataset, as summarized in Section 2.b.4.

TEP and EWG Members (also listed in Measure Submission Form, Ad.1) represented a range of perspectives, including physicians and nurses with cancer care and chemotherapy expertise, patient advocates, medical coders, and quality improvement and performance measurement professionals:

2018 EWG members

1. Robert Daly, MD, MBA – Memorial Sloan-Kettering Cancer Center (Staff Physician, Medical Oncology)
2. Stephen Edge, MD* – Roswell Park Memorial Institute (Vice President, Healthcare Outcomes and Policy, Professor of Oncology and Surgical Oncology)
3. Michael Hassett, MD, MPH* – Dana Farber Cancer Center (Attending Physician, Medical Oncology; Assistant Professor, Medicine, Harvard Medical School)
4. Scott Huntington, MD, MPH – Yale New Haven Hospital (Attending Physician, Hematology)
5. Denise Morse, MBA – City of Hope Cancer Treatment and Research Center (Senior Manager, Quality Analytics)
6. Joseph Ross, MD, MHS – Yale University School of Medicine (Associate Professor of General Medicine and of Public Health)
7. Weijing Sun, MD – University of Kansas Cancer Center (Director of Medical Oncology and Associate Director of University of Kansas Cancer Center)
8. Allison Snyderman, PhD* - Memorial Sloan-Kettering Cancer Center (Outcomes Researcher)

*Also served as member of TEP and 2014 PPS-Exempt Cancer Workgroup

2017 EWG members

1. Susan Armstrong—City of Hope Cancer Treatment and Research Center (Senior Manager, Coding and Data Quality)
2. Arnold Chen, MD, MPH – Mathematica Policy Research (Clinician, Senior Researcher)
3. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
4. Joseph Ross, MD, MHS – Yale University School of Medicine (Associate Professor of General Medicine and of Public Health)
5. Tracy Spinks, CPH—MD Anderson Hospital, Cancer Care Delivery (Program Director)
6. Denise Stone, RN, MBA – Mathematica Policy Research (Clinician, Lead Program Analyst)

2016 EWG members

1. Peter B. Bach, MD, MAPP—Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
2. Stephen Edge, MD—Baptist Cancer Center (Cancer Center Director)
3. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
4. Karl Lorenz, MD, MSHS—UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
5. Allison Snyderman, PhD —Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Researcher)
6. Tracy Spinks, CPH—MD Anderson Hospital, Cancer Care Delivery (Program Director)

2015 EWG members

1. Peter B. Bach, MD, MAPP—Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
2. Stephen Edge, MD—Baptist Cancer Center (Cancer Center Director)
3. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
4. Karl Lorenz, MD, MSHS—UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
5. Allison Snyderman, PhD —Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Researcher)
6. Tracy Spinks, CPH—MD Anderson Hospital, Cancer Care Delivery (Program Director)

PPS-Exempt Cancer hospital workgroup members

1. J. Robert Beck, MD—American Oncologic Hospital (Fox Chase) (Senior Vice President and Chief Academic Officer)
2. Joe Jacobson, MD—Dana Farber Cancer Institute (Chief Quality Officer)
3. Barbara Jagels, MHA, RN, OCN—Seattle Cancer Care Alliance (Fred Hutchinson Cancer Research Center) (Director of Nursing and Clinical Excellence)
4. Dana Jenkins—Roswell Park Memorial Institute (Vice President of Organizational Improvement)
5. Tricia Kassab, RN, MS, CPHQ, HACP—City of Hope National Medical Center (Vice President of Quality and Patient Safety)
6. Jeremy Miransky, PhD—Memorial Hospital for Cancer and Allied Disease (MSKCC) (Quality Analytics Manager)
7. Shyroll Morris, MBA, MPH—University of Miami Hospital and Clinics
8. Thomas Ross, MS—H. Lee Moffitt Cancer and Research Institute Hospital, Inc. (Director of Quality and Safety)

9. Anthony Senagore, MD—University of Southern California Kenneth Norris Jr. Cancer Hospital (Chief of Colorectal Surgery)
10. Ron Walters, MD, MHA, MBA—The University of Texas MD Anderson Cancer Center (Associate Vice President of Medical Operations and Informatics)
11. Saul Weingart, MD, PhD —Dana Farber Cancer Institute (Vice President for Quality Improvement and Patient Safety)

TEP members

1. Peter B. Bach, MD, MAPP—Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
2. Stephen Edge, MD—Baptist Cancer Center (Cancer Center Director)
3. Andrew Glass, MD—Kaiser Permanente Northwest, Center for Health Research (Senior Investigator)
4. Mark Gorman—Independent Consultant (Patient Advocate)
5. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
6. Karl Lorenz, MD, MSHS UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
7. Joan McClure, MS—National Comprehensive Cancer Network, Clinical Information and Publications (Senior Vice President)
8. Bruce Minsky, MD—MD Anderson Hospital, Department of Radiation Oncology (Professor and Director of Clinical Research)
9. Shirley Stagner, MSN, ONP, AOCNP—Lawrence Hospital Center, Cancer Survivorship Program (Nurse Practitioner)
10. Janet H. Van Cleave, PhD, MSN, AOCNP—New York University College of Nursing (Assistant Professor)
11. Sandra L. Wong, MD MS—University of Michigan Health System, Division of Surgical Oncology (Physician)

Current Submission

Empiric Validity

Comparator Measures

Stewards of NQF-endorsed measures going through the re-endorsement process are required to demonstrate external validity testing at the time of maintenance review, or if this is not possible, justify the use of face validity only. To meet this requirement for the chemotherapy measure, we attempted to identify measures in the same causal pathway for the same or similar populations. Following a measure scan and evaluation, and consultation with measurement experts, we did not identify any measures that were suitable for comparison. While ideally, we would compare the chemotherapy measure with process measures that would be predicted to be associated with the outcome based on the logic model presented in the evidence form, there are no existing validated process measures with publicly available data that can be used for this purpose. We also did not identify outcome measures that could be used for comparison purposes. Below we describe the process by which we searched for and evaluated potential measures for comparison.

NQF-Endorsed Measures

To identify candidate measures for validity analyses, we first searched NQF's Quality Positioning Service (QPS) for NQF endorsed measures that addressed outpatient services and measured care at the facility level. We then evaluated each of these measures to determine if they could be used as a comparator measure (if they measured the same type of facility or location of service, and then if they fell on the same casual pathway as the chemotherapy measure).

Measures in CMS's Hospital Outpatient Quality Reporting (HOQR) Program

In addition, because not all measures are NQF endorsed, we evaluated the 14 measures in CMS's HOQR Program to determine if any were suitable for empiric analyses. We report the results of these analyses in the next section.

Improvement in measure scores:

To provide external evidence of measure validity, we compared the distribution of performance scores between 2019 and 2021. (We do not include results from 2020 public reporting because they are based on six months of data due to CMS' COVID data waiver that removes six months of data – January 1, 2020-June 30, 2020 -- from use for quality reporting.)

References

Krumholz HM, Brindis RG, Brush JE, et al. Standards for statistical models used for public reporting of health outcomes: An American Heart Association scientific statement from the Quality of Care and Outcomes Research Interdisciplinary Writing Group: cosponsored by the Council on Epidemiology and Prevention and the Stroke Council endorsed by the American College of Cardiology Foundation. Circulation. 2006; 113(3):456-462.

National Quality Forum. National voluntary consensus standards for patient outcomes, first report for phases 1 and 2: A consensus report. Available at: http://www.qualityforum.org/projects/Patient_Outcome_Measures_Phases1-2.aspx. Accessed June 7, 2017.

[Response Ends]

2b.03. Provide the statistical results from validity testing.

Examples may include correlations or t-test results.

[Response Begins]

Previous Submission

Face Validity as Assessed by the 2018 EWG:

All 8 EWG members completed the face validity survey. All 8 respondents (100%) felt the measure had face validity, indicating that they strongly, moderately, or somewhat agreed with the following statement: "The risk-standardized admissions rates and risk-standardized emergency department rates obtained from the chemotherapy measure as specified can be used to distinguish between better and worse quality facilities." Specifically, 2 members (25%) strongly agreed, 5 members (62.5%) moderately agreed, and 1 member (12.5%) somewhat agreed.

Two members also submitted comments as part of this process. One member noted that it is important to ensure results for cancer hospitals are not compared directly to those for non-PCH HOPDs, since separate risk models are used for these two populations. The other comment signaled support for the measure methodology, noting that the measure methods are comprehensive.

Current Submission

External Empiric Validity

Evaluation of NQF-endorsed potential comparator measures

Of the 116 measures in NQF's Quality Positioning System that measured care for outpatient services at the facility level, 42 are currently NQF endorsed. Excluding the chemotherapy measure under consideration, we then reviewed the 41 remaining measures for their suitability for this analysis (see table below).

Review criteria	Number of measures	Notes
Total number of NQF-endorsed measures for the care setting and at the facility level	41	Excluding the chemotherapy measure under discussion.

Review criteria	Number of measures	Notes
Measures excluded because not measured at HOPDs (e.g., an ED or ASC measure)	4	*
Measures excluded because target population is pediatric	5	*
Measures excluded because they address an outcome or process that is not in the same casual pathway	27	Mental health (6); infectious disease (mostly HIV) (10); cardiovascular (3); surgery (2) and radiology, orthopedics, GI, reproductive, safety (1 each)
Misclassified in QPS	2	Hospital-Wide readmission measures that do not measure the HOPD setting (2)
Total Number of Measures Excluded	**38**	*
Total Number of Potential Measures Remaining	**3**	*

Table 8: Evaluation of NQF-endorsed potential comparator measures

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The three measures that remained following our analysis are:

- Two measures that address a similar population (overlapping target audience) and similar outcome (hospital visit):
    - **Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy**: This measure captures emergency visits, observation stays, and inpatient admission for patients within 7 days after a screening colonoscopy in Medicare Fee-For-Service patients aged 65 and over.
    - **Hospital Visits after Hospital Outpatient Surgery**: This measure captures emergency visits, observation stays, and inpatient admissions within 7 days for patients who had surgery in an HOPD.

We determined that although these measures capture a similar target audience and outcome, they do not address the same cohort (different procedures) and represent quality in different settings within an HOPD. We determined that these measures are not suitable for comparison purposes.

- One measure that addresses cancer
    - **Patients with Advanced Cancer Screened for Pain at Outpatient Visits**: This measure identifies adult patients with advanced cancer who were screened for the presence and intensity of pain at each outpatient visit among those with Stage IV cancer who are alive 30 days or more after diagnosis and who have at least 1 primary care or cancer-related/specialty outpatient visit.

This measure was previously used in the PPS-except cancer hospital (PCH) Program but is no longer active; even if active results would be available for only 11 hospitals (those that are in the PCH Program).

Evaluation of HOQR measures:

We also evaluated the 14 measures in CMS's Hospital Outpatient Quality Reporting Program (HOQR) (see table below). We evaluated the HOQR measures because some will overlap with those evaluated above (NQF-endorsed measures from QPS). HOQR also includes measures that are not NQF endorsed.

Review criteria	Number of measures	Notes
Total number HOQR measures	13	Excluding the chemotherapy measure under discussion.
Measures excluded because they target the ED	5	*

Review criteria	Number of measures	Notes
Measures excluded because it does not fall on the casual pathway	6	4 outpatient imaging measures, one screening measure, and one cataract surgery PROM
Total Number of Measures Excluded	11	*
Total Number of Potential Measures Remaining	2	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy OP-36: Hospital Visits after Hospital Outpatient Surgery

Table 9: Evaluation of potential HOQR comparator measures

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The two remaining measures are the same two that were identified through our evaluation of NQF-endorsed measures. As noted above, while these measures capture a similar target audience and outcome, they do not address the same cohort (different procedures) and represent quality in different settings within an HOPD, and therefore these measures are not suitable for comparison purposes.

Improvement

Our results show that there is improvement across both PCH and non-PCH HOPDs, for both the admission outcome and the ED outcome between 2019 and 2021. Table 10 compares results from 2019 to results from 2021, for observed (national) rates, and risk-standardized facility-level measure scores. (As noted elsewhere, we did not compare 2020 results because the measure was calculated with only 6 months of data; due because claims data for January 1, 2020 – June 30, 2020 are excluded from use in the measures under CMS's Extraordinary Circumstances Exception (ECE) policy)[CMS, 2020].

Improvement in National Observed Outcome Rates

- In 2019, PCH-HOPDs had a national observed admissions rate of 14.0%, compared with 11.7% in 2021, and a national 2019 observed ED visit rate of 6.3%, compared with 4.9% in 2021 (Table 10).
- Among non-PCH HOPDs, the national observed admissions rate was 12.6% in 2019, compared with 9.4% in 2021; the national observed ED visit rate was 5.9% in 2019, compare with 5.2% in 2021 (Table 10).

**	PCH-HOPDs– 2019 Observed National Average	PCH-HOPDs– 2021 Observed National Average	Non-PCH HOPDs: 2019 Observed National Average	Non-PCH HOPDs: 2021 Observed National Average
Admission Rate (%)	14.0	11.7	12.6	9.4
ED Visit Rate (%)	6.3	4.9	5.9	5.2

Table 10: National observed outcome rates for PCH and non-PCH HOPDs, 2019 vs. 2021*

*Dates of data: 2019: July 1, 2018-June 30, 2019, 2019; 2021: January 1, 2021-November 30, 2021.

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Improvement in risk-standardized measure scores

Tables 11 and 12 show facility performance on measure scores, comparing results from 2019 and 2021 (as noted earlier, we do not include results from 2020 public reporting because they are based on six months of data due to CMS' COVID data waiver that removes six months of data – January 1, 2020-June 30, 2020-- from use for quality reporting).

Facility performance in 2021 has improved compared to facility performance in 2019, across the entire distribution, for both outcomes (RSAR, RSDER) for non-PCH HOPDs (Table 11) and for PCH-HOPDs (Table 12). For

example, median performance on the RSAR for non-PCH HOPDs was 12% in 2019, and 9.3% in 2021. Similarly, median RSDER performance was 6.1% in 2019, and 5.2% in 2021 (Table 11).

Percentile	2019 RSARs (%) (n=3,484)	2021 RSARs (%) (n=3,289)	2019 RSEDRs (%) (n=3,484)	2021 RSEDRs (%) (n=3,289)
100% Max	18.7	18.6	11.3	9.1
75% Q3	12.4	9.7	6.4	5.4
50% Median	12.0	9.3	6.1	5.2
25% Q1	11.7	9.0	6.0	5.0
0% Min	8.7	6.3	3.4	3.0
Mean	12.1 (1.0)	9.5 (1.0)	6.22 (0.7)	5.2 (0.5)

Table 11: Non-PCH HOPDs: Comparison of facility-level performance on the chemotherapy measure: 2019 vs. 2021*

*Dates of data: 2019: January 1, 2019-December 31, 2019; 2021: January 1, 2021-November 30, 2021.

Percentile	2019 RSARs (%) (n=11)	2021 RSARs (%) (n=11)	2019 RSEDRs (%) (n=11)	2021 RSEDRs (n=11)
100% Max	16.6	14.1	8.8	6.9
75% Q3	15.7	13.2	7.4	5.6
50% Median	14.5	11.8	6.1	4.7
25% Q1	13.6	10.7	4.9	4.4
0% Min	11.3	9.2	4.8	3.8

Table 12: PCH-HOPDs: Comparison of facility-level performance on the chemotherapy measure: 2019 vs. 2021*

*Dates of data: 2019: July 1, 2018-June 30, 2019; 2021: January 1, 2021-November 30, 2021.

References

Centers for Medicare & Medicaid Services (CMS). CMS Announces Relief for Clinicians, Providers, Hospitals and Facilities Participating in Quality Reporting Programs in Response to COVID-19. 2020; https://www.cms.gov/Newsroom/Press-Releases/Cms-Announces-Relief-Clinicians-Providers-Hospitals-And-Facilities-Participating-Quality-Reporting. Accessed March 3, 2022.

Centers for Medicare & Medicaid Services (CMS). COVID-19 Quality Reporting Programs Guidance Memo. 2020; https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf. Accessed March 3, 2022.

[Response Ends]

2b.04. Provide your interpretation of the results in terms of demonstrating validity. (i.e., what do the results mean and what are the norms for the test conducted?)

[Response Begins]

Previous submission

Face Validity

There was perfect agreement (100%) among EWG members that the measure has face validity, i.e., that it measures what it is intended to measure – the quality of care provided to cancer patients receiving outpatient chemotherapy treatment. The EWG members were actively involved with the measure's reevaluation during the spring of 2018 and reviewed both the current measure specifications and distribution of performance prior to assessing face validity. We conclude the measure's validity to be at least moderate based on their assessment.

Current submission

Empiric Validity

As noted above in section 2b.03, we systematically examined all available NQF-endorsed and CMS programmatic measures that target HOPDs but were unable to identify quality measures (process or outcome) that were suitable comparators for the chemotherapy measure.

However, in comparing performance on this measure, in terms of national rates, and facility-level performance between 2019 and 2021, we found substantial improvement in performance on this measure, for both PCH and non-PCH-HOPDs. Changes to the measure during this timeframe had an impact smaller than the magnitude of the improvement. While it is difficult to account for all of the possible confounders without additional analyses, it is possible these differences reflect quality improvement. Evidence of improvement is also supported by quality improvement programs that have been put in place to improve patient care to improve the inpatient measure score (as a direct result of implementation of the chemotherapy measure) [Smith & Carlson, 2021] and several additional quality improvement projects that address the emergency room visit outcome [Quality Improvement Library, 2016].

Taken together, the face validity and the improvement results support the overall validity of the measure.

References

Smith M, Carlson J. Reducing ED Visits and Hospital Admissions after Chemotherapy with Predictive Modeling of Risk Factors. Oncology Issues. 2021;36(4):40-44. doi:10.1080/10463356.2021.1927638

Quality Improvement Library | ASCO Practice Central. Asco.org. Published 2016. https://practice.asco.org/quality-improvement/quality-programs/quality-training-program/quality-improvement-library

[Response Ends]

2b.05. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified.

Describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided in Importance to Measure and Report: Gap in Care/Disparities.

[Response Begins]

The measure scores are hospital-level RSAR and RSEDRs, produced separately for PCH-HOPDs and non-PCH HOPDs. The RSAR is calculated as the ratio of the number of predicted qualifying inpatient admissions to the number of expected qualifying inpatient admissions multiplied by the national observed qualifying inpatient admission rate. Similarly, the RSEDR is calculated as the ratio of the number of predicted qualifying ED visits to the number of expected qualifying ED visits multiplied by the national observed qualifying ED visit rate.

For each hospital, the numerator of the RSAR or RSEDR ratio is the number of hospital admissions or ED visits predicted for the hospital's patients, accounting for its observed rate, the age, sex, chemotherapy exposure, radiotherapy exposure, cancer diagnoses and clinical comorbidities. The denominator is the number of hospital visits expected nationally for the hospital's patient population.

To calculate a hospital's predicted-to-expected (P/E) ratio, the measure uses a two-level hierarchical logistic regression model that accounts for the clustering of patients within hospitals and variation in sample size. The log-odds of the outcome for an index chemotherapy procedure is modeled as a function of the patient demographic, exposure, cancer diagnoses, clinical comorbidities, and a random hospital-specific intercept. A ratio greater than

one indicates that the hospital's patients and have more inpatient admissions or ED visits than expected, compared to an average hospital with similar patient complexity. A ratio less than one indicates that the hospital's patients have fewer inpatient admissions or ED visits than expected, compared to an average hospital with similar patient complexity.

We characterize the degree of variability by:

1. Reporting the distribution of the RSAR and RSEDRs.
2. Assessing facility performance by comparing the 95% confidence interval around the RSAR or RSEDR with the program-specific national observed rate, and categorizing the results as follows:

- Better than national rate: If the entire 95% confidence interval of the facility's rate is lower than the national observed rate.
- No different from the national rate: If the 95% confidence interval of the facility's rate includes the national observed rate.
- Worse than national rate: If the entire 95% confidence interval of the facility's rate is higher than the national observed rate.
- Number of cases too small: If a facility does not have at least 25 patients qualifying for the measure, CMS cannot reliably determine how well the facility is performing and therefore does not assign a performance category.

3. Providing the median odds ratio (MOR) [Merlo et al., 2006]. The median odds ratio represents the median increase in odds of a hospital inpatient admission or visit if a patient received outpatient chemotherapy at a higher risk hospital compared to a lower risk hospital. It is calculated by taking all possible combinations of hospitals, always comparing the higher risk hospital to the lower risk hospital. The MOR is interpreted as a traditional odds ratio would be.

Reference

Merlo J, Chaix B, Ohlsson H, Beckman A, Johnell K, Hjerpe P, Råstam L, Larsen K. (2006) A brief conceptual tutorial of multilevel analysis in social epidemiology: Using measures of clustering in multilevel logistic regression to investigate contextual phenomena. J Epidemiol Community Health, 60(4):290-7.

[Response Ends]

2b.06. Describe the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities.

Examples may include number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined.

[Response Begins]

Previous submission:

Measure score distribution: Among cancer hospitals, the median RSAR and RSEDR were 13.7% and 6.7%, respectively. The values ranged from 12.3% to 15.2% for RSARs and 3.6% to 9.1% for RSEDRs. For non-PCH HOPDs, the median RSAR and RSEDR were 12.5% and 5.6%, respectively. The values ranged from 8.9% to 18.5% for RSARs and 2.9% to 15.2% for RSEDRs. The percentiles of the distribution are shown below in Table 13.

*	PCH-HOPDs	*	Non-PCH HOPDs	*
Percentile	**RSARs (%)**	**RSEDRs (%)**	**RSARs (%)**	**RSEDRs (%)**
Minimum	**12.3**	**3.6**	**8.9**	**2.9**

*	PCH-HOPDs	*	Non-PCH HOPDs	*
1st	12.3	3.6	10.2	4.2
5th	12.3	3.6	11.1	4.8
10th	13.4	4.1	11.6	5.2
25th	13.4	4.4	12.2	5.6
50th (median)	13.7	6.7	12.5	5.6
75th	14.8	8.9	13.0	6.2
90th	14.8	9.1	13.9	6.8
95th	15.2	9.1	14.8	7.4
99th	15.2	9.1	16.4	8.6
Maximum	15.2	9.1	18.5	15.2

Table 13: Distribution of RSARs and RSEDRs for PCH- and Non-PCH HOPDs

*Cells intentionally left empty

Performance categories: Among the 11 PCH-HOPDs, 1 was identified as performing significantly better on the RSAR, 3 were identified as performing significantly better on the RSEDR, and 3 were identified as performing significantly worse. For the 3,562 non-PCH HOPDs, the measure had additional ability to discriminate performance, with 13 hospitals performing significantly better on the RSAR, 65 performing significantly worse on the RSAR, 26 hospitals performing significantly better on the RSEDR, and 33 performing significantly worse on the RSDER.

Median odds ratio: The median odds ratio for PCH-HOPDs was 1.82 for the RSAR and 2.04 for the RSEDR, and for non-PCH HOPDs it was 1.39 for the RSAR and 1.45 for the RSEDR.

Current submission

Measure score distribution: Among PCH-HOPDs, the median RSAR and RSEDR were 11.8% and 4.7%, respectively. The values ranged from 9.2% to 14.1% for RSARs and 3.8% to 6.9% for RSEDRs. For non-PCH HOPDs, the median RSAR and RSEDR were 9.3% and 5.2%, respectively. The values ranged from 6.3% to 18.6% for RSARs and 3% to 9.1% for RSEDRs. The percentiles of the distribution are shown below in Table 14. Histograms showing the distribution of hospital performance for each outcome and each facility type are shown in Figures 3 and 4.

*	PCH-HOPDs	*	Non-PCH HOPDs	*
Percentile	RSARs (%)	RSEDRs (%)	RSARs (%)	RSEDRs (%)
Minimum	9.2	3.8	6.3	3
1st	9.2	3.8	7.2	3.9
5th	9.2	3.8	8.1	4.5
10th	10.5	4.2	8.5	4.7
25th	10.7	4.4	9	5
50th (median)	11.8	4.7	9.3	5.2
75th	13.2	5.6	9.7	5.4
90th	13.5	6.5	10.6	5.8
95th	14.1	6.9	11.4	6.3
99th	14.1	6.9	12.8	7.1
Maximum	14.1	6.9	18.6	9.1

Table 14: Distribution of RSARs and RSEDRs for PCH- and Non-PCH HOPDs

*Cells intentionally let empty

Figure 3: Distribution of RSAR and RSEDR for PCH-HOPDs

Figure 4: Distribution of RSAR (red bars) and RSEDR (blue bars) for non-PCH HOPDs

Performance Categories: Among the 11 PCH-HOPDs, 1 was identified as performing significantly better on the RSAR, and 1 worse. None were identified as performing significantly better on the RSEDR, and 2 were identified as performing significantly worse. For the 3,278 non-PCH HOPDs, 14 hospitals performed significantly better on the RSAR and 68 performed significantly worse. 25 hospitals performed significantly better on the RSEDR, and 15 performed significantly worse.

Facility type	PCH-HOPDs (n=11)	PCH-HOPDs (n=11)	Non-PCH HOPDs (n=3,278)	Non-PCH HOPDs (n=3,278)
Outcome	**RSAR**	**RSEDR**	**RSAR**	**RSEDR**
Worse than National Rate	**1**	**2**	**68**	**15**
No Different than National Rate	**9**	**9**	**1,392**	**1,434**
Better than National Rate	**1**	**0**	**14**	**25**
Too Few Cases (<25)	**0**	**0**	**1,804**	**1,804**

Table 15: Performance Categories for PCH and non-PCH HOPDs: January 1, 2021 - November 30, 2021

Median odds ratio: The median odds ratio for PCH-HOPDs was 1.18 for the RSAR and 1.24 for the RSEDR; for non-PCH HOPDs it was 1.29 for the RSAR and 1.30 for the RSEDR.

*	PCH-HOPDs (n=11)	Non-PCH Hospitals (n=3,278)
RSAR Median Odds Ratio	**1.18**	**1.29**
RSEDR Median Odds Ratio	**1.24**	**1.30**

Table 16: Median odds ratio for PCH and non-PCH HOPDs

*Cells intentionally left empty

[Response Ends]

2b.07. Provide your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities.

In other words, what do the results mean in terms of statistical and meaningful differences?

[Response Begins]

The chemotherapy measure produces measure scores that demonstrate meaningful differences in performance across measured entities.

Previous submission

The distribution shows a clinically meaningful range of measure scores (RSARs, RSEDRs) for PCH-HOPDs and non-PCH HOPDs (Table 13). In addition, the median measure scores indicate that patients receiving outpatient chemotherapy who are treated at PCH-HOPDs are expected to experience an inpatient admission on average 13.7% of the time, and an emergency department visit 6.7% of the time; patients treated at non-PCH HOPDs are expected to experience an inpatient admission 12.5% of the time, and an emergency department visit 5.6% of the time.

Furthermore, for hospital admission rates (RSARs) the best-performing PCH-HOPDs (12.3%) are performing 10% better than an average performer, while the worst-performing PCH-HOPDs (15.2%) are performing 11% worse than an average performer. For ED visit rates (RSEDRs), the best-performing PCH-HOPDs (3.6%) are performing 46% better than an average performer, while the worst-performing PCH-HOPDs (9.1%) are performing 36% worse than an average performer. For non-PCH HOPDs' admission rates (RSARs), the best-performing hospitals (8.9%) are performing about 30% better than an average performer, while the worst-performing hospitals (18.5%) are performing 48% worse than an average performer. For ED visit rates (RSEDRs), the best-performing non-PCH HOPDs (2.9%) are performing 48% percent better than an average performer, while the worst-performing hospitals (15.2%) are performing 1.7 times (or 171%) worse than an average performer.

This variation shows a clear quality gap, as some facilities can achieve substantially lower rates than the average performer, while other facilities are performing meaningfully worse than an average performer. It is important to note that here the average performer refers to a facility with the same case and procedure mix performing at the average.

The significance testing results suggest that the measure could detect meaningful differences in the quality of care received for adult cancer patients receiving chemotherapy treatment in the hospital outpatient setting. Among non-PCH HOPDs, the measure detected outliers for the RSAR (13 significantly better, 65 significantly worse) and 59 outliers for the RSEDR (26 significantly better, 33 significantly worse). Despite there only being 11 PCH-HOPDs, the measure also detected outliers for these facilities, with 1 outlier identified for the RSAR (significantly better) and 6 outliers identified for the RSEDR (3 significantly better, 3 significantly worse).

Finally, the median odds ratio suggests a meaningful increase in the risk of an inpatient hospital admission or ED visit if chemotherapy was administered at a higher risk facility compared to a lower risk facility. For instance, the PCH inpatient admissions outcome rate has a median odds ratio of 1.82 which indicates that a patient has an 82%

increase in the odds of a hospital inpatient admission if the same procedure was performed at higher risk facility compared to a lower risk facility. Median odds ratios across the four models ranged from 1.39–2.04 indicating the impact of quality on the outcome rate is substantial.

Current submission

Similar to the Previous submission, the distribution of measure scores is clinically meaningful for PCH-HOPDs and non-PCH HOPDs. In addition, the results indicate that patients receiving outpatient chemotherapy who are treated at PCH-HOPDs are expected to experience an inpatient admission on average 11.8% of the time, and an emergency department visit 4.7% of the time; patients treated at non-PCH HOPDs are expected to experience an inpatient admission 9.3% of the time, and an emergency department visit 5.2% of the time.

Furthermore, for hospital admission rates (RSARs) the best-performing PCH-HOPDs (9.2%) are performing 22% better than an average (median) performer, while the worst-performing PCH-HOPDs (15.2%) are performing about 19% worse than an average performer. For ED visit rates (RSEDRs), the best-performing PCH-HOPDs (3.8%) are performing 19% better than an average performer, while the worst-performing PCH-HOPDs (6.9%) are performing 47% worse than an average performer. For non-PCH HOPDs' admission rates (RSARs), the best-performing hospitals (6.3%) are performing about 32% better than an average performer, while the worst-performing hospitals (18.6%) are performing 100% worse than an average performer. For ED visit rates (RSEDRs), the best-performing non-PCH HOPDs (3%) are performing 42% percent better than an average performer, while the worst-performing hospitals (9.1%) are performing 75% worse than an average performer. This variation shows a clear quality gap, as some facilities can achieve substantially lower rates than the average performer, while other facilities are performing meaningfully worse than an average performer. It is important to note that here the average performer refers to a facility with the same case and procedure mix performing at the average.

The significance testing results (performance categories) suggest that the measure has the ability to detect meaningful differences in the quality of care received for adult cancer patients receiving chemotherapy treatment in the hospital outpatient setting. Among non-PCH HOPDs, the measure detected 82 outliers for the RSAR (14 significantly better, 68 significantly worse) and 40 outliers for the RSEDR (25 significantly better, 15 significantly worse). Despite there only being 11 PCH-HOPDs, the measure also detected outliers for these facilities, with 2 outliers identified for the RSAR (1 significantly better, 1 significantly worse) and 2 significantly worse outliers identified for the RSEDR.

Finally, the median odds ratio suggests a meaningful increase in the risk of an inpatient hospital admission or ED visit if chemotherapy was administered at a higher risk facility compared to a lower risk facility. For instance, the non-PCH inpatient admissions outcome rate has a median odds ratio of 1.29 which indicates that a patient has an 29% increase in the odds of a hospital inpatient admission if the same procedure was performed at higher risk facility compared to a lower risk facility. Median odds ratios across the four models ranged from 1.18–1.30 indicating the impact of quality on the outcome rate is substantial.

Overall, our results from the current submission are similar to the past submission and there continues to a quality gap to reduce the expected rate and the variation in rates across facilities.

[Response Ends]

2b.08. Describe the method of testing conducted to identify the extent and distribution of missing data (or non-response) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders). Include how the specified handling of missing data minimizes bias.

Describe the steps—do not just name a method; what statistical analysis was used.

[Response Begins]

CMS claims and enrollment data are routinely validated for completeness, and we examined the extent of missing data for key variables during measure calculation. No patients or observations were excluded due to missing data.

[Response Ends]

2b.09. Provide the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data.

For example, provide results of sensitivity analysis of the effect of various rules for missing data/non-response. If no empirical sensitivity analysis was conducted, identify the approaches for handling missing data that were considered and benefits and drawbacks of each).

[Response Begins]

Not applicable.

[Response Ends]

2b.10. Provide your interpretation of the results, in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders), and how the specified handling of missing data minimizes bias.

In other words, what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis was conducted, justify the selected approach for missing data.

[Response Begins]

Not applicable; there was no missing data.

[Response Ends]

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) OR to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eCQMs). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b.11. Indicate whether there is more than one set of specifications for this measure.

[Response Begins]

No, there is only one set of specifications for this measure

[Response Ends]

2b.12. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications.

Describe the steps—do not just name a method. Indicate what statistical analysis was used.

[Response Begins]

[Response Ends]

2b.13. Provide the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications.

Examples may include correlation, and/or rank order.

[Response Begins]

[Response Ends]

2b.14. Provide your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications.

In other words, what do the results mean and what are the norms for the test conducted.

[Response Begins]

[Response Ends]

2b.15. Indicate whether the measure uses exclusions.

[Response Begins]

Yes, the measure uses exclusions.

[Response Ends]

2b.16. Describe the method of testing exclusions and what was tested.

Describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used?

[Response Begins]

Previous submission

We evaluated five possible exclusions throughout the initial development and reevaluation of the measure:

1. First, we considered the removal of patients with leukemia because of the high toxicity of treatment and expected readmissions due to relapse.
2. Second, we considered the removal of patients who do not have a full year of prior enrollment data to ensure complete data for the risk-adjustment model.
3. Third, we considered removal of patients who do not have at least one chemotherapy treatment followed by 30 days of enrollment for full data availability to identify outcomes.
4. Fourth, we considered the removal of patients younger than 65 years of age because patients aged 18-64 enrolled in Medicare may be systematically different than those patients 65 and older.
5. Finally, we considered the removal of patients who were receiving chemotherapy and had a cancer diagnosis during the performance period but did not have a cancer diagnosis on the index chemotherapy claim and did have a diagnosis for an auto-immune condition. Based on stakeholder feedback, these patients are assumed to be receiving chemotherapy to treat an auto-immune condition rather than to treat cancer.

We reviewed each of these exclusions with our TEP and/or EWGs. TEP and EWG members raised concerns about the exclusion of patients aged 18-64, expressing a desire for a broad cohort and indicating that there was no

clinical reason to exclude this group. We therefore explored the appropriateness of including these patients by (1) reviewing patient characteristics separately for these two subsets, (2) reviewing the observed performance rates for the two separate subsets, and (3) fitting the risk-adjustment model separately for these two subsets.

Expert input indicated that the remaining four exclusions were clinically appropriate or required for data completeness (see Notice of Intent to Submit or Measure Submission Form, Section sp.16 for more information):

1. patients with a diagnosis of leukemia at any time during the performance period,
2. patients who were not enrolled in Medicare FFS Parts A and B in the year before their first outpatient chemotherapy treatment during the performance period,
3. patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure, and
4. cases in which patients receive chemotherapy to treat a qualifying autoimmune condition, rather than to treat cancer. Such cases have a qualifying chemotherapy code, and an autoimmune diagnosis, but no cancer diagnosis. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

We examined overall frequencies and proportions of the total cohort excluded for each exclusion criterion. We then looked at the distribution of the exclusions across hospitals. Lastly, we calculated the observed performance rate with and without accounting for exclusions. The results are presented below.

Current submission

We calculated overall frequencies and proportions of the total cohort excluded for each exclusion criteria in the final measure.

[Response Ends]

2b.17. Provide the statistical results from testing exclusions.

Include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores.

[Response Begins]

Previous submission

We explored the potential bias of including patients aged 18-64 in the measure using the 2012–2013 dataset during the measure's initial development. Specifically, we compared differences in the 18-64 and 65 and older populations by comparing: (1) patient characteristics, (2) observed inpatient admission and ED visit rates, and (3) risk-adjustment model fit statistics for the two populations. We found that patients aged 18-64 represented 13% of the final measure cohort, and while the younger population has higher observed outcome rates, the risk-adjustment model parameter estimates were similar for both age groups. Based on these findings, as well as the recommendation of our TEP, we determined there was not a strong statistical or clinical reason to exclude the younger patients from the measure cohort; all adult patients 18 years and older remain in the eligible cohort.

Applying our measure inclusion criteria (all adult Medicare FFS patients with a diagnosis of cancer aged 18 years or older at the start of the performance period who received a qualifying chemotherapy procedure) to the Medicare FFS FY 2016 Dataset resulted in an initial cohort of 354,849 unique patients overall, with 30,006 patients from PCH-HOPDs and 324,843 from non-PCH HOPDs. We then applied the remaining four exclusion criteria (see the Intent to Submit Notice and Measure Submission Form, Section 2b.17, for exclusion rationale):

1. patients with a diagnosis of leukemia at any time during the performance period,
2. patients who were not enrolled in Medicare FFS Parts A and B in the year before their first outpatient chemotherapy treatment during the performance period,

3. patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure, and
4. cases in which patients receive chemotherapy to treat a qualifying autoimmune condition, rather than to treat cancer. Such cases have a qualifying chemotherapy code, and an autoimmune diagnosis, but no cancer diagnosis. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

This resulted in excluding 65,306 (18.4%) of patients eligible for the cohort from the measure in the FY2016 dataset overall. Among the excluded patients, 6,529 were from PCH-HOPDs and 58,777 were from non-PCH HOPDs, representing 21.8% and 18.1% of their respective measure-eligible cohorts (Table 17). Thus, the final Medicare FFS FY 2016 Dataset included 289,543 unique patients overall, with 23,477 at PCH-HOPDs and 266,066 at non-PCH HOPDs

*	PCH-HOPDs	*	Non-PCH HOPDs	*
Exclusion	**n**	**%**	**n**	**%**
(1) Leukemia	2,510	8.4	22,414	6.9
(2) No Medicare FFS A/B Enrollment 12 Months Prior to First Index Chemo	4,298	14.3	37,543	11.6
(3) No Medicare FFS A/B Enrollment 30 Days Following Index Chemo	245	0.8	4,081	1.3
(4) Receiving Chemotherapy for Autoimmune Condition	4	0.0	333	0.1
All Exclusions**	6,529	21.8	58,777	18.1

Table 17: Count and Percent of Excluded Patients

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***Note: Patients are eligible for more than one exclusion, therefore the count of all exclusions is lower than the sum of the individual exclusions.*

Current submission

*	PCH-HOPDs	*	*	Non-PCH HOPDs	*	*
Exclusion	**n**	**%**	**Distribution (%) (Min, 25th, 50th, 75th percentile, Max)** **[n=1,474]**	**n**	**%**	**Distribution (%) (Min, 25th, 50th, 75th percentile, Max)** **[n=11]**
(1) Leukemia	**2,557**	**7.4**	**(3.33, 17.63, 21.43, 25.32, 66.67)**	**22,352**	**6.3**	**(18.68, 22.57, 24.33, 30.62, 38.10)**

*	PCH-HOPDs	*	*	Non-PCH HOPDs	*	*
(2) No Medicare FFS A/B Enrollment 12 Months Prior to First Index Chemo	6,892	19.8	(0.00, 5.31, 7.41, 9.76, 37.08)	58,779	16.6	(7.63, 8.36, 9.68, 11.53, 16.58)
(3) No Medicare FFS A/B Enrollment 30 Days Following Index Chemo	3,418	9.8	(0.00, 12.10, 15.37, 18.75, 58.43)	29,373	8.3	(16.64, 17.37, 20.20, 22.94, 29.53)
(4) Receiving Chemotherapy for Autoimmune Condition	45	0.1	(0.00, 3.33, 5.41, 7.39, 49.57)	3,938	1.1	(1.84, 5.32, 8.24, 9.73, 11.26)
All Exclusions**	9,022	25.9	(0.00, 0.00, 0.54, 1.55, 43.24)	81,241	22.9	(0.00, 0.05, 0.08, 0.18, 0.45)
Final Cohort	25,763	74.1	*	272,753	77.1	*

Table 18: Count, Percent, and Distribution of Excluded Patients based on Initial Cohort (for facilities with at least 25 cases)

**Cells intentionally left blank.*

***Note: Patients are eligible for more than one exclusion, therefore the count of all exclusions is lower than the sum of the individual exclusions.*

[Response Ends]

2b.18. Provide your interpretation of the results, in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results.

In other words, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion.

[Response Begins]

Previous submission

After extensive literature review, examination of existing measures, consideration of requirements to have adequate risk adjustment and identification of admissions or ED visits, and discussion with the TEP and EWGs, we determined these four exclusion criteria are necessary for a valid measure. The goal was to be as inclusive as possible while creating a clinically coherent cohort.

Testing of the distribution of exclusion criteria across hospitals suggests modest variation among providers. The uneven distribution of excluded populations and procedures supports our decision that these exclusions are required. Failure to exclude these populations may distort the measure score and unfairly disadvantage certain hospitals. Additional rationales for exclusions are detailed in the Intent to Submit Notice and Measure Submission

Form, Section sp.16 After exclusions were applied, the measure captured the majority (81.6%) of all qualifying patients. The exclusions are very narrowly targeted and necessary to ensure a clinically coherent measure cohort and a cohort with complete data available for risk adjustment and identification of admissions or ED visit outcomes.

Current submission

These submissions remain valid from a measure development and clinical perspective. No additional exclusions were identified since the Previous submission. With the current cohort, the overall proportion of patients excluded and the proportion for each individual exclusion is similar to the Previous submission. In the current update, about 77% of all qualifying patients remain in the measure. The exclusions are very narrowly targeted and necessary to ensure a clinically coherent measure cohort and a cohort with complete data available for risk adjustment and identification of admissions or ED visit outcomes.

[Response Ends]

2b.19. Check all methods used to address risk factors.

[Response Begins]

Statistical risk model with risk factors (specify number of risk factors)

[Statistical risk model with risk factors (specify number of risk factors) Please Explain]

21 risk factors for the inpatient admission outcome model and 16 risk factors for hte ED visit outcome

[Response Ends]

2b.20. If using statistical risk models, provide detailed risk model specifications, including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.

[Response Begins]

The measure has two mutually exclusive outcomes: (1) patients in the cohort admitted to any acute-care hospital with one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of an outpatient chemotherapy administration at the reporting hospital, and (2) patients in the cohort that did not have a qualifying inpatient admission, but were seen at any ED with one of the qualifying diagnoses within 30 days of an outpatient chemotherapy administration at the reporting hospital. As a result, we developed two risk-adjustment models, one for each dependent variable—inpatient admissions and ED visits.

The measure uses a two-level hierarchical logistic regression model to estimate facility-level risk-standardized admission rates (RSARs) and risk-standardized emergency department rates (RSEDRs). This approach accounts for the clustering of patients within facilities and variation in sample size across facilities.

The measure has four risk-adjustment models, one for each outcome, reported separately for PCH-HOPDs and non-PCH HOPDs (two outcomes each reported for two facility types). The risk-adjustment model for inpatient admissions has 21 variables (age, sex, chemotherapy exposure, concurrent radiotherapy exposure, 9 comorbidity variables, and 8 cancer diagnosis categories), and the risk-adjustment model for ED visits has 16 variables (age, sex, chemotherapy exposure, concurrent radiotherapy exposure, 6 comorbidity variables, and 6 cancer diagnosis categories). The ED visit model does not include the variables for renal disease, diabetes, metabolic disorder, lymphoma, or prostate cancer that the inpatient admission model includes because these variables were not predictive of risk for the outcome in the ED setting. The same risk factors are included for both PCH-HOPDs and non-PCH hospital models, but the coefficients vary according to differences in the underlying patient populations for these two facility types.

Risk variable definitions:

Chemotherapy exposure is defined as the number of chemotherapy treatments in the performance period for a patient a given provider. Exposure to concurrent radiotherapy assesses whether the first index outpatient chemotherapy case – which is the case included in the measure denominator – was accompanied by concurrent radiotherapy. Chemotherapy treatments are defined in the attached 2021 Chemotherapy Measure Data Dictionary on sheets using the "S.9 Denominator-Chemo Procedure," "S.9 Denominator – Chemo Encounter," and "S.9 Denominator – Chemo Medication" codes.

Concurrent radiotherapy is defined as having a radiotherapy procedure present on the same claim as the first index chemotherapy case or on a separate claim within 14 days prior to the first index chemotherapy case. Individual (ICD-10) diagnosis codes, procedure codes, HCPCS codes and CPT codes are used to identify chemotherapy and radiotherapy exposure. Concurrent Radiotherapy is defined in the attached 2018 Chemotherapy Measure Data Dictionary on sheets using the "S.15 Risk Factor-Radiotherapy" codes.

We define the comorbidity variables in the models using the CMS Condition Categories (CCs), which are clinically meaningful groupings of more than 69,000 ICD-10 diagnosis codes. During measure development and in consultation with our TEP, the CCs selected for inclusion were bundled with other clinically related CCs for empirical assessment of significance within the model. The result was nine bundled CCs—diabetes, metabolic disorders, gastrointestinal (GI) disorders, psychiatric disorders, neurological conditions, cardiovascular disease, respiratory disorders, renal disease, and other injuries.

The cancer types included in the model are defined using ICD-10 diagnosis codes (see attached 2021 Chemotherapy Measure Data Dictionary on sheets using the "S.15 Risk Factor" codes). During measure development and based on input from our TEP, these were aggregated into nine clinically related and decently sized groupings—breast cancer, digestive cancer, genitourinary cancer, respiratory cancer, lymphoma, prostate cancer, secondary cancer of the lymph nodes, secondary cancer of solid tumor, and other cancers.

Model Variables – inpatient admissions

1. Age (continuous)
2. Sex (male)
3. Exposure (Number of hospital OPD chemotherapy treatments during period)
4. Respiratory disorders (CC 110 – 113)
5. Renal disease (CC 132, 134 – 140)
6. Diabetes (CC 17 – 20)
7. Other injuries (CC 174)
8. Metabolic disorder (CC 21-26)
9. Gastrointestinal disorder (CC 27-32; 34; 36-38)
10. Psychiatric disorder (CC 50-69)
11. Neurological conditions (CC 70-81)
12. Cardiovascular disease (CC 82-109)
13. Breast cancer
14. Digestive cancer
15. Respiratory cancer
16. Lymphoma
17. Other cancer
18. Prostate cancer
19. Secondary – lymph
20. Secondary – solid
21. Concurrent Radiotherapy

Model Variables – ED visits

1. Age (continuous)
2. Sex (male)
3. Exposure (Number of hospital OPD chemotherapy treatments during period)
4. Respiratory disorders (CC 110 – 113)
5. Other injuries (CC 174)
6. Gastrointestinal disorder (CC 27-32; 34; 36-38)
7. Psychiatric disorder (CC 50-69)
8. Neurological conditions (CC 70-81)
9. Cardiovascular disease (CC 82-109)
10. Breast cancer
11. Digestive cancer
12. Respiratory cancer
13. Other cancer
14. Secondary – lymph
15. Secondary – solid
16. Concurrent Radiotherapy

[Response Ends]

2b.21. If an outcome or resource use measure is not risk-adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (i.e., case mix) is not needed to achieve fair comparisons across measured entities.

[Response Begins]

[Response Ends]

2b.22. Select all applicable resources and methods used to develop the conceptual model of how social risk impacts this outcome.

[Response Begins]

Published literature

Internal data analysis

[Response Ends]

2b.23. Describe the conceptual and statistical methods and criteria used to test and select patient-level risk factors (e.g., clinical factors, social risk factors) used in the statistical risk model or for stratification by risk.

Please be sure to address the following: potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10 or other statistical tests; correlation of x or higher. Patient factors should be present at the start of care, if applicable. Also discuss any "ordering" of risk factor inclusion; note whether social risk factors are added after all clinical factors. Discuss any considerations regarding data sources (e.g., availability, specificity).

[Response Begins]

Our approach to risk adjustment was tailored to, and appropriate for, a publicly reported outcome measure as articulated in published scientific guidelines [Krumholz et al., 2006; Normand & Shahian, 2007]. In this section, we detail both the initial development of the risk-adjustment models, and then their subsequent refinement during reevaluation to include concurrent radiotherapy as a risk variable.

Initial Model Development

We detail the sequential method for selecting patient-level risk factors below.

Candidate Risk-Adjustment Variables

Candidate risk-adjustment variables were patient-level risk adjustors that are expected to be predictive of the outcomes based on prior literature, clinical judgment, and empirical analysis. We limited our initial selection of candidate variables for inclusion in our preliminary risk-adjustment model to variables with a strong clinical rationale for inclusion as identified in the literature and through clinical expert input. Identification of these variables is described below.

Demographic variables: In alignment with the specifications of other NQF endorsed claims-based outcome measures, as well as the NQF guidelines at the time of development, we included age and sex as candidate covariates. [Note: Due to changes in NQF policy, additional social risk factors were considered during continued assessment of this measure as described later in this section.]

Comorbidities: The model adjusts for case mix differences based on the comorbidities of the patient at the time of the first outpatient chemotherapy treatment during the performance period. During model development, we defined comorbidities using Condition Categories (CCs) from Version 12 (V12) of the CMS-HCC risk-adjustment model, which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis codes. With a subset of our TEP, we reviewed all 189 CCs to determine the clinical appropriateness and prevalence within the cohort) for potential inclusion in the model. (Note: During subsequent years, these CCs were updated to Version 22 (V22) of the CMS-HCC model as part of measure reevaluation.)

Specific considerations included the number of patients in our cohort potentially affected, whether the condition affects admission for one of the ten outcome-qualifying diagnoses, and whether inclusion of the condition in the model would incentivize appropriate treatment, even when that variable is theoretically unrelated to admission for one of the identified reasons. For example, patients with diabetes may have gastric paresis, a condition that slows emptying of the stomach and increases the likelihood of nausea. The CCs selected for inclusion were bundled with other clinically related CCs for empirical assessment of significance within the model. The result was nine bundled CCs—diabetes, metabolic disorders, gastrointestinal (GI) disorders, psychiatric disorders, neurological conditions, cardiovascular disease, respiratory disorders, renal disease, and other injuries.

Indicator of disease severity: We explored cancer type as an indicator of disease severity available in claims data by assessing the distribution of patients across a granular level of cancer diagnoses. In conjunction with a subset of our TEP, we aggregated these granular cancer types into nine clinically related and decently sized groupings—breast cancer, digestive cancer, genitourinary cancer, respiratory cancer, lymphoma, prostate cancer, secondary cancer of the lymph nodes, secondary cancer of solid tumor, and other cancers.

Exposure: We also assessed the number of chemotherapy treatments during the performance period (that is, exposure). The exposure variable is necessary because the measure estimates the risk-adjustment models at the patient level and the number of outpatient chemotherapy treatments varies by patient. Patients with more treatments during the period have an increased probability of experiencing an outcome because the algorithm looks for an outcome after each treatment. The exposure variable is the count of outpatient chemotherapy administrations the patient experienced at the attributed hospital during the performance period.

Interactions: Through discussion with our 2015 Expert Working Group (see Section 2b.20, above, and Measure Submission Form and for full membership list), we determined the most clinically relevant interactions are likely to be between the age variable and the different cancer types. Based on this input, we tested age-cancer type interaction terms as candidate covariates.

Variable Selection

To select the final variables to include in the risk-adjustment model, we fit a logistic regression model to predict the outcome with the candidate variable set. To develop a parsimonious model, we then removed non-significant

variables from the initial model using a stepwise purposeful selection method described by Hosmer and Lemeshow ['Disparities in Cancer Care", 2006; Hosmer, 1999]. Our goal was to minimize the number of variables in the model while preserving model performance (as measured by the c-statistic). During this process, for each of the two models, the least significant variable in the model was removed one at a time until only statistically significant ($p<0.05$, assessed using a likelihood ratio test) variables remained in the model. Interaction terms between age and cancer type were tested and were only retained in the model if significant at a level of $p<0.01$. The higher threshold for statistical significance of interaction terms was to ensure that only interactions that have a higher likelihood of being true interactions were included.

Previous submission

Social Risk Factors Conceptual Model

Following the selection process for clinically relevant risk factors described above, we assessed the potential need to incorporate additional social risk factors into our risk-adjustment model. In this section, we describe the conceptual model that guided our work. In Section 2a.08, we described the three variables evaluated in our analysis (race, Medicaid dual eligible status, and neighborhood SES factors composited into the AHRQ SES Composite Index).

The potential causal pathways by which social risk factors influence the risk of admission or ED visit following outpatient chemotherapy are varied and complex. The presence of disparities in chemotherapy outcomes are due to multiple complementary causes. To help inform our conceptualization of the pathways by which social risk factors affect admissions and ED visits for patient receiving chemotherapy treatment in a hospital outpatient setting, we performed a literature search. The studies indicated that individuals that identify as a racial minority, with low socioeconomic status (SES), with charity care or self-pay insurance, are women, or are unmarried were more likely to experience a gap in cancer care in the outpatient chemotherapy setting than their counterparts. Please refer to question 1 of the "ChemoMeasure_NQF Appendix_SDS" for more information on the literature review.

The following highlights possible social risk-related conceptual pathways that are important to consider:

1. Relationship of social risk with health. People who face sociodemographic disadvantages usually have worse health status, which in turn leads to worse health outcomes compared to people who do not experience these disadvantages. This means that chemotherapy patients who have lower health literacy, income, education, and no insurance might experience a higher symptom burden or have greater disease severity, and in turn have more ED visits and hospital admissions due to having worse health status in general. This pathway could be accounted for within the existing clinical risk-adjustment variables in the current model.
2. Access to care. Limited access to health care may prevent individuals from early detection of cancer, making them more likely to be diagnosed with late-stage cancer that could have been treated more effectively or cured if diagnosed earlier [National Cancer Institute, 2016]. Worse access to care also impacts patients' ability to contact their physicians when they are experiencing cancer-related symptoms or adverse effects from treatment, which may make them more likely to experience ED visits, hospital admissions, ambulance use, and hospital mortalities compared to cancer patients that are diagnoses at an earlier stage [Kotajima et al., 2014].
3. Differential care across hospitals. Cancer patients at minority-serving hospitals are less likely to receive adequate pain treatment [Fisch et al., 2012]. Poor and minority patients are also more likely to be seen in safety-net hospitals and these hospitals may lack the financial resources to make certain services available, such as specialized palliative care teams, making these patients more likely to require acute care, such as an ED visit or hospital admission, for symptom management.

The combination of treatment disparities, increase symptom occurrence and severity, and inadequate pain management may place minority cancer patients at greater risk of experiencing a gap in outpatient chemotherapy care, which may increase the likelihood of ED visits and hospital admissions.

2017/2018 Model Reevaluation

Updates to Comorbidities: In 2017 we updated the CCs used to identify the comorbidities in the model to Version 22 (V22) of the CMS-HCC model. There were no changes made to comorbidities used in the model after EWG members confirmed clinical appropriateness and prevalence within the cohort for existing comorbidities in the model.

Updates to Exposure: Following stakeholder feedback that administration of concurrent radiotherapy increases the likelihood of adverse events among patients receiving chemotherapy, we solicited feedback from our 2018 EWG members regarding the clinical appropriateness of this as either a new measure exclusion, or a risk factor. The group ultimately advised us to include this as a variable in the risk-adjustment models as, in the group's opinion, this approach will ultimately incentivize better coordination and management of these cases. The group recommended that concurrent radiotherapy be defined as receipt of radiotherapy on the date of chemotherapy or up to 14 days before administration of chemotherapy. In order to capture cases that meet these criteria we identified qualifying radiation therapy procedure codes using ICD-10 procedure codes, Current Procedure Terminology codes, and Healthcare Common Procedure Coding System codes. This increased the number of risk factors in the inpatient admissions model to 21, and in the ED visits model to 16. The measure score and testing results in the NQF application reflect these updates to the measure's risk models.

Current submission

As part of the current Fall 2022 submission, we re-examined the role that social risk factors have in predicting the outcome of a hospital visit after chemotherapy. Being responsive to NQF's most recent guidance on risk models, including social risk factors, below we provide a conceptual model of how social risk factors that are present at the start of patient care can influence the outcome [NQF, 2022]. This conceptual model is based in part on published literature outlined below, on existing empiric data for this measure, and in part on conceptual relationships. As per NQF guidance, released in August 2021 [NQF, 2022]. we have considered age, gender, race and ethnicity, urbanicity/rurality, Medicare and Medicaid dual eligibility, indices of social vulnerability (such as the Area Deprivation Index and Agency for Healthcare Research and Quality [AHRQ] SES Index score) and markers of functional risk (such as frailty) n the conceptual model.

Summary of Literature

Race

There are many disparities related to race and its impact on cancer detection and cancer outcomes [Karanth et al., 2019; Esnaola & Ford, 2012; Zavala et al., 2020], however here we will focus on the outcome for this measure: hospital visits following chemotherapy.

First, delays in detection and treatment of cancer may lead to worse health at the start of chemotherapy, more toxic chemotherapy regimens, and subsequently greater risk of a hospital visit.

For example, in a study using data from the National Cancer Data Base, non-white women were more likely to receive chemotherapy treatment for breast cancer because of advanced stage cancer and higher-grade tumors [Killelea et al., 2015]. In addition, a systematic review found that Black cancer patients are at greater risk than white patients of experiencing clinically significant delays of 90 days or longer for chemotherapy [Green et al., 2018]. In addition, nonwhite patients with lower socioeconomic status were found to be more likely to experience higher symptom burden during outpatient chemotherapy treatment [Miaskowski et al., 2014].

Second, differential care during chemotherapy may lead to worse outcomes, including a higher rate of hospital visits following chemotherapy. For example, Hispanic or Latino, Black, Asian, and other minority patients are twice as likely to be undertreated for pain in the outpatient oncology setting compared to non-Hispanic whites [Fisch et al., 2012]. With a higher symptom occurrence and inadequate treatment, these patients may be more likely to visit the ED than patients that experience less severe symptoms. In fact, one study found that Black cancer patients with low socioeconomic status were more likely to visit the ED than patients of high socioeconomic status or were non-black [Henson et al., 2015]. In addition, the Community Tracking Study Physician Survey found that black Medicare beneficiaries were more likely to be cared for by less-well-trained providers [Bach et al., 2004].

Socioeconomic Status

Socioeconomic status describes the state of income, wealth, education, occupation, and living conditions for individuals. For chronic ambulatory-sensitive conditions, patients with low socioeconomic status consistently

experience higher rates of hospitalization [Wallar et al., 2020]. In addition, a recent report found that patients with low socioeconomic status had higher overall rates of hospital admissions, readmissions, emergency department visits and complications, compared to the average patient [Averill & Mills, 2021]. For cancer, specifically, socioeconomic status has also consistently been reported to be an important social risk factor across a range of cancer types [Karanth et al., 2019; Esnaola & Ford, 2012; Zavala et al., 2020Those with low socioeconomic status receiving outpatient chemotherapy may face challenges related to a higher symptom burden and inadequate treatment of symptoms compared to their counterparts [Henson et al., 2015]. In some situations, race and ethnicity combined with socioeconomic status can lead to greater disparity in health outcomes. For example, one study found that Black cancer patients with low socioeconomic status had the highest rates of ED visits compared with non-Black cancer patients (of low or high socioeconomic status) and compared with Black cancer patients with high socioeconomic status [Henson et al., 2015].

Rurality

Residence in a rural geography impacts unique social risk for poor health outcomes, beyond those that are singularly explained by one's wealth or socioeconomic status [Levit et la., 2020]. The impact of these challenges can be due to barriers in rural areas such as limited public transportation options, more limited availability of broadband internet for telehealth visits, limited availability of local home-based services and supports, and fewer choices to acquire healthy food. For cancer, specifically, patients face various barriers that affect the quality of care received and their overall health outcomes. Such barriers include limited access to medical and oncology providers, long travel times, and low participation in clinical trials. Travel distance is also associated with multiple negative clinical outcomes for rural patients, including later stage of diagnosis, less timely receipt of chemotherapy, and delaying or declining treatment. A cohort study of patients with colon cancer, for example, found that patients who traveled > 50 miles to a diagnostic facility were more likely to present with metastatic disease than those who travel shorter distances [JCO Oncology Practice, 2020]. Another study found that patients who lived closer to the hospital experienced a higher rate of repeated admissions than patients that lived further away [Aprile et al., 2013]. Patients in rural areas that have fewer services may have a lower risk of hospital admission and a higher risk of emergency care use, depending on what is available in their area [Greenwood-Ericksen & Kocher, 2019].

Other sociodemographic risk factors

Some studies also showed other sociodemographic factors, such as sex, marital status, and proximity to hospitals, are related to ED visits or hospital admissions. Among breast cancer patients, older and unmarried women consumed more health-care resources, including admissions to the ED or hospital, then their younger and married counterparts [Baena-Cañada et al., 1990]. Similarly, women and older patients receiving outpatient chemotherapy more frequently report fatigue as a symptom of chemotherapy [Siefert, 2010]. Women also had a 29% higher rate of repeated admissions and ED visits than men [Aprile et al., 2013].

Conceptual Model

Based on the literature described above, and on additional conceptual relationships, we identified and characterized social risk factors that may impact the outcome (Figure 5, Table 19). For some of these factors, providers may be able to implement mitigating interventions (such as providing access to translators or easy-to-understand home care instructions for patients with low health literacy). We note that we did not include insurance status as a risk factor because the target audience for this measure is Medicare Fee-For-Service patients. Figure 5 diagrams the pathways that influence the outcomes for patients receiving chemotherapy in an HOPD. Table 19 identifies the specific risk factors, the variables available for testing, and if they are currently accounted for in the measures' risk model. Table 20 reviews strategies for how HOPDs might mitigate the impact of these risk factors.

Figure 5: Conceptual model for the chemotherapy measure outcome

Factors that influence the outcome include:

1. **Hospital-provided care directly related to the outcome**, which can reduce a patient's risk or increase a patient's risk. Some of this care can directly impact the outcome (such as following standards of care, hiring and maintaining high quality staff, and following best practices). This includes access to high-quality timely care with the appropriate needed services.

2. Patient level risk factors present at the start of care, which can include clinical, demographic, and social risk factors. These can be broken into two categories – factors for which hospitals can provide mitigating care, and factors which hospitals cannot control.

2a. Factors for which **hospital-provided care can likely mitigate** the impact (such as providing translators or easy-to-understand home care instructions), at least in part.

2b. Factors that are **beyond the hospital's control** and cannot be mitigated by hospital-based interventions.

Based on our literature review and empiric data, including feedback from subject matter experts in social risk factor adjustment, we have identified patient-level risk factors present at the start of care that can influence the outcome (Table 19). For each patient-level factor, we indicate how the factor may be related to the outcome, and if there is a variable that is available for testing. Table 20 outlines how hospitals may be able to mitigate the impact of these risk factors. We note that casual pathways can be very complex and that this is a high-level overview of each factor and its potential role in the outcome.

Risk factor including social risk factors	How the risk factor conceptually impacts the outcomes	Variable(s)	Is a variable available for use with claims?	Is the variable currently in the risk model?
Age	Higher age higher risk	Age	Yes	Yes
Sex	Women or men at higher risk depending on outcome	Sex	Yes	Yes

Risk factor including social risk factors	How the risk factor conceptually impacts the outcomes	Variable(s)	Is a variable available for use with claims?	Is the variable currently in the risk model?
Comorbidities	**Certain comorbidities increase risk**	**Various ICD-10 groupings**	**Yes**	**Yes**
Frailty	**More frail higher risk**	**ICD-10 group**	**Yes**	**Yes**
Exposure to racism	**Non-white at higher risk**	**Race**	**Yes**	**No**
Income	**Low income at higher risk**	**Low AHRQ SES/Dual Eligible**	**Yes**	**No but disparity method addresses dual eligibility***
Education	**Lower education at higher risk**	**Low AHRQ SES**	**Yes**	**No, however there is some overlap with dual eligibility***
Access to timely care	**More rural higher risk for ED visit**	**Geographic location (urban/rural)**	**Yes**	**No**
Access to high quality care	**Proximity to low-quality hospitals increases risk**	**No variable available**	**No**	**No**

Table 19: Patient-level risk factors (social/demographic/functional) at the start of care, the impact on outcome, available variables, and potential for mitigation by HOPDs

*CORE, under contract with CMS, developed two disparty methods to examine the care of dual eligible patients, one that compares care within a hospital and one that compares care for dual eligible against an average hospital. See section 2b.30 for more details.

In our conceptual model and outlined in Table 20, we have identified three patient-level variables which are already accounted for in the risk adjustment model:

- Age
- Sex
- Comorbidities
- Frailty

We also identified five risk factors (Table 20) that identified in the literature (see literature summary above) or are known to be empirically associated with the outcome, and for which there is evidence that HOPDs can mitigate the impact of the variable on the outcome. We note that the evidence for mitigation is not available for this specific measure, but is generalized from the available evidence, much of which focuses on preventing readmission [Centers for Medicare & Medicaid Services. 2018], a similar outcome. Because several of these variables overlap and have similar drivers of poor outcomes (such as education and income, and race and income) we address the mitigating strategies below as a series of topics and the recommended strategies. We also acknowledge that mitigating exposure to racism [Hoestetter and Klein, 2021], in particular, is a complex issue and that hospitals may initially struggle to develop and implement effective approaches [Ricks et al., 2021].

Strategy	Description of interventions	Related social risk factors
Improving follow up care after the chemotherapy treatment	• Early transition planning and follow up for patients at high risk • Communicate with patients about importance of follow up care; assist with scheduling appointments • Offer telehealth options • Engage family/caregivers	Income Education Exposure to racism Rurality
Improve access to a usual source of care	• Ensure patient is connected with a usual source of care (primary care provider or specialist)	Income Education Exposure to racism
Reduce language/literacy barriers	• Identify patients as risk (language and literacy barriers) • Ensure access to translation services • Communicate at home or follow up care instructions in patients' native language and in a culturally competent manner • Simplify instructions • Communicate instructions at the appropriate literacy level • Engage family/caregivers	Low health literacy Limited English proficiency
Reduce socioeconomic barriers	• Connect patients with community-based resources that address the need (e.g. housing and food insecurity, transportation, employment). • Connect underinsured patients with supplemental insurance • Connect with social support services	Income Education
Reduce biased care	• Track metrics stratified by race and ethnicity • Quality improvement • Staff training • Diversity of staff, trainees, and Board of Directors	Exposure to racism Income
Improve access to timely care	• Advance care transition planning and follow up for patients at high risk • Access to telehealth	Exposure to racism Income Rurality
Improve access to high-quality care	• Recruit, train and retain high-quality staff • Follow standards of care and use a learning healthcare system • Address workforce shortages and burnout	Exposure to racism Income Education

Table 20: Strategies and interventions to reduce the impact of social risk factors

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[Response Ends]

2b.24. Detail the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.

[Response Begins]

Previous submission

The final results of our initial model development work resulted in 20 variables in the inpatient admission outcome model and 15 variables in the ED outcome model with p values <0.05. The (age x cancer type) interaction terms were retained if p for interaction was <0.01. For the inpatient admission outcome model, only the interaction of (age x digestive cancer) was significant (p-value for interaction <0.001). However, due to the minimal improvement in model fit [AIC (76245 -> 76238) and c-statistic (0.725 -> 0.725)] and our desire to create the most parsimonious model, we did not include any interaction terms in our final model. No interaction terms met this criterion for the ED visit outcome model.

In addition, the final model did not include SDS variables. See Section 2b4.4b for more information.

The following variables were selected as the final risk-adjustment variables for the inpatient admission outcome model before the addition of concurrent radiotherapy risk variable in 2017-2018 (see discussion below)

1. Age (continuous)
2. Sex (male)
3. Exposure (Number of hospital OPD chemotherapy treatments during period)
4. Respiratory disorders (CC 110 – 113)
5. Renal disease (CC 132, 134 – 140)
6. Diabetes (CC 17 – 20)
7. Other injuries (CC 174)
8. Metabolic disorder (CC 21-26)
9. Gastrointestinal disorder (CC 27-32; 34; 36-38)
10. Psychiatric disorder (CC 50-69)
11. Neurological conditions (CC 70-81)
12. Cardiovascular disease (CC 82-109)
13. Breast cancer
14. Digestive cancer
15. Respiratory cancer
16. Lymphoma
17. Other cancer
18. Prostate cancer
19. Secondary – lymph
20. Secondary – solid

The following variables were selected as the final risk-adjustment variables for the ED visit outcome model before the addition of concurrent radiotherapy risk variable in 2017-2018 (see discussion below).

1. Age (continuous)
2. Sex (male)
3. Exposure (Number of hospital OPD chemotherapy treatments during period)
4. Respiratory disorders (CC 110 – 113)
5. Other injuries (CC 174)
6. Gastrointestinal disorder (CC 27-32; 34; 36-38)
7. Psychiatric disorder (CC 50-69)
8. Neurological conditions (CC 70-81)
9. Cardiovascular disease (CC 82-109)
10. Breast cancer

11. Digestive cancer
12. Respiratory cancer
13. Other cancer
14. Secondary – lymph
15. Secondary – solid

In 2018 we evaluated the impact of adding concurrent radiotherapy into the two existing models, based on stakeholder feedback and clinical input from our 2018 EWG members. We found that concurrent radiotherapy was significant at $p < 0.05$ in all four models (both outcomes, for each facility type) and did not markedly change the coefficients or significance of other included variables. In addition, the model c-statistics remained strong, and were 0.6933 for the RSAR and 0.6470 for the RSEDR at PCH-HOPDs, and 0.7114 for the RSAR and 0.6504 for the RSEDR at non-PCH HOPDs. As a result, we added this risk factor to our models, resulting in 21 risk factors for the admissions model and 16 risk factors for the ED visits model. With this revision, the list of variables included in the final risk-adjustment models are:

Model Variables – inpatient admissions

1. Age (continuous)
2. Sex (male)
3. Exposure (Number of hospital OPD chemotherapy treatments during period)
4. Respiratory disorders (CC 110 – 113)
5. Renal disease (CC 132, 134 – 140)
6. Diabetes (CC 17 – 20)
7. Other injuries (CC 174)
8. Metabolic disorder (CC 21-26)
9. Gastrointestinal disorder (CC 27-32; 34; 36-38)
10. Psychiatric disorder (CC 50-69)
11. Neurological conditions (CC 70-81)
12. Cardiovascular disease (CC 82-109)
13. Breast cancer
14. Digestive cancer
15. Respiratory cancer
16. Lymphoma
17. Other cancer
18. Prostate cancer
19. Secondary – lymph
20. Secondary – solid
21. Concurrent Radiotherapy

Model Variables – ED visits

1. Age (continuous)
2. Sex (male)
3. Exposure (Number of hospital OPD chemotherapy treatments during period)
4. Respiratory disorders (CC 110 – 113)
5. Other injuries (CC 174)

6. Gastrointestinal disorder (CC 27-32; 34; 36-38)
7. Psychiatric disorder (CC 50-69)
8. Neurological conditions (CC 70-81)
9. Cardiovascular disease (CC 82-109)
10. Breast cancer
11. Digestive cancer
12. Respiratory cancer
13. Other cancer
14. Secondary – lymph
15. Secondary – solid
16. Concurrent Radiotherapy

Risk Factor	PCH risk frequency, N (%)	PCH Admission Coefficients	PCH admission Odds Ratios (95% CI)	PCH ED Visits Coefficient	PCH ED Visits Odds Ratios (95% CI)
Age, mean (SD)	73.30 (7.9)	-0.01	1.0 (1.0-1.0)	-0.01	1.0 (1.0-1.0)
Male	14,588 (56.6)	0.01	1.0 (0.9-1.1)	-0.16	0.9 (0.8-1.0)
Number of Outpatient Chemotherapy Treatments	5 (2-10)	0.01	1.0 (1.0-1.0)	0.04	1.0 (1.0-1.1)
Respiratory Disorder (CC 110-113)	6,550 (25.4)	0.17	1.2 (1.1-1.3)	0.05	1.1 (0.9-1.2)
Renal Disease (CC 132, 134-140)	6,199 (24.1)	0.28	1.3 (1.2-1.4)	*	*
Diabetes (CC 17-20)	7,455 (28.9)	0.07	1.1 (1.0-1.2)	*	*
Other Injuries (CC 174)	5,763 (22.4)	0.10	1.1 (1.0-1.2)	0.04	1.1 (0.9-1.2)
Metabolic Disorders (CC 21-26)	21,944 (85.2)	0.25	1.3 (1.1-1.5)	*	*
GI Disorders (CC 27-32, 34, 36-38)	18,609 (72.2)	0.34	1.4 (1.3-1.6)	0.62	1.9 (1.6-2.2)
Psychiatric Disorders (CC 50-69, 202, 203)	11,553 (44.8)	0.31	1.4 (1.3-1.5)	0.21	1.2 (1.1-1.4)
Neurological Conditions (CC 70-81)	8,332 (32.3)	0.07	1.1 (1.0-1.2)	0.07	1.1 (1.0-1.2)
Cardiovascular Disease (CC 82-109)	22,636 (87.9)	0.23	1.3 (1.1-1.5)	0.13	1.1 (0.9-1.4)
Breast Cancer	3,435 (13.3)	0.07	1.1 (0.9-1.2)	0.04	1.05 (0.87-1.26)
Digestive Cancer	4,306 (16.7)	0.52	1.7 (1.5-1.9)	0.12	1.1 (1.0-1.3)
Respiratory Cancer	4,334 (16.8)	0.5	1.7 (1.5-1.8)	0.08	1.1 (0.9-1.3)
Lymphoma	3,992 (15.5)	1.01	2.8 (2.4-3.1)	*	*
Other Cancer	7,590 (29.5)	0.37	1.4 (1.3-1.6)	0.18	1.2 (1.1-1.4)

Risk Factor	PCH risk frequency, N (%)	PCH Admission Coefficients	PCH admission Odds Ratios (95% CI)	PCH ED Visits Coefficient	PCH ED Visits Odds Ratios (95% CI)
Prostate Cancer	6,557 (25.5)	-0.31	0.7 (0.6-0.8)	*	*
Anal Cancer	223 (0.9)	0.25	1.3 (0.9-1.9)	-0.02	1.0 (0.5-1.8)
Bladder Cancer	2,461 (9.6)	0.04	1.04 (0.9-1.2)	-0.03	1.0 (0.8-1.2)
Ovarian Cancer	1,234 (4.8)	0.48	1.6 (1.4-1.9)	0.3	1.3 (1.1-1.7)
Pancreatic Cancer	1,460 (5.7)	0.74	2.1 (1.8-2.4)	0.36	1.4 (1.2-1.8)
Secondary Neoplasm of the Lymph Nodes	9,093 (35.3)	0.24	1.3 (1.2-1.4)	0.13	1.1 (1.0-1.3)
Secondary Neoplasm - Solid Tumors	15,803 (61.3)	0.76	2.1 (1.9-2.4)	0.13	1.1 (1.0-1.3)
Concurrent Radiotherapy	1,412 (5.5)	0.25	1.3 (1.1-1.5)	0.16	1.2 (0.9-1.5)

Table 21: PCH-HOPDs: Risk model variable coefficients and odds ratios (N=25,763 eligible patients)

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Risk Factor	Non-PCH HOPD risk frequency N (%)	Non-PCH HOPD Admission Coefficient	Non-PCH HOPD Admission Odds Ratios (95% CI)	Non-PCH HOPD ED Visit Coefficient	Non-PCH HOPD ED Visit Odds Ratios (95% CI)
Age	73.77 (8.3)	-0.01	1.0 (1.0-1.0)	-0.01	1.0 (1.0-1.0)
Male	146,865 (53.9)	0.01	1.0 (1.0-1.0)	-0.17	0.9 (0.8-0.9)
Number of Outpatient Chemotherapy Treatments	4 (2-10)	0.02	1.0 (1.0-1.0)	0.04	1.0 (1.0-1.0)
Respiratory Disorder (CC 110-113)	78,816 (28.9)	0.22	1.2 (1.2-1.3)	0.13	1.4 (1.1-1.2)
Renal Disease (CC 132, 134-140)	71,519 (26.2)	0.33	1.4 (1.4-1.4)	*	*
Diabetes (CC 17-20)	81,978 (30.1)	0.09	1.1 (1.1-1.1)	*	*
Other Injuries (CC 174)	57,207 (21.0)	0.1	1.1 (1.1-1.1)	0.14	1.2 (1.1-1.2)
Metabolic Disorders (CC 21-26)	226,649 (83.1)	0.25	1.3 (1.2-1.3)	*	*
GI Disorders (CC 27-32, 34, 36-38)	18,6425 (68.4)	0.23	1.3 (1.2-1.3)	0.35	1.4 (1.4-1.5)
Psychiatric Disorders (CC 50-69, 202, 203)	115,940 (42.5)	0.14	1.2 (1.1-1.2)	0.19	1.2 (1.2-1.3)

Risk Factor	Non-PCH HOPD risk frequency N (%)	Non-PCH HOPD Admission Coefficient	Non-PCH HOPD Admission Odds Ratios (95% CI)	Non-PCH HOPD ED Visit Coefficient	Non-PCH HOPD ED Visit Odds Ratios (95% CI)
Neurological Conditions (CC 70-81)	71,561 (26.2)	0.03	1.0 (1.0-1.1)	0.05	1.1 (1.0-1.1)
Cardiovascular Disease (CC 82-109)	235,948 (86.5)	0.27	1.3 (1.2-1.4)	0.2	1.2 (1.2-1.3)
Breast Cancer	42,834 (15.7)	-0.01	1.0 (0.9-1.0)	-0.02	1.0 (0.9-1.0)
Digestive Cancer	45,283 (16.6)	0.4	1.5 (1.4-1.5)	0.14	1.2 (1.1-1.2)
Respiratory Cancer	50,459 (18.5)	0.54	1.7 (1.7-1.8)	0.13	1.1 (1.1-1.2)
Lymphoma	45,007 (16.5)	0.63	1.9 (1.8-1.0)	*	*
Other Cancer	68,530 (25.1)	0.28	1.3 (1.3-1.4)	0.13	1.1 (1.1-1.2)
Prostate Cancer	58,363 (21.4)	-0.43	0.7 (0.6-0.7)	*	*
Anal Cancer	2,690 (1.0)	0.4	1.5 (1.3-1.7)	0.24	1.3 (1.1-1.5)
Bladder Cancer	28,805 (10.6)	0.03	1.0 (1.0-1.1)	-0.14	0.9 (0.8-0.9)
Ovarian Cancer	11,529 (4.2)	0.31	1.4 (1.3-1.5)	0.13	1.1 (1.1-1.2)
Pancreatic Cancer	12,284 (4.5)	0.87	2.4 (2.3-2.5)	0.35	1.4 (1.3-1.5)
Secondary Neoplasm of the Lymph Nodes	54,285 (19.9)	0.26	1.3 (1.3-1.3)	0.13	1.1 (1.1-1.2)
Secondary Neoplasm - Solid Tumors	128,216 (47.0)	0.76	2.1 (2.1-2.2)	0.32	1.2 (1.3-1.4)
Concurrent Radiotherapy	14,017 (5.1)	0.32	1.4 (1.3-1.5)	0.15	1.2 (1.1-1.3)

Table 22: Non-PCH HOPDs: Risk model variable coefficients and odds ratios (N = 272,753 eligible patients)

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[Response Ends]

2b.25. Describe the analyses and interpretation resulting in the decision to select or not select social risk factors.

Examples may include prevalence of the factor across measured entities, availability of the data source, empirical association with the outcome, contribution of unique variation in the outcome, or assessment of between-unit

effects and within-unit effects. Also describe the impact of adjusting for risk (or making no adjustment) on providers at high or low extremes of risk.

[Response Begins]

Previous submission

This section includes results from analyses conducted during initial model development and more recently during 2018 re-evaluation activities.

Initial Model Development. As described elsewhere, during the initial model development process we considered three variables in our social risk analysis: (1) race (black, other), (2) Medicaid dual eligible status, and (3) neighborhood SES factors composited into the AHRQ SES Composite Index. We conducted several analyses, presented below, including (1) variation in patient SDS risk factors across hospitals; (2) the association between social risk factor variables and the outcomes; (3) the impact of including social risk factor variables as part of risk-adjustment on model performance; and (4) the impact of including social risk factor variables as part of risk-adjustment on hospital rankings. Key findings and our conclusion are described below. A complete summary of our initial social risk factor assessment, including analysis tables, can be found in the measure technical report.

Current submission

This section updates social risk factor testing results using the 2022 Endorsement Maintenance Dataset and social risk factor variables described in section 2a.08 and adds results for a new risk factor (rurality).

Analysis #1: Variation in Prevalence of Social Risk Factors across Hospitals

Previous submission

Initial development

There is substantial variation in the prevalence of black, Medicaid dual-eligible, and low SES patients (scores below 43.27 on the AHRQ SES Composite Index) in the measure cohort across hospitals. For the measure, the percentage of patients who are black ranges from 0% to 100% across hospitals, with a median of 0.7% (interquartile range [IQR] 0%-10.6%). The percentage of patients who are Medicaid dual eligible ranges from 0% to 100% across hospitals, with a median of 18.1% (IQR 9.0% - 30.7%). The percentage of patients with low SES ranges from 0% to 100% across hospitals, with a median of 19.0% (IQR 2.2% - 52.5%).

2018 Re-evaluation

As part of our 2018 reevaluation, we updated our analysis examining the impact of social risk factors on the measure calculation. We evaluated two indicators of social risk: 1) race, specifically Black or not and 2) the low AHRQ SES index. Dual status was not examined due to lack of availability in our re-evaluation data.

There is substantial variation in the prevalence of Black patients and patients with low SES (AHRQ SES Composite Index values below 42.7) across patients in the measure cohort across hospitals in the FY 2016 dataset. For the measure cohort, the facility-level percentage of patients who are Black ranges from 0% to 100%, with a median of 0% (interquartile range [IQR] 0%-8.1%). The facility-level percentage of patients with low SES ranges from 0% to 100%, with a median of 23.8% (IQR 7.5% - 47.4%).

Current submission:

For the current submission, we updated the results for non-PCH HOPDs for the three social risk factor variables tested in the Previous submission (race [Black]; low AHRQ SES, dual eligibility) and have added a third variable, urban vs. rural residence. We did not, however, include results for PCH-HOPDs because there are only 11 hospitals. Rural residence is defined using the categories 7, 7.2, 7.3, 7.4, 8, 8.2, 8.3, 8.4, 9, 9.1, 9.2, 10, 10.2, 10.3, 10.4, 10.5, 10.6 of the Rural Urban Commuting Area Codes. Low AHRQ SES Index is defined as an AHRQ SES Index scores of 46 or lower (the lowest quartile).

Table 23 shows the facility-level distribution of the four social risk factors among non-PCH HOPDs during the January 1, 2021-November 30, 2021 period. The median facility-level proportion of patients is 7.6% for dual eligibility, 11.8% for Low AHRQ SES, 7.6% for dual eligibility, 2.9% for race (Black), and 7.1% for rural location.

Variable (# of HOPDs)	Median % (IQR)
Dual eligibility (N=1,474)	7.6 (4.0-12.6)
Low AHRQ SES (N=1,471)	11.8 (5.6-22.6)
Race (Black) (N=1,474)	2.9 (0.0-9.1)
Rural (N=1,472)	7.1 (1.1-24.0)

Table 23: Facility-level distribution of social risk factors among non-PCH HOPDs

Analysis #2: *Association between SDS variables and observed outcomes*

Previous submission:

Initial Development

At the patient-level, our analysis shows that "high social risk" patients (as characterized by three individual indicators: Medicaid dual-eligibility, race as black, and low SES) receiving hospital-based outpatient chemotherapy are more likely to have an inpatient admission and emergency department (ED) visit within 30 days than "low social risk" patients.

- Dual eligible patients were more likely to have an inpatient admission or ED visit than non-dual eligible patients (13.7 percent of dual eligible vs 9.7 percent of non-dual eligible for inpatient admission, and 6.2 percent of dual eligible vs 3.8 percent of non-dual eligible for ED visits);
- Black patients were more likely to have an inpatient admission or ED visit than non-black patients (12.9 percent of black patients vs 10.0 percent of non-black for inpatient admission, and 5.5 percent of black patients vs 4.0 percent of non-black for ED visits); and
- Patients with low SES were more likely to have an inpatient admission or ED visit than patients with higher SES (11.5 percent of patients with low SES vs 9.4 percent of patients with high SES for inpatient admission, and 4.8 percent of patients with low SES vs 3.6 percent of patients with high SES for ED visits).

2018 Re-evaluation

To evaluate the patient-level association of these risk factors with the outcomes, we first quantified the observed rate by each group. We found that Black patients had higher rates of inpatient admissions, with an observed inpatient admission rate of 14.2% relative to 12.6% for all other patients, as shown in Table 7. This same pattern was true for observed rates of ED visits; the observed rate for Blacks was 7.6%, whereas it was 5.8% for all others. Patients with low SES also had higher rates of inpatient admissions, with the observed rate of 14.4% relative to 12.4% for patients without low SES, as shown in Table 8. Similarly, patients with a low SES Index value had an observed rate of 7.1% of ED visits relative to 5.7% for non-low SES Index patients. The same pattern held true when results were examined separately for Black or low SES Index values at PCH-HOPDs versus non-PCH HOPDs (Tables 24 and 25).

Hospital Type	Inpatient Admission Observed Rate	*	ED Visit Observed Rate	*
*	Low SES Index	All Others	Low SES	All Others
All Hospitals	14.4	12.4	7.1	5.7
PCH Hospitals	15.9	13.8	6.7	6.3
Non-PCH HOPDs	14.3	12.3	7.1	5.7

Table 24: National Observed Rates for Patients with Low Socioeconomic Status (<42.7 AHRQ SES Composite Index Values) vs. All Others

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Hospital Type	Inpatient Admission Observed Rate	*	ED Visit Observed Rate	*
*	African-American	All Others	African-American	All Others
All Hospitals	14.2	12.6	7.6	5.8
PCH Hospitals	14.8	13.9	6.9	6.3
Non-PCH HOPDs	14.1	12.5	7.7	5.7

Table 25: National Observed Rates for African-American Patients vs. All Others

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Current submission

Because there are only 11 PCH-HOPDs, we focused our current analyses on non-PCH-HOPDs. For patients who visited non-PCH HOPDs, observed ED/observation rates were higher for patients with Low AHRQ SES, dual eligibility, and Black race. Observed ED/observation rates were **lower** for patients in rural areas (Table 26). Observed inpatient admissions rates were higher for all categories of risk factors (Table 26).

Risk Factor	Observed Inpatient Admission Rate with Social Risk Factor	Observed Inpatient Admission rate without Social Risk Factor	Observed ED rate with Social Risk Factor	Observed ED rate without Social Risk Factor
Dual Eligible	11.9	9.2	7.4	5.0
Low AHRQ SES	10.5	9.3	6.1	5.1
Race (Black)	10.0	9.4	6.3	5.1
Rural	8.2	9.6	6.8	5.0

Table 26: Observed outcomes for patients with and without risk factors, for patients who received treatment at non-PCH HOPDs

Analysis #3: Odds ratios for social risk factors in multivariate model

Previous submission

We then evaluated the patient-level association of these social risk factors with the outcome after adjustment for the age, sex, chemotherapy exposure, concurrent radiotherapy, clinical comorbidities and cancer type variables currently in the inpatient admission and ED visit models. Each factor's effect was quantified using odds ratios (ORs) and testing for significance. In addition, we evaluated the change in the models' predictive ability (c-statistic and range of predictability) when adding SDS factors to the model.

As shown in Table 9, for **non-PCH HOPDs**, Black race was not statistically significant for either the RSAR and RSEDR models. In the RSAR model, Black race had a p-value of 0.412, and OR of 1.06, with the 95% confidence interval (CI) for the OR of 0.92 – 1.23. In the RSEDR model, Black race had a p-value of 0.580, with an OR of 1.06 (95% CI: 0.86, 1.30). The association between Low SES Index and the RSAR and RSDER were similarly non-significant for non-PCH HOPDs. In the RSAR model, Low SES Index had a p-value of 0.248, and an OR of 1.07 (95% CI: 0.95, 1.20), while in the RSDER model Low SES Index had a p-value of 0.942, with an OR of 0.99 (95% CI: 0.84, 1.17).

Among the 11 **cancer hospitals**, both Black and Low SES Index status had a significant association (at $p < 0.001$) with the outcome in the RSAR and RSEDR models. For Black race, the OR was 1.08 (95% CI: 1.04, 1.13) in the RSAR model, and 1.30 (95% CI: 1.24, 1.36) in the RSEDR model. For low SES Index status, the OR was 1.06 (95% CI: 1.03, 1.10) for the RSAR model, and 1.16 (95% CI: 1.11, 1.21) for the RSEDR model.

For **both non-PCH and cancer hospitals**, the addition of either the Black race or the low SES Index social risk factor had little effect on model c-statistics or predictive ability, as shown in Tables 31 and 32.

Outcome	Facility Type	Social Risk Factor	p-value	OR (LB, UB)	
RSAR	Non-PCH	Black	0.412	1.06 (0.92 – 1.23)	
RSEDR	Non-PCH	Black	0.580	1.06 (0.86 – 1.30)	
RSAR	Cancer	Black	<.0001	1.08 (1.04 – 1.13)	
RSEDR	Cancer	Black	<.0001	1.30 (1.24 – 1.36)	
RSAR	Non-PCH	Low AHRQ SES	0.248	1.07 (0.95 – 1.20)	
RSEDR	Non-PCH	Low AHRQ SES	0.942	0.99 (0.84 – 1.17)	
RSAR	Cancer	Low AHRQ SES	0.0003	1.06 (1.03, 1.10)	
RSEDR	Cancer	Low AHRQ SES	<.0001	1.16 (1.11 – 1.21)	

Table 27: Patient-level relationship between social risk factors and the measure outcome

Current submission

To understand how the social risk variables function in the measure's multivariate risk models, we calculated odds ratios for each outcome for each social risk factor (Tables 28 and 29). For the inpatient admission outcome, odds ratios for the rural variable were significant and less than 1; odds ratios for the other variables were significant and greater than 1 (Table 28). For the emergency/observation admission outcome, all odds ratios were significant and greater than 1 (Table 29).

Social risk factor	Multivariate OR (95% CI)	Multivariate p-value
Dual eligible	**1.13 (1.09-1.19)**	**<0.001**
Low AHRQ SES	**1.05 (1.01-1.09)**	**0.006**
Black	**1.05 (1.00-1.11)**	**0.034**
Rural	**0.87 (0.83-0.90)**	**<0.001**

Table 28: Odds ratios for inpatient admission outcome by social risk factor (multivariate)

Social risk factor	Multivariate OR (95% CI)	Multivariate p-value
Dual eligible	1.30 (1.23-1.37)	<0.001
Low AHRQ SES	1.15 (1.10-1.21)	<0.001
Black	1.21 (1.14-1.28)	<0.001
Rural	1.47 (1.40-1.54)	<0.001

Table 29: Odds ratios for ED visit outcome, by social risk factor (multivariate)

Analysis #4: Model Performance with and without social risk factor variables

Previous submission

Models exhibit similar performance with and without including social risk variables in the risk adjustment. Specifically,

- C-statistics exhibit very similar model discrimination between risk adjustment using original risk factors and using original risk factors plus social risk variables. For example, for the Validation Split Sample, the inpatient admission measure C-statistics are 0.725 for the model that does not adjust for social risk variables and 0.728 for the model that adjusts for social risk variables. For the ED visit measure, the C-statistics are 0.636 without adjusting for social risk and 0.644 when adjusting for social risk.
- The model calibration results are very similar between risk adjustment using original risk factors and using original risk factors plus social risk variables.
- The results of overfitting indices remained similar with and without adding social risk variables in the risk-adjustment model.

Model	c-statistic without Low SES Index Risk Factor	c-statistic with Low SES Index Risk Factors	Predictive Ability without Low SES Index Risk Factor (%)	Predictive Ability with Low SES Index Risk Factor (%)
Cancer Hospitals: RSAR	**0.711**	**0.711**	**3.0 – 31.4**	**3.0 – 31.4**
Cancer Hospitals: RSEDR	**0.650**	**0.651**	**2.5 – 12.5**	**2.5 – 12.5**
Non-PCH HOPDs: RSAR	**0.693**	**0.693**	**3.2 – 31.4**	**3.2 – 31.4**
Non-PCH HOPDs: RSEDR	**0.647**	**0.647**	**2.4 – 13.1**	**2.4 – 13.1**

Table 30: Comparison of Risk Model Discrimination Statistics with and without low AHRQ SES Index risk factor

Model	c-statistic without Black Risk Factor	c-statistic with Black Risk Factors	Predictive Ability without Black Risk Factor (%)	Predictive Ability with Black Risk Factor (%)
Cancer Hospitals: RSAR	0.711	0.711	3.0 – 31.4	3.0 – 31.4
Cancer Hospitals: RSEDR	0.650	0.652	2.5 – 12.5	2.4 – 12.6
Non-PCH HOPDs: RSAR	0.693	0.693	3.2 – 31.4	3.2 – 31.4
Non-PCH HOPDs: RSEDR	0.647	0.647	2.4 – 13.1	2.4 – 13.1

Table 31: Comparison of Risk Model Discrimination Statistics with and without race (Black) variable

Current submission

For the current submission we examined model performance using three approaches: calculating the C-statistic and predictive ability (Table 33), showing model calibration through risk-decile plots (see Figures 23-30 in section 2b.29), for the base model in comparison to the base model plus each individual social risk factor. Model performance, including calibration was nearly identical following the addition of each social risk factor to the base model.

Outcome	Model (base model or base model plus the additional social risk factor)	C-statistic	Predictive ability (%)
RSAR	**Base model**	**0.723**	**1.9 - 25.4**
RSAR	**Low SES**	**0.723**	**1.9 - 25.4**
RSAR	**Dual eligible**	**0.723**	**1.9 - 25.4**
RSAR	**Black**	**0.723**	**1.9 - 25.4**
RSAR	**Rural**	**0.723**	**1.9 - 25.4**

Table 32: C-statistic for the RSAR for the base risk model and the base model plus each social risk factor

Outcome	Model (base model or base model plus the additional social risk factor)	C-statistic	Predictive ability (%)
RSEDR	**Base model**	**0.669**	**1.9 - 12.0**
RSEDR	**Low SES**	**0.669**	**1.9 - 12.0**
RSEDR	**Dual eligible**	**0.670**	**1.9 - 12.0**
RSEDR	**Black**	**0.669**	**1.9 - 12.0**
RSEDR	**Rural**	**0.673**	**1.8 - 12.2**

Table 33: C-statistic for the RSEDR for the base risk model and the base model plus each social risk factor

Analysis #5: Measure score in relation to hospital-proportion of patients with social risk factors

Previous submission

Distribution of RSARs and RSEDRs

We further examined the potential impact of these social risk factors on measure scores by comparing RSAR and RSEDR distributions at facilities by proportion of patients with social risk factors (i.e., percent Black or percent with low SES Index value). Facilities were stratified by the proportion of patients at the facility with each factor, and placed into quartiles based on these proportions. For example, facilities with few Black patients in their sample would be in the first quartile while facilities seeing high numbers of Black patients would be in the fourth quartile. We performed a similar analysis for quartiles of the SES Index. These stratified distributions were examined for systematic differences in RSARs and RSEDRs across quartiles. Because a large portion of hospitals with very few (< 25 patients) had no Black patients, we restricted both the analysis of results for Black and SES Index quartiles to the 1,535 hospitals with at least 25 patients, which is consistent with public reporting of the measure. In addition, we focus on results for non-PCH HOPDs, since there are only 11 cancer hospitals and stratifying by quartile would be comparing only a few hospitals. There are 1,524 non-PCH HOPDs with at least 25 patients in the FY 2016 dataset.

As shown in Table 34, facilities with the highest proportion of Black patients (Q4) had slightly higher RSARs throughout the distribution relative to facilities with the lowest proportion of these patients (Q1). However, the opposite was true for the RSEDRs, with facilities with the highest proportion of Black patients experiencing slightly lower rates throughout the distribution, as found in Table 34. With regard to facilities with the highest proportion of low SES Index patients (Q4), both RSAR and RSEDR values were slightly higher relative to facilities with the lowest proportion of low SES Index patients (Q1) (see Tables 34 and 35).

At the *hospital-level*, no between-hospital effects were observed for hospital case-mix by Medicaid dual-eligibility, race, or the AHRQ SES Composite Index. Specifically, there was no clear relationship between the median risk-standardized rates and hospitals' case mix by these three social risk factors. In addition, the distributions of risk-standardized rates overlapped significantly across hospitals grouping by these three social risk factors, suggesting that hospitals caring for a greater percentage of high social risk patients have similar rates of inpatient admission and ED visits within 30 days of hospital-based outpatient chemotherapy. For example, the hospitals in the lowest quartile of proportion of black patients had a median risk-adjusted admission rate of 10.2, the second quartile had a rate of 10.6, third quartile had a median rate of 10.1, and the top quartile of hospitals with proportion of black patients had a rate of 10.2. For full presentation of results please see the measure technical report.

Finally, to further understand the relationship between the RSAR and RSEDRs and escalating proportions of patients with high social risk (i.e., higher percentage Black patients and higher percentage of low SES Index patients), we plotted RSARs and RSEDRs versus the hospital-level proportion of percent Black and low SES Index patients. We restricted this analysis to non-PCH HOPDs with at least 25 patients that were in the highest quartiles for both social risk factors. We then calculated a Pearson correlation statistic to evaluate the relationship at the hospital-level between the risk-adjusted rates and these social risk factors.

As shown in Figures 6 and 7, there was no association between RSAR or RSEDR values and the facility-level percentage of Black patients. This was confirmed by the Pearson Correlation coefficient, which was 0.047 for the RSAR (p-value = 0.361) and 0.096 for the RSEDR (p-value = 0.061). Similarly for the facility-level percentage of low

SES Index patients, there was no significant association with the RSAR or RSEDR, as shown in Figures 8 and 9. This was supported by the Pearson Correlation coefficient, which was -0.022 for the RSAR (p-value = 0.661) and 0.004 for the RSEDR (p-value = 0.945).

Figure 6: RSAR vs. Percent Black, among non-PCH HOPDs with highest proportion of Black patients (Q4) (hospitals with >25 patients; n=1,524 hospitals)

Pearson correlation coefficient: 0.047

Figure 7: RSEDR vs. Percent Black, among non-PCH HOPDs with highest proportion of Black patients (Q4) (hospitals with >25 patients; n=1.524 hospitals)

Pearson correlation coefficient: 0.096

Figure 8: RSAR vs. Percent Low SES Index, among non-PCH HOPDs with highest proportion of Low SES Index Patients (Q4) (hospitals with >25 patients; n=1,524 hospitals)

Pearson correlation coefficient: -0.022

Figure 9: RSEDR vs. Percent Low SES Index, among non-PCH HOPDs with highest proportion of Low SES Index Patients (Q4) (hospitals with >25 patients; n=1.524 hospitals)

Pearson correlation coefficient: 0.004

Current submission

To explore the relationship between the hospitals' proportion of patients with social risk factors and measure scores we compared measure score distributions for both outcomes across the four social risk factors (Tables 34 and 35) stratified into quartiles of the proportion of patients with each social risk factor. **For the RSAR**, measure scores are slightly higher for Low AHRQ SES, dual eligible, and race (Black) variables, but the distributions overlap. For the rural indicator, RSARs are slightly lower for the fourth quartile compared with the first quartile (Table 34). **For the RSER**, measure scores are similar between the first and fourth quartile for all except the rural variable; for the rural variable RSERs are higher for the fourth quartile across the entire distribution (Table 35).

Social risk factor	Low AHRQ SES	Low AHRQ SES	Dual Eligible	Dual Eligible	Race (Black)	Race (Black)	Rural	Rural
Quartile for proportion of patients with social risk factor	**Q1**	**Q4**	**Q1**	**Q4**	**Q1**	**Q4**	**Q1**	**Q4**
Number of facilities	370	368	370	369	394	368	368	368
Number of patients	52,054	45,626	58,686	52,408	28,934	80,497	67,528	41,037
RSAR	*	*	*	*	*	*	*	*

Social risk factor	Low AHRQ SES	Low AHRQ SES	Dual Eligible	Dual Eligible	Race (Black)	Race (Black)	Rural	Rural
100% Max	14.7	18.6	15.5	18.6	15.2	14.1	14.7	16.1
90%	11.6	11.3	11.3	11.6	10.8	11.5	11.8	11.1
75% Q3	10.3	10.3	10.1	10.5	9.8	10.6	10.8	10.1
50% Median	9.3	9.5	9.2	9.6	9.1	9.6	9.7	9.3
25% Q1	8.6	8.7	8.5	8.8	8.6	8.7	8.8	8.6
10%	8.1	8.1	8.0	8.1	8.1	8.1	8.1	8.1
0% Min	6.7	7.0	6.3	6.3	6.8	7.0	6.4	6.6

Table 34: Inpatient Admission (RSAR): Facility proportion of patients with SRFs comparing the 1st and 4th quartiles of the hospital-proportion of patients with social risk factors

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Social risk factor	Low AHRQ SES	Low AHRQ SES	Dual Eligible	Dual Eligible	Race, Black	Race (Black)	Rural	Rural
Quartile for proportion of patients with the social risk factor	**Q1**	**Q4**	**Q1**	**Q4**	**Q1**	**Q4**	**Q1**	**Q4**
Number of facilities	370	368	370	369	394	368	368	368
Number of patients	52,054	45,626	58,686	52,408	28,934	80,497	67,528	41,037
RSEDR	*	*	*	*	*	*	*	*
100% Max	7.7	9.0	7.7	9.0	9.0	7.7	7.2	9.1
90%	6.3	6.3	6.1	6.3	6.5	6.1	5.8	6.6
75% Q3	5.6	5.7	5.5	5.7	5.8	5.5	5.3	6.0
50% Median	5.2	5.2	5.1	5.2	5.4	5.0	4.9	5.5
25% Q1	4.8	4.8	4.7	4.8	5.0	4.7	4.6	5.1
10%	4.5	4.5	4.5	4.5	4.7	4.3	4.1	4.8
0% Min	3.0	3.5	3.0	3.2	3.7	3.2	3.0	4.1

Table 35: ED Visit (RSEDR): Facility proportion of patients with SRFs comparing the 1st and 4th quartiles of the hospital-proportion of patients with social risk factors

*Cells intentionally left empty

We then further explored the relationship between measure scores and the proportion of patients with social risk factors for those facilities with the highest proportion of patients (the 4th quartile) with social risk factors. We calculated the Pearson Correlation Coefficient between the proportion of patients with social risk factors and the measure score, for facilities in the 4th quartile for the proportion of patients with social risk factors (Table 36, Table 37), for both outcomes. Figures 10, 11, and 12 show scatter plots for the variables where the 4th quartile of facilities for the proportion of patients with the variable was significantly correlated with measure scores.

For the RSAR, only the proportion of dual eligible patients was significantly positively correlated with measure scores (Table 36) ($p<0.05$). For the RSEDR low AHRQ SES and race (Black), were significantly positively correlated. We note however, that the relationship between the proportion of patients with social risk and correlations with measure scores is complex – for example, the first quartile for the facility proportion of the dual eligible variable is also positively correlated with the RSAR measure score (Figure 10).

Risk factor	Pearson Correlation Coefficient	p-value
Dual Eligible	**0.124**	**0.019**
Low AHRQ SES	**0.008**	**0.885**
Dual Eligible	**0.124**	**0.019**
Race (Black)	**-0.056**	**0.291**
Rural	**-0.098**	**0.06**

Table 36: RSAR: Pearson Correlation between the measure scores and the hospital-proportion of patients with social risk factors for the 4th quartile of patients with social risk factors

Risk factor	Pearson Correlation Coefficient	p-value
Dual Eligible	**0.031**	**0.553**
Low AHRQ SES	**0.111**	**0.035**
Race (Black)	**0.206**	**<0.001**
Rural	**0.011**	**0.836**

Table 37: RSEDR: Pearson Correlation between the measure scores and the hospital-proportion of patients with social risk factors for the 4th quartile of patients with social risk factors

Figure 10: Non-PCH HOPDs: RSAR correlation with the proportion of patients with dual eligibility. (4th quartile is in blue)

Figure 11: Non-PCH HOPDs: RSER correlation with the proportion of patients with low AHRQ SES (4th quartile is in blue).

Figure 12: Non-PCH HOPDs: RSER correlation with the proportion of patients with race, Black (4th quartile is in blue).

Analysis 6: Hospital rankings and correlation of measure scores with and without social risk variables in the model

Previous submission

Rankings (Spearman)

There is very high agreement of hospital rankings between risk-adjustment models which incorporate social risk variables and those that do not (Spearman rank correlation = 0.988 for the inpatient admission model and 0.984 for the ED visit model), suggesting that accounting for the social risk factors will not have a major impact on hospital rankings.

Correlations (Pearson)

Because our analysis showed that in **PCH HOPDs**, there was a significant patient-level association of both social risk factors (Black race and low SES Index) with the outcome, we examined the impact of including these variables as risk-adjusters in our model on the hospital-level measure scores. We found that entering these variables into the risk-adjustment model did not substantially change measure scores for cancer hospitals. Correlation coefficients between the measure score with and without adjustment for these factors were 1 or near 1 (see Table 38 below). This indicates that including these social risk factors in hospital-level measure scores for cancer hospitals will result in virtually no differences in hospital-level results after accounting for other risk factors included in the risk model.

Outcome	Social Risk Factor	Pearson Coefficient	p-value
RSAR	African-American	0.99982	<.0001
RSEDR	African-American	1.00000	<.0001

Outcome	Social Risk Factor	Pearson Coefficient	p-value
RSAR	**Low SES Index**	**0.99898**	**<.0001**
RSEDR	**Low SES Index**	**0.99999**	**<.0001**

Table 38: Correlation between hospital-level measure scores (Pearson Coefficients) with and without social risk factors for PCH hospitals

Current submission

We examined correlations (Pearson) between measure scores with and without social risk factors for both outcomes and all variables (Table 39) and found that measure scores were highly correlated, suggesting little impact of adding the social risk factor on measure scores. The lowest correlation coefficient was for the rural outcome for the RSEDR outcome (0.987) which was still highly correlated. All other correlations were =>0.998.

Outcome	Social Risk Factor	Pearson Coefficient	p-value
RSAR	**Low-SES**	**0.999**	**<.0001**
RSEDR	**Low-SES**	**0.998**	**<.0001**
RSAR	**Dual Eligible**	**0.999**	**<.0001**
RSEDR	**Dual Eligible**	**0.998**	**<.0001**
RSAR	**Black**	**>0.999**	**<.0001**
RSEDR	**Black**	**0.999**	**<.0001**
RSAR	**Rural**	**0.999**	**<.0001**
RSEDR	**Rural**	**0.987**	**<.0001**

Table 39: Pearson correlation between measure scores calculated with and without each social risk factor

Finally, we calculated differences in measure scores for each facility comparing measure scores with and without social risk factors. We found differences were very small, again suggesting that adding these variables to the risk model would have little overall impact on measure scores (Table 40).

Outcome	Social Risk Factor	Average absolute difference in measure score	Median absolute difference in measure scores
RSAR	Low-SES	0.00060	-0.00055
RSEDR	Low-SES	0.00082	-0.00095
RSAR	Dual Eligible	0.00097	-0.00200
RSEDR	Dual Eligible	0.00019	-0.00087
RSAR	Black	-0.00004	-0.00070
RSEDR	Black	-0.00180	0.00069
RSAR	Rural	0.00200	-0.00170
RSEDR	Rural	0.00950	-0.00730

Table 40: Mean and median absolute differences in measure scores calculated with and without social risk factors

Social risk factor summary and conclusion

Previous submission

Initial Model Development: Conclusions

There are clear patient-level effects, but at the hospital level, accounting for patient social risk factors has minimal to no impact on model performance or hospital performance ranking for both the admission or ED measure,

indicating that the added risk of being high social risk is captured within current risk variables and arguing against inclusion of patient social risk factors in the chemotherapy measure. Given these findings, we did not include social risk factors in the initial risk-adjustment model for this measure.

2018 Reevaluation: Conclusions

We found that in cancer hospitals, there are clear patient-level effects, as reflected in the significant, relationships between these social risk factors and the two measure outcomes, after adjusting for other risk factors. However, inclusion of social risk factors had no impact on model performance. At the hospital level, the distribution of RSARs and RSEDRs were not consistently higher or lower for facilities with higher proportions of Black patients, and facilities with fewer low SES Index values had higher values of RSARs and RSEDRs throughout the distribution. There was no obvious statistical relationship between these variables and the measure outcome, as demonstrated by the non-linear, non-significant correlation results. Furthermore, at the hospital level, including the variables in the model did not change hospital-level measure scores. Given these findings, we did not change our original conclusion that SDS factors should not be included in the risk-adjustment models for this measure.

This is consistent with CMS's concern that facilities should not be held to different standards for patients with social risk factors. CMS remains committed to considering options for accounting for social risk factors within individual measures and in the OQR (82 FR 59427) and PCHQR (82 FR 38421) programs.

Current Submission

In contrast to the 2018 results, with this update (using data from January 1, 2021 to November 30, 2021) we found that for non-PCH-HOPDs there were significant associations (odds ratios >1.0 and significant p value) between the social risk factors we tested and the outcome in a multivariable model including the base model's risk factors. For example, for the RSAR, three social risk variables (low AHRQ SES, dual eligible, and race (Black)) were significantly associated with the outcome, and for the RSEDR, all four variables that we tested were significantly associated (low AHRQ SES, dual eligible, race (Black) and Rural). Because there are only 11 PCH-HOPDs we did not include results for those hospitals.

In terms of model performance, we show that models with and without each social risk factor perform almost identically, with almost identical c-statistics, predictive ability, and risk decile plots. This indicates that the existing unadjusted model performs well for patients with those social risk factors and that adding the social risk factors to the model does not improve model performance or discrimination. In addition, the risk model shows good calibration for each of the social risk variables.

When examining measure scores, we found that measure scores calculated with and without social risk factors were highly correlated, and that differences in measure scores calculated with and without social risk factors were very small. This suggests that overall, each social risk factor has very little impact on measure scores.

However, for the hospitals with the highest proportion of social risk factors (about 300 or so in the 4th quartile for the proportion of patients with social risk actors), we did see a small but significant correlation between measure scores and the proportion of patients with the social risk factor for the dual eligible variable and the RSAR, and for the low AHRQ variable and race (Black) variable, and the RSEDR. However, there are also significant correlations with the first quartile for some of the variables so the relationship is more complex.

CMS, the measure steward, has long been concerned about the impact of social risk factors on its measures in its programs and has taken steps to address these concerns. For example, in the Hospital Readmission Reduction Program (HRRP), hospitals are peer grouped by the proportion of patients with dual eligibility. In addition, as mentioned earlier in section 2b.30, the measure developer (Yale/CORE) has developed methods (the within hospital and across hospital disparities methods) to stratify hospital performance by social risk factor. For this chemotherapy measure, CMS has calculated results using the two disparity methods and the dual eligible variable, one of the risk factors we find has a significant association with the outcome. Those results will be shared confidentially with facilities in September of 2022. We provide more information about those methods and the results below in section 2b.30.

CMS has further chosen to not adjust the Chemotherapy measure for race. CMS feels it is not appropriate to add these variables to the risk model given the potential unintended consequences of masking disparities and/or signaling that differential care is acceptable. In addition the chemotherapy measure is within the Hospital

Outpatient Quality Reporting Program, which is a pay-for-reporting program and therefore providers that serve a high proportion of patients with social risk factors would not be financially penalized.

[Response Ends]

2b.26. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used). Provide the statistical results from testing the approach to control for differences in patient characteristics (i.e., case mix) below. If stratified ONLY, enter "N/A" for questions about the statistical risk model discrimination and calibration statistics.

Validation testing should be conducted in a data set that is separate from the one used to develop the model.

[Response Begins]

We performed a number of tests to evaluate the model performance during initial development, and then re-examined key statistics during subsequent measure reevaluation. For this endorsement maintenance submission we have updated these analyses.

Previous submission

Initial Model Development. We assessed adequacy of the patient-level risk-adjustment models (described above). We evaluated the model performance first in the 2012-2013 Medicare FFS Development Split Sample. We then re-tested the model performance in the 2012-2013 Medicare FFS Validation Split Sample. We did this separately for both the inpatient admission outcome model and the ED visit outcome model.

Using the 2012-2013 Medicare FFS Development Split Sample, we computed three summary statistics for assessing the risk-adjustment model performance: area under the receiver operating characteristic (ROC) curve (c-statistic), predictive ability, and over-fitting indices. We then compared the model performance in the development sample with its performance in the validation sample.

- The c-statistic is a measure of how accurately a statistical model is able to distinguish between a patient with and without a hospital visit. For binary outcomes, the c-statistic is identical to the ROC. A c-statistic of 0.50 indicates random prediction, implying that patient risk factors contribute no additional information. A c-statistic of 1.0 indicates perfect prediction, implying that patients' outcomes can be predicted completely by their risk factors.
- Discrimination in predictive ability measures the ability to distinguish high-risk from low-risk subjects. Good model discrimination is indicated by a wide range between the lowest and highest deciles.
- We assess model calibration by calculating over-fitting indices. Over-fitting refers to the phenomenon in which a model describes the relationship between predictive variables and outcome well in one group of patients, but fails to provide valid predictions in another distinct group of patients. Over-Fitting indices ($\gamma 0$, $\gamma 1$) provide evidence of over-fitting and require several steps to calculate. Estimated values of $\gamma 0$ far from 0 and estimated values of $\gamma 1$ far from 1 provide evidence of over-fitting.

Model Reevaluation. To assess performance of the patient-level risk-adjustment model, the area under the receiver operating characteristic curve, as measured by the c-statistic, was calculated. Observed inpatient admission rates and ED visit rates were compared to predicted inpatient admission and ED visit probabilities across predicted rate deciles to assess calibration, and the range of observed inpatient admission rates and ED visit admission rates between the lowest and highest predicted deciles was also calculated to assess model discrimination.

Several analyses to validate the patient-level risk-adjustment model were performed. First, we compared model performance for the updated model with prior years' models. The c-statistic and model discrimination (predictive ability) were compared. Second, we examined the stability of the risk variable frequencies and regression coefficients between the current model and prior years' models.

Current submission

CORE's measures undergo an annual measure reevaluation process, which ensures that the risk-standardized models are continually assessed and remain valid, given possible changes in clinical practice and coding standards over time. Modifications made to measure cohorts, risk models, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, and empirical analyses, including assessment of coding trends that reveal shifts in clinical practice or billing patterns. Input is solicited from a workgroup composed of up to 20 clinical and measure experts, inclusive of internal and external consultants and subcontractors.

We provide a link to the 2020 facility specific report for this measure. The report describes what CORE did for 2020 public reporting, including:

- Updated the ICD-10 code-based specifications used in the measure. Specifically:
  - Numerator
    - The addition of 1 ICD-10 code
  - Denominator
    - The addition of 19 HCPCS codes to the chemotherapy medication category
    - The removal of 11 HCPCS codes from the chemotherapy medication category
  - Risk Adjustment
    - The addition of 81 ICD-10 codes to the Concurrent Radiotherapy risk variable
- Monitored code frequencies to identify any warranted specification changes due to possible changes in coding practices and patterns;
- Reviewed potentially clinically relevant codes that "neighbor" existing codes used in the measures to identify any warranted specification changes;
- Reviewed select pre-existing ICD-10 code-based specifications with our workgroup to confirm the appropriateness of specifications unaffected by the updates;
- Evaluated and validated model performance
- Evaluated the stability of the risk-adjustment models

CORE notes that after initial measure development we do not re-test our risk models for overfitting using a dataset that is external to the testing sample. In our risk models, coefficients are updated each time the measure is calculated. Therefore, random statistical fluctuations in model coefficients across repeated reporting cycles are part of the overall random error in the facility performance estimates. CORE believes that this approach is not a validity issue for this type of model, unlike the case of a static risk model.

[Response Ends]

2b.27. Provide risk model discrimination statistics.

For example, provide c-statistics or R-squared values.

[Response Begins]

Initial Model Development Results

Inpatient admission outcome model

2012-2013 Medicare FFS Development Split Sample results:

- c-statistic=0.73
- Predictive ability (lowest decile %, highest decile %): 2.09-27.70%

2012-2013 Medicare FFS Validation Split Sample results:

- c-statistic=0.72
- Predictive ability (lowest decile %, highest decile %): 2.16-27.98%

ED visit outcome model

2012-2013 Medicare FFS Development Split Sample results:

- c-statistic=0.63
- Predictive ability (lowest decile %, highest decile %): 1.91-8.33%

2012-2013 Medicare FFS Validation Split Sample results:

- c-statistic=0.64
- Predictive ability (lowest decile %, highest decile %): 1.93-8.22%

2018 Model Reevaluation Results

Inpatient admission outcome model

2016 Medicare FFY Dataset, PCH-HOPDs:

- c-statistic=0.6933
- Predictive ability (lowest decile %, highest decile %): 3.21 – 31.40%

2016 Medicare FFY Dataset, Non-PCH HOPDs:

- c-statistic=0.7114
- Predictive ability (lowest decile %, highest decile %): 2.98 – 31.43%

ED visit outcome model

2016 Medicare FFY Dataset, PCH-HOPDs:

- c-statistic=0.6470
- Predictive ability (lowest decile %, highest decile %): 2.35 – 13.1%

2016 Medicare FFY Dataset, Non-PCH HOPDs:

- c-statistic=0. 6504
- Predictive ability (lowest decile %, highest decile %): 2.47 – 12.46%

Current submission

Table 41 shows the C-statistic and predictive ability for each outcome for each facility type.

Outcome	Facility	C-statistic	predictive ability, % (lowest decile - highest decile)
RSAR	**non-PCH**	**0.723**	**1.9 - 25.4**
RSEDR	**non-PCH**	**0.669**	**1.9 - 12.0**
RSAR	**PCH**	**0.721**	**2.0 - 30.0**
RSEDR	**PCH**	**0.657**	**1.7 - 10.6**

Table 41: Model Development Results

[Response Ends]

2b.28. Provide the statistical risk model calibration statistics (e.g., Hosmer-Lemeshow statistic).

[Response Begins]

Initial Model Development Results

Inpatient admission outcome model

2012-2013 Medicare FFS Development Split Sample results:

- Calibration: (γ0, γ1) = (0,1)

2012-2013 Medicare FFS Validation Split Sample results:

- Calibration: (γ0, γ1) = (0.01, 1.00)

ED visit outcome model

2012-2013 Medicare FFS Development Split Sample results:

- Calibration: (γ0, γ1) = (0,1)

2012-2013 Medicare FFS Validation Split Sample results:

- Calibration: (γ0, γ1) = (-0.04, 0.99)

[Response Ends]

2b.29. Provide the risk decile plots or calibration curves used in calibrating the statistical risk model.

The preferred file format is .png, but most image formats are acceptable.

[Response Begins]

Risk-decile plots for the Previous submission and this endorsement maintenance submission ("current submission") are shown below.

Previous submission

Figure 13: Inpatient admission outcome model: plot of observed vs. predicted values for risk deciles (2012-2013 Medicare FFS Development Split Sample)

A second plot using 2012-2013 Medicare FFS Validation Split Sample showed very similar results.

Figure 14: ED visit outcome model: Plot of observed vs. predicted values for risk deciles (2012-2013 Medicare FFS Development Split Sample)

A second plot using 2012-2013 Medicare FFS Validation Split Sample showed very similar results.

2018 Model Reevaluation Results

Figure 15: Inpatient admission outcome model, PCH-HOPDs: Plot of observed vs. predicted values for risk deciles (2016 Medicare FFS Data)

Figure 16: Inpatient admission outcome model, Non-PCH HOPDs: Plot of observed vs. predicted values for risk deciles (2016 Medicare FFS Data)

Figure 17: Emergency Department Visits outcome model, PCH-HOPDs: Plot of observed vs. predicted values for risk deciles (2016 Medicare FFS Data)

Figure 18: Emergency Department Visits outcome model, Non-PCH HOPDs: Plot of observed vs. predicted values for risk deciles (2016 Medicare FFS Data)

Current submission

Below we provide updated risk-decile plots for the entire patient population, as well as for each social risk factor sub-population using data from the 2022 EM dataset. Risk-decile plots for all the social risk factors we tested are shown in "SRF calibration" tab of the data dictionary.

PCH-HOPDs

Figures 19 and 20: Risk-decile plot among all patients (among PCH HOPDs) for the Inpatient Admission Model (Figure 19) and the ED/Observation Model (Figure 20).

Figure 19: Risk decile plot for all patients; Inpatient Admission Model (PCH HOPDs)

Figure 20: Risk decile plot for all patients; ED/Observation Model (PCH HOPDs)

Non-PCH HOPDs

All Patients

Figures 21 and 22: Risk-decile plot among all patients (patients among non-PCH facilities) for the Inpatient Admission Model (Figure 21) and the ED/Observation Model (Figure 22).

Figure 21: Risk decile plot for all patients; Inpatient Admission Model (non-PCH HOPDs)

Figure 22: Risk decile plot for all patients; ED/Observation Model (non-PCH HOPDs)

Figure 23: Risk decile plot for dual eligible patients; Inpatient Admission Model (non-PCH HOPDs)

Figure 24: Risk decile plot for dual eligible patients; ED/Observation Model (non-PCH HOPDs)

Figure 25: Risk decile plot for patients with low AHRQ SES; Inpatient Admission Model (non-PCH HOPDs)

Figure 26: Risk decile plot for patients with low AHRQ SES; ED/Observation Model (non-PCH HOPDs)

Figure 27: Risk decile plot for Black patients; Inpatient Admission Model (non-PCH HOPDs)

Figure 28: Risk decile plot for Black patients; ED/Observation Model (non-PCH HOPDs)

Figure 29: Risk decile plot for Rural patients; Inpatient Admission Model (non-PCH HOPDs)

Figure 30: Risk decile plot for Rural patients; ED/Observation Model (non-PCH HOPDs)

[Response Ends]

2b.30. Provide the results of the risk stratification analysis.

[Response Begins]

Details of the disparities methodology, data, and data characteristics for the stratification approach can be found in the accompanying attachment entitled "Disparity Methodology Report."

Below we provide the results that categorize performance on the within- and across facility disparities methods, described in section 2b.30, for non-PCH HOPDs.

The Within-Facility Disparity Method

The goal of the *Within-Facility Disparity Method* is to illuminate disparities between dual eligible and non-dual eligible patients at a single facility. It answers the question: "Will two patients who differ only with respect to their dual eligible status have different outcomes after receiving care at a given facility?" In other words, this method is intended to illuminate whether dual eligible patients seen at a facility for an eligible procedure have worse (or better) outcomes than non-dual eligible patients seen at the same facility. This method will allow us to measure the gap, or disparity effect, across facilities to assess whether some facilities have a greater gap in the care they give to dual eligible and non-dual eligible patients.

The Within-Facility Disparity Method estimates the difference in hospital visit rates between dual eligible and non-dual eligible patients at a particular facility. To be included in this analysis, HOPDs must have at least 12 dual eligible patients and 12 non-dual eligible patients; 695 (20.1%) non-PCH and 11 (100%) of PCH-HOPDs met the reporting threshold, respectively.

In Table 42 below, visit rate differences were categorized into three performance groups indicating better, similar, and worse outcomes for their dual eligible population. Using an interval of 1% rate difference to differentiate facilities, the results show that no facilities had notably better performance for their dual eligible patients and that 62% of non-PCH HOPDs had worse outcomes for the Inpatient Admission outcome and 100% of non-PCH-HOPDs had worse outcomes for the ED outcome for their dual eligible population.

We did not include results for the PCH-HOPDs in this analysis due to the small number of hospitals (n=11), too small to draw conclusions from performance categorization.

Measure Name	Total Number of Eligible Facilities^	Better Outcomes for Dual Eligible patients (RD<-1%) (% of reportable facilities)	Similar Outcomes for Dual Eligible and non-Dual Eligible patients (RD between-1% and 1%) (% of reportable facilities)	Worse Outcomes for Dual Eligible patients (RD > 1%) (% of reportable facilities)	Number of Cases Too Small (% of eligible facilities)^^
Non-PCHHOPD, Inpatient Admissions	2,174	0	263	432	1,479
Non-PCH HOPD,ED Visit	2,174	0	0	695	1,479

Table 42: Within-hospital disparity method: visit rate difference (per 1,000 procedures) for non-PCH HOPDs, by category

^Eligible facilities defined as facilities with at least1 dual eligible patient and 1 non-dual eligible patient

^^HOPDs must have at least 12 dual eligible patients and 12 non-dual eligible patients

Across Facility Disparity Method

The goal of the *Across-Facility Disparity Method* is to measure and compare facility performance for the subgroup of dual eligible patients included in a measure cohort. This analysis calculates a dual eligible-specific risk-standardized outcome rate for only dual eligible patients for each facility. This method answers the question: "How does facility A perform for their dual eligible patients when compared to facility B?" It reflects a traditional approach to stratification; however, we only report results for the dual eligible sub-population.

Table 43 shows the dual eligible-specific RSARs/RSEDRs assessed across three categories of performance: Better than the national Rate (>1% below the National Rate), No different than the National Rate (between -1% and 1% of National Rate) and Worse than the National Rate (>1% Above National Rate). An interval of 1% difference was used to differentiate the reporting categories. Overall, a small proportion of facilities received results for the *Across-Facility Disparity Method*. Similar to the *Within-Facility Disparity Method* we did not include results PCH-HOPDs in this analysis.

For non-PCH HOPDs, about 85 percent of facilities did not have enough cases for a result. **For the 337 non-PCH HOPDs with a result**: for the Inpatient Admission outcome, 78 (23%) were worse than the national rate, 62 (18%) were better, and 197 (58%) were no different. For the ED visit outcome, 48 (14%) were worse, 58 (17%) were better, and 231 (69%) were no different than the national rate.

Measure Name	Total Number of Eligible Hospitals^	Better than the National Rate (>1% below National Rate) (% of reportable facilities)	No Different than the National Rate(between -1% and 1% of National Rate) (% of reportable facilities)	Worse than the National Rate (>1% Above National Rate)(% of reportable facilities)	Number of Cases Too Small (% of eligible facilities)
Non-PCH HOPDs, Inpatient Admissions	2,174	62	197	78	1,837
Non-PCH HOPDs, ED Visits	2,174	58	231	48	1,837

Table 43: Distribution of Dual-Eligible-specific RSARs and RSEDRs for non-PCH HOPDs

[Response Ends]

2b.31. Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix).

In other words, what do the results mean and what are the norms for the test conducted?

[Response Begins]

Previous submission

Initial Model Development. For both models, model performance was similar in the development and validation datasets, with strong model discrimination and fit. Predictive ability was also similar across datasets. The c-statistics of 0.73 (inpatient) and 0.63 (ED visit) indicate good model discrimination. The models indicated a wide range in predictive ability between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects. The calibration value of close to 0 and close to 1 indicates good calibration of the model. Additionally, the risk decile plots show that the model performs similarly in each of the risk deciles across a broad range of risk.

2018 Model Reevaluation. After updating the models to include concurrent radiotherapy and refitting on the newer dataset, we continued to observe strong model discrimination and fit for both outcomes, in both PCH-HOPDs and non-PCH HOPDs. The c-statistics ranged from 0.6470 (RSAR, for PCH-HOPDs) to 0.7114 (RSEDR, for non-PCH HOPDs), indicate good model discrimination. The models continued to show a wide range in predictive ability between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects.

Current submission

With testing in the updated dataset, we continue to observe strong model discrimination and fit for both outcomes, in both PCH-HOPDs and non-PCH HOPDs. The c-statistics, ranging from 0.657 to 0.723 indicate good model discrimination. The models continued to show a wide range in predictive ability between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects. In addition, we show that the models perform similarly with patients with social risk factors (low AHRQ SES, dual eligible, race (Black), and rural).

[Response Ends]

2b.32. Describe any additional testing conducted to justify the risk adjustment approach used in specifying the measure.

Not required but would provide additional support of adequacy of the risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed.

[Response Begins]

Not applicable. No additional testing was performed.

[Response Ends]

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3.01. Check all methods below that are used to generate the data elements needed to compute the measure score.

[Response Begins]

Coded by someone other than person obtaining original information (e.g., DRG, ICD-10 codes on claims)

[Response Ends]

3.02. Detail to what extent the specified data elements are available electronically in defined fields.

In other words, indicate whether data elements that are needed to compute the performance measure score are in defined, computer-readable fields.

[Response Begins]

ALL data elements are in defined fields in a combination of electronic sources

[Response Ends]

3.03. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using data elements not from electronic sources.

[Response Begins]

Not applicable.

[Response Ends]

3.04. Describe any efforts to develop an eCQM.

[Response Begins]

Not applicable.

[Response Ends]

3.06. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

[Response Begins]

Previous Submission

Measure development, testing, and the 2017 national dry run for implementation in the PCHQR and OQR programs showed that the measure cohort can be defined and outcomes reported using routinely collected Medicare claims and enrollment data. The measure is primarily based on key fields in the claims data that are used for payment and, therefore, have a high level of completeness across claims and are considered reliable.

Current Submission

There have been no reported difficulties regarding data collection, availability, missing data, timing and frequency, or any other implementation issues.

[Response Ends]

Consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

3.07. Detail any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm),

Attach the fee schedule here, if applicable.

[Response Begins]

Previous Submission

The measure relies on ICD-10, CPT, UB-04, and HCPCS codes to identify the measure cohort, measure outcomes, and risk factors. There are no licensing requirements or fees for use of ICD-10 and HCPCS data. While the CPT and UB-04 data are readily available on the CMS claims, we note two copyrights:

The American Medical Association (AMA) holds a copyright to the CPT codes utilized in the measure specifications. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

The American Hospital Association (AHA) holds a copyright to the Uniform Bill Codes ("UB") utilized in the measure specifications. Anyone desiring to use the UB Codes in a commercial product to generate measure results, or for any other commercial use, must obtain a commercial use license directly from the AHA. To inquire about licensing, please contact ub04@healthforum.com.

Current Submission

ICD-10, CPT, and HCPCS codes continue to be used to identify the measure cohort, outcomes, and risk factors. The measure has no fees, licensing, or other requirements.

[Response Ends]

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement, in addition to demonstrating performance improvement.

4a.01. Check all current uses. For each current use checked, please provide:

- **Name of program and sponsor**
- **URL**
- **Purpose**
- **Geographic area and number and percentage of accountable entities and patients included**
- **Level of measurement and setting**

[Response Begins]

Public Reporting

[Public Reporting Please Explain]

The PCHQR program is a public reporting program implemented by CMS for the 11 PPS-Exempt Cancer Hospitals. It is intended to equip consumers with quality-of-care information to make informed decisions about healthcare options. It is also intended to encourage hospitals and clinicians to improve the quality of care provided to Medicare beneficiaries by ensuring that providers are aware of and reporting on best practices for their respective facilities and type of care.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

- **Name of program and sponsor:** PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, CMS
- **URL:** https://qualitynet.cms.gov/pch/pchqr
- **Purpose:** The PCHQR program is intended to equip consumers with quality-of-care information to make more informed decisions about healthcare options. It is also intended to encourage hospitals and clinicians to improve the quality of inpatient care that is provided to Medicare beneficiaries. A major part of the program supports improvement by ensuring that providers are aware of and reporting on best practices for their respective facilities and type of care.
- **Geographic area and number and percentage of accountable entities and patients included:** National, 11 facilities
- **Level of measurement and setting:** Facility, hospital inpatient, and hospital outpatient settings (depending on the measure within the program)

Payment Program

[Payment Program Please Explain]

The Hospital OQR program is a pay-for-reporting program implemented by CMS for outpatient hospital services. The Hospital OQR Program promotes higher quality, more efficient health care for Medicare beneficiaries through

measurement. All acute care hospitals paid by Medicare and subject to the Outpatient Prospective Payment System (OPPS) are included; during the 2017 dry run, 3,571 hospitals were eligible for the OQR program.

Hospital Outpatient Quality Reporting

- **Name of program and sponsor**: Hospital Outpatient Quality Reporting (OQR), CMS
- **URL**: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram
- **Purpose**: The Hospital OQR Program is a quality data reporting program for outpatient hospital services implemented by CMS. CMS focuses on reporting measure data that have a high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries.
- **Geographic area and number and percentage of accountable entities and patients included**: National program; the number of accountable entities and patients varies by the specific measure within the program.
- **Level of measurement and setting**: Facility; Hospital Outpatient Department

[Response Ends]

4a.02. Check all planned uses.

[Response Begins]

Measure Currently in Use

[Response Ends]

4a.03. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing), explain why the measure is not in use.

For example, do policies or actions of the developer/steward or accountable entities restrict access to performance results or block implementation?

[Response Begins]

Not applicable.

[Response Ends]

4a.04. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes: used in any accountability application within 3 years, and publicly reported within 6 years of initial endorsement.

A credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.

[Response Begins]

Not applicable.

[Response Ends]

4a.05. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

Detail how many and which types of measured entities and/or others were included. If only a sample of measured entities were included, describe the full population and how the sample was selected.

[Response Begins]

Previous Submission

Prior to the measure's first public reporting in the Hospital OQR and PCHQR programs, CMS held a confidential, national dry run with all eligible facilities (OQR: 3,571 facilities; PCHQR: 11 facilities) during August/September 2017. During this period, all facilities had the opportunity to ask questions about the measure specifications and their non-public, facility-level results and detailed patient-level data for the FY 2016 data period provided in Facility-Specific Reports (FSRs). CMS provided reports to the 11 PCH hospitals and 3,571 non-PCH hospitals during the dry run. We received and responded to 216 questions during this period, three from PCHs and 213 from non-cancer hospitals.

CMS adopted the measure for public reporting in the Hospital OQR program beginning in CY 2020 (81 FR 79764) and in the PCHQR program for confidential reporting, beginning in FY2019, and future public reporting (81 FR 57190). Prior to publicly reporting measure results on Hospital Compare, CMS will release annual Facility-Specific Reports (FSRs) to facilities in both the OQR and PCHQR programs which provide the facility with a summary of their performance on the measure, national performance on the measure, patient data, and characteristics of the patient population at the facility and in the nation. Facilities in the OQR program also receive semi-annual claims-detail reports (CDRs), which provide them with patient data for their facility so that they can see how they are performing ahead of the release of the annual FSR.

Facilities wishing to ask questions regarding the measure are able to do so using the question-and-answer tool on QualityNet. Additionally, each program's QualityNet site includes a measure page for this measure. The page includes measure methodology, a fact sheet, frequently asked questions, and archived information from the measure dry run.

Facility-level results are then published on CMS's Hospital Compare website, where they are available to the general public.

Current Submission

Facilities can continue to ask questions about the measure through the question-and-answer tool on QualityNet. Detailed measure information (updated methodology, data dictionaries, fact sheets) continues to be available for stakeholders on the QualityNet site.

The Q&A tool can be accessed at this URL: https://cmsqualitysupport.servicenowservices.com/qnet_qa.

[Response Ends]

4a.06. Describe the process for providing measure results, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

[Response Begins]

Previous Submission

Facilities in the PCHQR and OQR programs receive confidential FSRs once per calendar year. The FSR provides the facility with a summary of their performance on the measure, national performance on the measure, detailed patient data, and characteristics of the patient population at the facility and in the nation. In addition to the FSR, facilities in the OQR program receive two CDRs per calendar year that provide interim detailed patient-level data for their facility prior to the annual FSR.

The first distribution of confidential FSRs occurred in August 2017 as part of the measure's national dry run. As part of the dry run, CMS held a 45-day public comment period from August 15 through September 29, 2017. During this period, facilities participating in the PCHQR and OQR programs had the opportunity to ask questions about the measure specifications and their non-public, facility-level results for the FY 2016 data period. We received 216 questions during this period, three from PCHs and 213 from non-cancer hospitals. In addition, CMS hosted a national provider call on August 23, 2017, to review the measure specifications, share national results, and answer stakeholder questions.

Facilities wishing to ask questions or looking for information regarding the measure are able to do so using the question-and-answer tool on QualityNet (www.qualitynet.org). Additionally, each program's QualityNet site includes a measure page for this measure. The page includes measure methodology, fact sheet, frequently asked questions, and archived information from the measure dry run. These materials are updated prior to every confidential or public reporting period for the measure.

Current Submission

For the HOQR program, facilities continue to receive FSRs and CDRs from PCHQR annually, as described above. CMS typically releases two CDRs and one FSR each year (although changes may be made to this schedule as needed). CMS announces the dates that FSRs and CDRs will be made available on the measure-specific page on QualityNet; https://qualitynet.cms.gov/outpatient/measures/chemotherapy

[Response Ends]

4a.07. Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how feedback was obtained.

[Response Begins]

Previous Submission

During the measure's national dry run, CMS held a 45-day public comment period from August 15 through September 29, 2017. During this period, facilities participating in the PCHQR and OQR programs had the opportunity to ask questions/comment about the measure specifications and their non-public, facility-level results for the FY 2016 data period. We received 216 questions during this period, three from PCHs and 213 from non-cancer hospitals. (See 4a2.2 for types of feedback received.)

We used the feedback from all of these sources to refine the measure specifications during the initial development phase and then during reevaluation. They served as a source of ongoing face validity review on key aspects of the measure, including the codes and logic used to define the cohort, outcomes, exclusions, and risk-adjustment models.

Current submission

Stakeholders can provide feedback through CMS's Q&A tool: https://cmsqualitysupport.servicenowservices.com/qnet_qa?id=ask_a_question or make a suggestion.

Since 2019, CMS has received 59 questions about this measure.

[Response Ends]

4a.08. Summarize the feedback obtained from those being measured.

[Response Begins]

Previous Submission

The majority of feedback from those being measured came during the 2017 national dry run of the measure. During the dry run, the most common feedback we received from facilities involved the following three topics:

1. Patients were included in the measure cohort who were receiving chemotherapy treatment for an autoimmune disease and not cancer;
2. Concern over patients being included in the outcome who were admitted for planned procedures (e.g., for stem cell transplantation); and,
3. Concern over patients being included in the cohort who had Leukemia in remission

Current Submission

Through Q&A, we received questions from stakeholders on the following topics:

1. Inclusion and exclusion criteria, including detailed questions about specific codes.
2. Sources of data used for risk adjustment.
3. Access to FSRs, CDRs, and SAS packs.
4. How to provide input into the list of medications within the measure specifications
5. Facility-specific inquiries into individual cases within their CDRs
6. How the outcome is defined and how multiple ED visits are handled.
7. How the measure score is calculated.

[Response Ends]

4a.09. Summarize the feedback obtained from other users.

[Response Begins]

Previous Submission

During the measure's first NQF endorsement review in 2016, members of the NQF Cancer Committee expressed concern over the inclusion of patients in the measure receiving concurrent chemotherapy and radiotherapy, noting that these patients are at higher risk for an outcome due to increased exposure to toxins. In response to this feedback, the 2018 EWG recommended revising the risk-adjustment model to ensure that facilities treating a higher proportion of patients receiving concurrent chemotherapy and radiotherapy were not penalized for providing treatment to higher-risk patients.

Current submission

The feedback we received through the Q&A tool were likely all from facility-based stakeholders.

[Response Ends]

4a.10. Describe how the feedback described has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

[Response Begins]

Previous Submission

In order to address the comments received from facilities being measured and other users, we implemented a number of updates to our measure specifications ahead of the implementation of the measure into the OQR program (note: due to timing issues, these changes in specifications were not included in the first year of PCHQR confidential reporting but will be included in subsequent years). Specifically, we:

1. Implemented a new case-level exclusion in which patients receiving chemotherapy to treat a qualifying autoimmune condition rather than cancer are excluded from the measure. Cases qualifying for this exclusion are identified by the presence of a chemotherapy code and an autoimmune diagnosis and the absence of a cancer diagnosis code;

2. Implemented new logic into the measure that identifies and excludes outcomes identified as "always planned." The measure considers inpatient hospital admissions with the following AHRQ Clinical Classification Software (CCS) procedures or diagnoses as always planned, and they do not qualify as an outcome for the chemotherapy measure: Procedures • AHRQ CCS 64 – Bone marrow transplant • AHRQ CCS 105 – Kidney transplant • AHRQ CCS 176 – Other organ transplantation (other than bone marrow corneal or kidney) Diagnoses • AHRQ CCS 45 – Maintenance chemotherapy; radiotherapy
3. Reviewed and revised the code set for exclusion of patients with leukemia to also exclude patients with leukemia in remission; and,
4. Added a new risk-adjustment variable to the risk models for both outcomes that assesses whether a patient is receiving concurrent radiotherapy and chemotherapy. We define concurrent treatment, based on recommendations from the measure's expert work group, as the receipt of radiotherapy on the date of chemotherapy or up to 14 days before the administration of chemotherapy [1].

Current submission

The feedback described above for the current cycle would be considered in future cycles of re-evaluation. The measure changes made to the measure currently under review came from prior internal and external stakeholder feedback provided to CORE.

2021 Measure Updates:

- Removal of 11 codes from the denominator (cohort), addition of 1 code to the numerator (outcome), the addition of 19 codes to the denominator (cohort), and the addition of 81 codes to the Concurrent Radiotherapy risk variable.

  Rationale: Each year, as part of reevaluation of the measure, CMS reviews the measure's existing code set as well as updates to ICD-10, CPT®, and HCPCS coding guidelines to ensure that the measure's code set is up to date.

2020 Measure Updates:

- Update to code the measure at the procedure level, not the claim level.

  Rationale: Facilities do not necessarily bill every day; they bill monthly or longer. This update ensures all individual chemotherapy treatments that are billed on the claim are adjusted for.

- Update to exclusion criteria to exclude all cases where chemotherapy was administered on the same date as hospital admission and during inpatient stays.

  Rationale: It would be uncommon for a patient to receive outpatient chemotherapy and then be admitted to the ER.

- Update to coding of the number of chemotherapy treatments risk variable to include only chemotherapy treatments that meet inclusion criteria.

  Rationale: This better reflects the probability of experience in outcome in the 30 days following the event.

2019 Measure Updates:

- Addition of stand-alone observation stays to the ED-visit measure outcome.

  Rationale: It has become increasingly common for observation stays to be used in place of hospital admissions or ED visits. This rate already captured observation stays billed with an ED 2021 Measure Updates: Surgery, Chemotherapy, Colonoscopy 64 visit, so this update adds in a small portion billed separately. This update improved the measure's ability to capture all hospital visits that may indicate gaps in the quality of care.

- Addition of four new cancer risk variables (anal cancer, bladder cancer, ovarian cancer, and pancreatic cancer) from existing, broader risk factor categories in both risk models.

  Rationale: Adding more specificity to cancer type in the risk models will account for patients with cancer types that may be more likely to experience an outcome and ensure that both models more accurately discriminate and predict facility performance.

References:

1. Church, D.N., Flubacger, M., Cameron, A., et al. "Toxicity of concurrent radiotherapy with CMF chemotherapy in the E-CMF adjuvant breast carcinoma regimen." Journal of Clinical Oncology 25, no. 18_suppl (June 20 2007) 582-582.

[Response Ends]

4b.01. You may refer to data provided in Importance to Measure and Report: Gap in Care/Disparities, but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included). If no improvement was demonstrated, provide an explanation. If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

[Response Begins]

Previous Submission

The measure has been adopted for public reporting in the Hospital OQR program beginning in CY 2020 (81 FR 79764) and for confidential reporting, beginning in FY2019, and future public reporting in the PCHQR program (81 FR 57190). [1] In preparation for the first year of public reporting in these programs, the measure underwent a confidential, national dry run in August/September 2017, using the FY 2016 dataset described in Sections 1.2 and 1.7 of the Testing Attachment. However, subsequent years of results are not yet available for comparison.

As described above, the Hospital OQR and PCHQR programs promote quality improvement through the public reporting of measure results. We expect there to be improvement in annual measure scores over time as public reporting of chemotherapy measure results through these two programs identifies and illuminates opportunities for improvement in outpatient chemotherapy care to providers, patients, and other stakeholders.

In addition to hospital performance being publicly reported, each participating hospital receives patient-level data outlining details of cases and outcomes attributed to their facility. Low-performing hospitals will be able to use this data to make informed decisions on how to improve current protocols or develop new interventions aimed at improving quality.

Footnote

1. This measure's testing form notes that the measure will be publicly reported in the PCHQR program beginning in FY2019; however, we were informed on September 25, 2018, that the measure would be confidentially reported to facilities in FY2019, with public reporting planned for a future year.

Current submission

As described in section 2b.03, between 2019 and 2021, we found substantial improvement in both observed national rates and facility-level risk-standardized scores for this measure for both PCH and non-PCH-HOPDs. This improvement is supported by quality improvement programs that have been put in place to improve patient care to improve the inpatient measure score (as a direct result of the implementation of the chemotherapy measure)] and several additional quality improvement projects that address the emergency room visit outcome [1,2].

References:

1. Smith, M and J Carlson, 2021. Reducing ED Visits and Hospital Admissions After Chemotherapy with Predictive Modeling of Risk Factors. Oncology Issues; 36:4.
2. ASCO Quality Improvement Library, https://practice.asco.org/quality-improvement/quality-programs/quality-training-program/quality-improvement-library; accessed November 1, 2022.

[Response Ends]

4b.02. Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.

[Response Begins]

Previous Submission

We did not identify any unintended consequences during measure development, model testing, or confidential reporting of the measure during its national dry run. However, during the NQF Measure Applications Partnership (MAP) review of this measure in December 2015, the MAP expressed concerns about a possible unintended consequence related to treatment decisions and underuse of appropriate care. The MAP's concern was that the measure might indirectly discourage more aggressive treatment plans that would have had clinical benefits. However, the purpose of the measure is to open lines of communication between the patient and provider on risks and preventative actions that can be taken for each type of treatment and set the expectations for the patient so they can make more informed decisions on healthcare utilization as well [1].

Furthermore, the measure is risk-adjusted to help account for the variation in patient mix and aggressiveness of treatment. For example, the aggressiveness of chemotherapy regimens can range by cancer type and patient age, which are accounted for in our models. We also adjust for the number of treatments and whether or not the patient is receiving radiotherapy concurrently, both of which may also be indicators of the aggressiveness of treatment. Lastly, the measure rate is not intended to be zero, and CMS recognizes that not all admissions and ED visits are avoidable. To this end, CMS only categorizes hospitals with rates significantly higher or lower than the national rate as performing either "worse" or "better," as described in more detail in Section 2b4 of the Testing Attachment. Improving patient/provider communication and appropriately adjusting the model mitigates the risk of unintended consequences.

We are committed to monitoring this measure's use and assessing potential unintended consequences over time.

Current submission

We did not identify any unintended consequences during measure implementation and public reporting. CMS remains committed to monitoring this measure's use and assessing unintended consequences.

Reference:

1. Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." Supportive Care in Cancer, vol. 21, no. 2, 2013, pp. 397–404

[Response Ends]

4b.03. Explain any unexpected benefits realized from implementation of this measure.

[Response Begins]

Not applicable. There were no unexpected findings identified during testing of this measure and the measure has not yet been publicly reported.

[Response Ends]

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

If you are updating a maintenance measure submission for the first time in MIMS, please note that the previous related and competing data appearing in question 5.03 may need to be entered in to 5.01 and 5.02, if the measures are NQF endorsed. Please review and update questions 5.01, 5.02, and 5.03 accordingly.

5.01. Search and select all NQF-endorsed related measures (conceptually, either same measure focus or target population).

(Can search and select measures.)

[Response Begins]

0383: Oncology: Medical and Radiation - Plan of Care for Pain

0384: Oncology: Medical and Radiation - Pain Intensity Quantified

[Response Ends]

5.02. Search and select all NQF-endorsed competing measures (conceptually, the measures have both the same measure focus or target population).

(Can search and select measures.)

[Response Begins]

[Response Ends]

5.03. If there are related or competing measures to this measure, but they are not NQF-endorsed, please indicate the measure title and steward.

[Response Begins]

OCM-2: Risk-adjusted proportion of patients with all-cause emergency department visits or observation stays that did not result in a hospital admission within the 6-month episode (CMS)

We note that the oncology care model ended in June 2022.

[Response Ends]

5.04. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s), indicate whether the measure specifications are harmonized to the extent possible.

[Response Begins]

Yes

[Response Ends]

5.05. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

[Response Begins]

Previous Submission

We identified three related NQF-endorsed measures. All three measures (NQF 0383, NQF 0384e, and NQF 1628) focus on cancer patients receiving outpatient chemotherapy; however, there are some key differences in measure scope and measure type. Measure scope: Each of the three related measures (NQF 0383, NQF 0384e, and NQF 1628) narrowly focuses on pain management and/or fatigue/anemia. The proposed measure does not target a specific symptom, but rather assesses the overall management of 10 important symptoms and complications that were more frequently cited in literature as reasons for ED visits and inpatient admissions following outpatient chemotherapy. Measure type: The three related measures (NQF 0383, NQF 0384e, and NQF 1628) are all process measures encouraging the use of screening and care plans to improve care. The proposed measure is an outcome measure not encouraging or measuring specific processes to detect and treat these conditions, but rather assessing the outcomes of the care being provided. The three process measures, which are not risk-adjusted, support the intent of the measure by reinforcing that those providing outpatient care should screen for and manage symptoms such as pain.

Current Submission

Adding to the above, NQF 0383 and 0384 are clinician-level measures, not facility-level measures, which are registry-based, not claims based. We note that NQF 1628 has lost endorsement.

In our measure search, we identified a non-NQF-endorsed measure, OCM-2, had been used in CMS's Oncology Care Model (OCM) through June 2022. It differs in its outcome (all-cause ED visits, compared with ED visits after chemotherapy for specific diagnoses), the setting of the outcome (ED visits/observation stays without an inpatient stay vs. ED/observation and inpatient visits), and in risk adjustment (model variables differ). The measures each serve their intended purposes, however: OCM-2 is part of a CMMI voluntary payment model and is used together with other quality measures and with cost of care information to reduce utilization and costs for treatment of cancer; the chemotherapy measure is part of a pay-for-reporting program that aims to improve the safety of chemotherapy administration.

[Response Ends]

5.06. Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality). Alternatively, justify endorsing an additional measure.

Provide analyses when possible.

[Response Begins]

Not applicable.

[Response Ends]

Appendix

Supplemental materials may be provided in an appendix.:

Available in attached file

Attachment: 3490_3490_3490_2020 OQR AUS Report-508.pdf

Attachment: 3490_3490_3490_Disparity Methodology Report-508.pdf

Contact Information

Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services

Measure Steward Point of Contact: Dollar-Maples, Helen, helen.dollar-maples@cms.hhs.gov

Measure Developer if different from Measure Steward: Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)

Measure Developer Point(s) of Contact: Grady, Jacqueline, jacqueline.grady@yale.edu

Peter, Doris, doris.peter@yale.edu

Hassan, Sapha, sapha.hassan@yale.edu

Additional Information

1. Provide any supplemental materials, if needed, as an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be collated one file with a table of contents or bookmarks. If material pertains to a specific criterion, that should be indicated.

[Response Begins]

Available in attached file

[Response Ends]

Attachment: 3490_3490_3490_2020 OQR AUS Report-508.pdf

Attachment: 3490_3490_3490_Disparity Methodology Report-508.pdf

2. List the workgroup/panel members' names and organizations.

Describe the members' role in measure development.

[Response Begins]

The 2018 Expert Workgroup (EWG) advised on refinements of the technical specifications during 2018 measure reevaluation, and provided an assessment of the measure's face validity. Prior EWGs similarly provided guidance either during the measure's initial development or subsequent revisions.

2018 EWG members
1. Robert Daly, MD, MBA – Memorial Sloan-Kettering Cancer Center (Staff Physician, Medical Oncology)
2. Stephen Edge, MD* – Roswell Park Memorial Institute (Vice President, Healthcare Outcomes and Policy, Professor of Oncology and Surgical Oncology)
3. Michael Hassett, MD, MPH* – Dana Farber Cancer Center (Attending Physician, Medical Oncology; Assistant Professor, Medicine, Harvard Medical School)
4. Scott Huntington, MD, MPH – Yale New Haven Hospital (Attending Physician, Hematology)
5. Denise Morse, MBA – City of Hope Cancer Treatment and Research Center (Senior Manager, Quality Analytics)
6. Joseph Ross, MD, MHS – Yale University School of Medicine (Associate Professor of General Medicine and of Public Health)
7. Weijing Sun, MD – University of Kansas Cancer Center (Director of Medical Oncology and Associate Director of University of Kansas Cancer Center)
8. Allison Snyderman, Ph.D.* - Memorial Sloan-Kettering Cancer Center (Outcomes Researcher)

*Also served as member of TEP and 2014 PPS-Exempt Cancer Workgroup

2017 EWG members
1. Susan Armstrong—City of Hope Cancer Treatment and Research Center (Senior Manager, Coding and Data Quality)
2. Arnold Chen, MD, MPH – Mathematica Policy Research (Clinician, Senior Researcher)
3. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
4. Joseph Ross, MD, MHS – Yale University School of Medicine (Associate Professor of General Medicine and of Public Health)
5. Tracy Spinks, CPH—MD Anderson Hospital, Cancer Care Delivery (Program Director)
6. Denise Stone, RN, MBA – Mathematica Policy Research (Clinician, Lead Program Analyst)

2016 EWG members
1. Peter B. Bach, MD, MAPP—Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)

2. Stephen Edge, MD—Baptist Cancer Center (Cancer Center Director)
3. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
4. Karl Lorenz, MD, MSHS—UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
5. Allison Snyderman, PhD —Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Researcher)
6. Tracy Spinks, CPH—MD Anderson Hospital, Cancer Care Delivery (Program Director)

2015 EWG members
1. Peter B. Bach, MD, MAPP—Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
2. Stephen Edge, MD—Baptist Cancer Center (Cancer Center Director)
3. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
4. Karl Lorenz, MD, MSHS—UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
5. Allison Snyderman, PhD —Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Researcher)
6. Tracy Spinks, CPH—MD Anderson Hospital, Cancer Care Delivery (Program Director)

PPS-Exempt Cancer hospital workgroup members
1. J. Robert Beck, MD—American Oncologic Hospital (Fox Chase) (Senior Vice President and Chief Academic Officer)
2. Joe Jacobson, MD—Dana Farber Cancer Institute (Chief Quality Officer)
3. Barbara Jagels, MHA, RN, OCN—Seattle Cancer Care Alliance (Fred Hutchinson Cancer Research Center) (Director of Nursing and Clinical Excellence)
4. Dana Jenkins—Roswell Park Memorial Institute (Vice President of Organizational Improvement)
5. Tricia Kassab, RN, MS, CPHQ, HACP—City of Hope National Medical Center (Vice President of Quality and Patient Safety)
6. Jeremy Miransky, PhD—Memorial Hospital for Cancer and Allied Disease (MSKCC) (Quality Analytics Manager)
7. Shyroll Morris, MBA, MPH—University of Miami Hospital and Clinics
8. Thomas Ross, MS—H. Lee Moffitt Cancer and Research Institute Hospital, Inc. (Director of Quality and Safety)
9. Anthony Senagore, MD—University of Southern California Kenneth Norris Jr. Cancer Hospital (Chief of Colorectal Surgery)
10. Ron Walters, MD, MHA, MBA—The University of Texas MD Anderson Cancer Center (Associate Vice President of Medical Operations and Informatics)
11. Saul Weingart, MD, PhD —Dana Farber Cancer Institute (Vice President for Quality Improvement and Patient Safety)

TEP members
1. Peter B. Bach, MD, MAPP—Memorial Sloan-Kettering Cancer Center, Center for Health Policy and Outcomes (Director)
2. Stephen Edge, MD—Baptist Cancer Center (Cancer Center Director)
3. Andrew Glass, MD—Kaiser Permanente Northwest, Center for Health Research (Senior Investigator)
4. Mark Gorman—Independent Consultant (Patient Advocate)
5. Michael J. Hassett, MD, MPH—Dana-Farber Cancer Institute, Outpatient Clinic and Treatment Center (Staff Physician, Breast Oncology)
6. Karl Lorenz, MD, MSHS UCLA, Department of Veterans Affairs (Associate Professor); Rand Health
7. Joan McClure, MS—National Comprehensive Cancer Network, Clinical Information and Publications (Senior Vice President)
8. Bruce Minsky, MD—MD Anderson Hospital, Department of Radiation Oncology (Professor and Director of Clinical Research)
9. Shirley Stagner, MSN, ONP, AOCNP—Lawrence Hospital Center, Cancer Survivorship Program (Nurse Practitioner)

10. Janet H. Van Cleave, PhD, MSN, AOCNP—New York University College of Nursing (Assistant Professor)
11. Sandra L. Wong, MD MS—University of Michigan Health System, Division of Surgical Oncology

[Response Ends]

3. Indicate the year the measure was first released.

[Response Begins]

2017

[Response Ends]

4. Indicate the month and year of the most recent revision.

[Response Begins]

October 2022

[Response Ends]

5. Indicate the frequency of review, or an update schedule, for this measure.

[Response Begins]

Annually

[Response Ends]

6. Indicate the next scheduled update or review of this measure.

[Response Begins]

Fall 2023

[Response Ends]

7. Provide a copyright statement, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]

8. State any disclaimers, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]

9. Provide any additional information or comments, if applicable. Otherwise, indicate "N/A".

[Response Begins]

N/A

[Response Ends]