Partnership for Quality Measurement
Powered by Battelle

Fall 2022 Cycle

Patient Experience and Function Final Technical Report

October 2023

This report is funded by the Centers for Medicare & Medicaid Services under contract number 75FCMC23C0010.

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Executive Summary

Patient experience and function (PEF) is an important topic area that encompasses patient functional status, satisfaction, and experience of care, as well as issues related to care coordination. At the core of all health care delivery is the patient's experience with the care provided. Patient experience of the direct care received occurs across all providers and care settings, and research shows that satisfactory patient experience leads to better patient outcomes and a reduction of nonessential utilization of services that result in increased expenditures for both patients and providers.[1]

Quality measures are necessary tools for assessing quality care gaps and improvements in patient experience and function, as well as the extent to which health care stakeholders are using evidence-based strategies to advance the quality of care. To support this effort, Battelle endorses and maintains performance measures related to patient experience and function through a standardized, consensus-based process.

For this project's measure review cycle, seven measures were submitted for endorsement consideration (Table 1). Two measures (CBE #2789 and CBE #3721) were withdrawn from consideration after the Scientific Methods Panel (SMP) review and were therefore not reviewed by the committee. As a result, endorsement for CBE #2789 is maintained until a future endorsement review cycle, and endorsement was not considered for the new measure, CBE #3721. Of the five remaining measures reviewed by the PEF standing committee, all five measures were recommended for endorsement. The Consensus Standards Approval Committee (CSAC) upheld the committee's endorsement recommendations.

Effective March 27, 2023, the National Quality Forum (NQF) is no longer the consensus-based entity (CBE) funded through the Centers for Medicare & Medicaid Services (CMS) National Consensus Development and Strategic Planning for Health Care Quality Measurement Contract. Battelle has been selected to oversee the endorsement & maintenance (E&M) of clinical quality and cost/resource use measures. Since the Fall 2022 cycle launched at NQF, measures submitted for Fall 2022 E&M cycle continued along the prior E&M protocols that were in place at time of the Fall 2022 "Intent to Submit." In addition, the Scientific Methods Panel review and the committee's measure evaluation meeting for the Fall 2022 cycle were conducted under NQF. Battelle took over the E&M work beginning with the public comment period to close out the Fall 2022 cycle. This included launching the Fall 2022 post-comment period, convening the E&M committees for the post-comment meeting, convening the CSAC to render a final endorsement decision, and executing the Appeals period.

Table 1. Measures Submitted for Endorsement Consideration

Measure Number	Measure Title	New/ Maintenance	Developer/Steward	Final Endorsement Decision
2789	Adolescent Assessment of Preparation for Transition (ADAPT) to Adult-Focused Health Care	Maintenance	Center of Excellence for Pediatric Quality Measurement	Withdrawn
2958	Informed, Patient Centered (IPC) Hip and Knee Replacement Surgery	Maintenance	Massachusetts General Hospital	Endorsed
2962	Shared Decision-Making Process	Maintenance	Massachusetts General Hospital	Endorsed
3718	Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer	New	Purchaser Business Group on Health	Endorsed
3720	Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer	New	Purchaser Business Group on Health	Endorsed
3721	Patient-Reported Overall Physical Health Following Chemotherapy among Adults with Breast Cancer	New	Purchaser Business Group on Health	Withdrawn

Measure Number	Measure Title	New/ Maintenance	Developer/Steward	Final Endorsement Decision
3734	Alignment of Person-Centered Service Plan (PCSP) with Functional Assessment Standardized items (FASI) needs	New	The Lewin Group/ Centers for Medicare & Medicaid Services	Endorsed

Summaries of the measure evaluation meetings are linked within the body of the report. Detailed summaries of the committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Patient experience is central to the provision of health care. It encompasses a wide variety of elements, including interactions with providers, treatments, costs, quality of life, and overall quality of care. A better patient experience is associated with improved patient health outcomes and adherence to ongoing care, as well as reduced malpractice and improved employee satisfaction for the providing institution.[2] Patient experience is primarily assessed through surveys that are designed to capture patient/caregiver-reported experience, satisfaction, and outcomes, including functional status.

Quality measures are tools to measure or quantify health care processes, outcomes, patient perceptions, and organizational structures and/or systems that are associated with the ability to provide high-quality health care. Furthermore, quality measures can be a powerful tool in helping identify performance gaps in patient experience and function, affecting patient outcomes and overall cost.

Battelle, a CBE, convenes volunteer committees to evaluate and build consensus around quality measures for endorsement based on a standardized set of criteria. For the Fall 2022 cycle, the Patient Experience and Function (PEF) standing committee reviewed measures focused on patient-reported symptoms related to chemotherapy and shared decision-making, including patient-informed decision making with hip and other joint surgery and alignment of patient care plans with functional status.

Patient-Reported Symptoms Related to Chemotherapy

Patient-reported outcome assessments are increasingly being integrated into care delivery, including oncology care. For chemotherapy, there is often a persistence of treatment-related symptoms, experienced by people receiving curative cancer treatment, for months and even years after the completion of treatment. These symptoms, such as pain interference and fatigue, can be managed if appropriately assessed as part of routine cancer care.

Shared Decision Making

Patient-centered care is a core component of high-quality health care, emphasizing the importance of informing and involving patients in medical decisions and ensuring that patients' goals and preferences are respected. Shared decision making can be a catalyst to routinely informing and involving patients in important medical decisions, which in turn increases the likelihood that patients will get the care they want, consistent with their goals and concerns. This is particularly important in cases of elective surgery, where there is no definitive clinical need, and the use of surgery must be determined by informed patient preference.

Patient Experience and Function Measure Evaluation

For this measure review cycle, the PEF standing committee (Appendix B) evaluated three new measures and two measures undergoing maintenance review against standard measure evaluation criteria. Two measures (CBE #2789 and CBE #3721) were not evaluated by the committee as both measures did not pass the SMP's review of scientific acceptability (i.e., reliability and validity). The developer of CBE #2789 subsequently requested to withdraw the measure from the Fall 2022 cycle to address the SMP's concerns. Therefore, endorsement was maintained for CBE #2789 until a future endorsement review and was not considered for the new measure, CBE #3721.

Table 2a. Number of Fall 2022 Patient Experience and Function Measures Submitted and Reviewed

	Maintenance	New	Total
Number of measures submitted for endorsement review	3	4	7
Number of measures withdrawn from consideration*	1	0	1
Number of measures not passing SMP review	1	1	2
Number of measures reviewed by the committee	2	3	5
Number of measures endorsed	2	3	5
Number of measures not endorsed	0	0	0

**Measure developers/stewards can withdraw a measure from measure endorsement review at any point before the CSAC meeting. Table 2b provides a summary of withdrawn measures.*

Table 2b. Measures Withdrawn from Consideration

Measure Number	Measure Title	Developer/Steward	New/ Maintenance	Reason for Withdrawal
2789	Adolescent Assessment of Preparation for Transition (ADAPT) to Adult-Focused Health Care	Center of Excellence for Pediatric Quality Measurement	Maintenance	Did not pass SMP review; developer withdrew measure before committee review and will resubmit during a future endorsement cycle

Scientific Methods Panel Measure Evaluation

Prior to the committee's review, the SMP reviewed six measures (CBE #2789, CBE #2958, CBE #2962, CBE #3718, CBE #3720, and CBE #3721) in this topic area for scientific acceptability (i.e., reliability and validity). It did not review CBE #3734, as the measure and/or testing methods were deemed to be non-complex by NQF. The SMP passed three measures on reliability and validity (CBE #2958, CBE #2962, and CBE #3718) during its measure evaluation meeting. It did not reach consensus on validity for one measure (CBE #3720) and did not pass the remaining two measures (CBE #2789 and CBE #3721) on both reliability and validity. For CBE #2789, the developer provided ambiguous testing for the patient/encounter- and accountable entity-level testing requirement. For CBE #3721, the SMP raised concern with the low reliability and validity testing results and challenges with the face validity testing.

Comments Received Prior to Standing Committee Evaluation

For this evaluation cycle, pre-evaluation public commenting was conducted under NQF. No pre-evaluation comments were submitted prior to the measure evaluation meeting on February 23 and 28, 2023.

Comments Received After Standing Committee Evaluation

Following the standing committee's measure evaluation meetings, the committee endorsement recommendations were posted on the PQM website for public comment. The commenting period opened on March 28, 2023, and closed on May 5, 2023. The committee received two comments pertaining to the measures under review and the committee endorsement recommendations. One comment received was for CBE #2958, expressing the need for a broader measure of shared informed decision-making for bone replacements throughout the body. The second comment was for CBE #3720, which raised concern with the impact of the coronavirus disease 2019 on physician practices and subsequently their performance scores.

Battelle convened the committee for the Fall 2022 post-comment web meeting on June 16, 2023, to review and provide feedback on the full text of comments received and to discuss and revote on reliability for one measure (CBE #3734), which did not achieve consensus on this must-pass criterion during the measure evaluation meeting, referred to as a "consensus not reached" (CNR) measure. A summary of comments for each measure reviewed is provided in Appendix A.

Summary of Potential High-Priority Gaps

During the standing committee's evaluation of the measures, no potential high-priority measurement gap areas emerged.

Summary of Major Concerns or Methodological Issues

During the standing committee's evaluation of the measures, the impact of coronavirus disease 2019 (COVID-19) on the performance scores was a concern, namely for the two patient-

reported chemotherapy symptom measures (CBE #3718 and CBE #3720). The developer for these measures conducted face validity testing, and in its evaluation, the PEF committee discussed the SMP's concern regarding four of the 12 oncologists noting that the chemotherapy symptoms of fatigue (CBE #3720) and pain interference (CBE #3718) may not be due to cancer but to the COVID-19 pandemic. This concern was also raised for CBE #3721, which the SMP did not pass. However, the PEF committee recognized that there are clinical practice guidelines, which recommend assessing stressors like the COVID-19 pandemic in chemotherapy patients. The developer further attested that the test sites communicated with the developer throughout the testing period, including during the public health emergency (PHE). The test sites paused testing while they responded to the PHE and adjusted clinical workflows. These test sites remained engaged and created additional approaches to administer surveys to patients during the PHE. Details of the standing committee's discussion and ratings of the criteria for each measure are included in Appendix A.

References

1. Agency for Healthcare Research and Quality. (August 2022). *What Is Patient Experience*. Retrieved August 24, 2023 from https://www.ahrq.gov/cahps/about-cahps/patient-experience/index.html

2. Agency for Healthcare Research and Quality. (February 2020). *Section 2: Why Improve Patient Experience?* Retrieved August 24, 2023 from https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/2-why-improve/index.html

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Under the NQF process, quorum is 66% of active standing committee members minus any recused standing committee members. Due to the exclusion of recused standing committee members from the quorum calculation, the required quorum for live voting may vary among measures. Quorum (12 out of 18 active standing committee members) was met and maintained throughout the review of CBE #2958 and CBE #2962 during the measure evaluation meetings. Quorum during the meetings was not achieved for CBE #3718, CBE #3720, and CBE #3734. Therefore, the committee discussed all remaining criteria for these measures and voted after the meeting using an online voting tool. The standing committee members not in attendance received a recording of the meeting and a link to submit online votes. Voting closed after 48 hours with at least the number of votes required for quorum. Voting results are provided below.

A measure is recommended for endorsement by the standing committee when greater than 60% of voting members select a passing vote option (i.e., Pass, High and Moderate, or Yes) on all must-pass criteria and overall suitability for endorsement. A measure is not recommended for endorsement when less than 40% of voting members select a passing vote option on any must-pass criterion or overall suitability for endorsement.

A.1 Measures Endorsed

CBE #2958 Informed, Patient Centered (IPC) Hip and Knee Replacement Surgery

Staff Assessment | Specifications

Numerator Statement: The numerator is the number of respondents who have an adequate knowledge score (60% or greater) and a clear preference for surgery.

Denominator Statement: The denominator includes the number of respondents from the target population who have undergone primary knee or hip replacement surgery for treatment of knee or hip osteoarthritis.

Exclusions: Respondents who are missing 3 or more knowledge items do not get a total knowledge score and are excluded. Similarly, respondents who do not indicate a preferred treatment are excluded. No other exclusions as long as the respondent has the procedure for the designated condition.

Adjustment/Stratification: None

Level of Analysis: Clinician: Group/Practice

Setting of Care: Ambulatory Care, Outpatient Services

Type of Measure: Outcome: PRO-PM

Data Source: Instrument-Based Data

Measure Steward: Massachusetts General Hospital

STANDING COMMITTEE EVALUATION

Table A.1-1.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-13; Pass-10; No Pass-3 (10/13 – 76.9%, Pass)	• The standing committee recognized that this maintenance Patient-Reported Outcome Performance Measure (PRO-PM) at the clinician group/practice level is derived from patient responses to the Hip or Knee Decision Quality Instruments. It assesses the proportion of participants who have a passing knowledge score (60% or higher) and a clear preference for surgery. These are considered to have met the criteria for an informed, patient-centered (IPC) decision. The target population is adult patients who had primary hip or knee replacement surgery for treatment of hip or knee osteoarthritis. • The developer stated that the purpose of engaging patients in decisions is to ensure that they are well-informed and receive their preferred treatment. • The standing committee acknowledged that the developer provided updated evidence for this measure: • A systematic review that found that informed, patient-centered decisions are associated with higher shared decision-making scores

Criterion	Total Votes	Rationale
		• A cross-sectional survey conducted at four hospitals affiliated with a large health system that found informed, patient-centered decisions were associated with better physical health and physical function outcomes for patients who had total hip or knee replacement surgery • A cluster randomized trial of decision support that found that IPC decisions predicted better outcomes following knee replacement surgery. • A standing committee member stated that there is a difference between informed decision making and shared decision making. Specifically, there is no question as to whether this is an important measure in practice, but there is a question as to whether it rises to the importance of a national quality measure. The developer replied, stating that this is a patient-reported outcome measure that assesses the quality of the patient's decision, which is an outcome in and of itself. When patients make more informed decisions, they tend to have better outcomes. • The standing committee did not have any additional comments and proceeded to pass the measure on evidence.
1b. Performance Gap	Total Votes-13; H-0; M-9; L-3; I-1 (9/13 – 69.2%, Pass)	• The standing committee recognized the developer-reported data from three new data sets (referred to as Samples 3, 4, and 5). • Sample 3 includes 3,470 patients who completed the items as part of the Orthopedic Patient Reported Outcomes Measurement system at a large health system from 2018 to 2022 and came from four sites (two academic medical centers and two community hospitals) with 53 arthroplasty surgeons. The mean IPC rate was 76.5% and individual site IPC scores ranged from 72% to 80% ($p<0.006$) • Sample 4 includes data collected from 2016 to 2018 from three sites with 8 surgeons and 559 patients who participated in a randomized trial comparing two different decision aids. The developer found the overall rate was 92% and the range was between 91% and 95% across sites. • Sample 5 includes data from four sites, 22 surgeons, and 405 patients who provided sufficient data to calculate an IPC score. Overall, IPC was 70%, and the rates ranged from 62% to 77% by site. • The developer examined the three Samples and found significant differences in IPC percent by: • Age in Sample 3 (Less than 65 years of age 74% v. 78%, $p=0.004$) • Gender in Sample 3 (Female 75% v. Male 79%, $p=0.003$) and Sample 5 (Female 65% v. Male 77%, $p=0.02$). • Race (White, non-Hispanic 93% v. Other Race/ethnicity 82%, $p=0.04$) and education (College degree or more 94.5% v. Less than college degree 88%, $p=0.01$) in Sample 4. • One standing committee member questioned whether the gap had changed over time. The developer replied that it did not have data on changes over time. However, the standing committee recognized that a gap remains and disparities are present in care across various patient groups. • The standing committee passed the measure on performance gap.

Table A.1-1.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	• Total Votes-13; Yes-11; No-2 (11/13 – 84.6%, Pass)
	• SMP Total Votes-9; H-6; M-2; L-0; I-1
		• The standing committee recognized that reliability testing was conducted at the accountable entity level and the patient/encounter level:
		  • At the accountable entity level, the reliability was calculated as the variability of the site divided by total variability. The developer reported that for four groups (site 1 had 16 samples, site 2 had 26 samples, site 3 had 26 samples, and site 4 had four samples), the reliability was 0.735.
		  • At the patient/encounter level, the developer examined the intraclass correlation coefficient (ICC) of the knowledge score at time #1 and time #2. For the preference item, the developer examined the kappa between the response at time #1 and response at time #2. The test-retest reliability of the knowledge score was examined in sample #1 with an ICC of 0.81 (95% CI ranging from 0.71 to 0.87). The test-retest reliability of the item assessing preferred treatment had a kappa of 0.801.
		• The committee recognized that the SMP passed the measure on reliability with no major concerns.
		• The standing committee therefore accepted the SMP's rating and passed the measure on reliability.

2b. Validity	• Total Votes-13; Yes-10; No-3 (10/13 – 76.9%, Pass)
	• SMP Total Votes-9; H-4; M-4; L-1; I-0
		• The standing committee recognized that validity testing was done at the accountable entity level and at the patient/encounter level.
		  • For the patient/encounter-level testing, the developer stated that the mean knowledge scores discriminated between patients in a decision aid group with 67% (SD of 21.2) compared to 51% (SD of 24.9) in the usual care group (p<0.001).
		  • For the accountable entity-level testing, the developer found that the IPC was significantly associated with improvements in overall (0.05 points [Standard Error of the Mean (SE) 0.02] for EuroQol-5 Dimension (EQ-5D), p=0.004) and disease-specific quality of life (4.22 points [SE 1.82] for knee p=0.02, and 4.46 points [SE 1.54] for hip, p=0.004).
		  • The developer stated that the IPC was related to overall (mean difference EQ-5D 0.04 points [0.02, 0.07], p<0.001) and disease-specific quality of life (mean difference 4.9 points [1.5, 8.3], p=0.004) for knee but not hip patients.
		• The SMP passed the measure on validity with no major concerns.
		• One standing committee member noted that it is difficult to tease apart knowledge and preferences. In addition, the survey was given after the surgery. Therefore, the survey results came too late and may not be actionable for providers. The developer explained that the measure has been used in a variety of settings and agreed that the ideal timing is preoperative

Criterion	Total Votes	Rationale
		rather than postoperative. However, the challenge is to operationalize the measure in terms of creating a way to reliably test the measure across systems. The goal of combining preoperative and postoperative results was to assess whether there was an informed preference, which is an ultimate measure of decision quality. • Lastly, the standing committee questioned whether risk adjustment should be used. The developer stated that the measure is not risk-adjusted, as everyone should have the same level of communication and knowledge, whether they have zero or multiple comorbidities. • The standing committee accepted the developer's responses and voted to accept the SMP's passing rating for validity.

Table A.1-1.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-13; H-0; M-9; L-3; I-1 (9/13 – 69.2%, Pass)	• The standing committee recognized the patient-report surveys can be administered online to support electronic capture via patient reported outcome registries or other online survey platforms. If administered via mail or paper, then it will require staff at sites to enter the patient data into an online database for analysis. • The developer reported that at one health system, the items have been incorporated into the Patient-Reported Outcomes registry and are captured and scored as part of routine orthopedic care for patients undergoing surgery for hip, knee, and spine conditions. • The standing committee recognized that there are no fees for the measure or for the use of the Hip or Knee Decision Quality Instruments used to generate the measure, provided that the surveys are used in accordance with the Creative Commons copyright license. • Some standing committee members had concerns about implementation costs and response rates. The developer explained that the response rate is approximately 43% and implementation costs are dependent upon the setting. The developer reported that the administration of these questions has been conducted across multiple sites, in multiple modes (predominantly paper and online surveys). A large health system has incorporated the items into their patient-reported outcomes registry for orthopedics, and the data are being collected as part of routine care in that system. Generally, patients find these surveys acceptable as indicated by good response rates and low missing data. However, whether administered as a stand-alone survey or as part of a patient-reported outcomes measure set, to obtain sufficiently high response rates often requires effort on the part of clinic staff (for example to remind patients to complete). • A question was raised by the committee regarding translating the survey to languages other than English and Spanish. The developer did not have specific plans to do this but could do so based on the demand.

Criterion	Total Votes	Rationale
		• The standing committee did not have any further questions and passed the measure on feasibility.

Table A.1-1.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-13; Pass-10; No Pass-3 (10/13 – 76.9%, Pass)	• The standing committee acknowledged that the measure is being piloted for use in the Blue Cross Blue Shield of Massachusetts Alternative Quality Contract, the Alliance Quality Path Program, and the Shared Decision-Making Program at the Massachusetts General Brigham Health System. The Alliance Quality Path Program specifies the measurement of decision quality and shared decision making as part of its criteria for recognition. • Some standing committee members questioned whether it is only used in one region. The developer stated that at least one large system has chosen to use the measure at this time. • The standing committee did not raise any additional questions and passed the measure on use.
4b. Usability	• Total Votes-13; H-0; M-9; L-1; I-3 (9/13 – 69.2%, Pass)	• The standing committee recognized that the developer does not provide trend data but does note studies using the IPC measure have found that patients provided with decision support interventions have significantly higher rates compared to usual care. More recent studies have also shown that when patients receive decision aids as part of routine care, scores can be quite high (91 to 95%), whereas in practices with few patients receiving decision aids, scores are much lower (72 to 80%). • A standing committee member questioned how the measure has impacted the actual surgeons being held accountable to the measure. • The developer explained that this is a group-level measure and groups can drill down to the physician level to obtain feedback. • The standing committee did not have any further questions and passed the measure on usability.

Table A.1-1.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• N/A	• No related or competing measures were noted.

Table A.1-1.6. Standing committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-13; Yes-10; No-3 (10/13 – 76.9%, Pass)	• The standing committee recommended the measure for continued endorsement.

Table A.1-1.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	None
Non-supportive comments	• One	Pre-evaluation comments • None Post-evaluation comment *Need for a broader measure* • The comment suggested the need for a broader measure of shared informed decision making for bone replacements throughout the body. The commenter emphasized that a person's experience after a replacement surgery may differ from their physical functioning. • The developer, in response to the comment, acknowledged the request for a more comprehensive measure while emphasizing that the current measure is procedure-specific due to its incorporation of a knowledge assessment. However, creating additional measures for other joint replacement procedures would be considered by the developer.

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-1.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0 (13/13 – 100%, Endorsed)	• The lead discussant and other CSAC members found no major concerns with the standing committee deliberations and endorsed the measure.

APPEALS BOARD EVALUATION

Table A.1-1.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #2962 Shared Decision-Making Process

Staff Assessment | Specifications

Numerator Statement: Patient answers to four questions about whether or not 4 essential elements of shared decision making (laying out options, discussing the reasons to have the intervention, discussing reasons not to have the intervention, and asking for patient input) are scored and summed. A group/practice score is the average of their patient scores.

Denominator Statement: While we believe that the survey will work for patients who have undergone any elective surgical procedure, we have proposed a limited set of surgeries based on existing data for these conditions.

All responding patients who have undergone one of the following 7 surgical procedures: back surgery for a herniated disc; back surgery for spinal stenosis; knee replacement for osteoarthritis of the knee; hip replacement for osteoarthritis of the hip; radical prostatectomy for prostate cancer; percutaneous coronary intervention (PCI) for stable angina, and mastectomy for early-stage breast cancer.

Exclusions: For back, hip, knee, and prostate surgery patients, there are no exclusions as long as the surgery is for the designated condition (for example, hip replacement for osteoarthritis not for hip fracture).

For PCI, we are focused on patients who are treated for stable coronary artery disease. As such, those who had a heart attack within 4 weeks of the PCI procedure are excluded, as are those who have had previous coronary artery procedures (either PCI or CABG).

For mastectomy, we are focused on females having mastectomy as the primary surgical treatment for breast cancer. Patients who had had a prior lumpectomy for breast cancer in the same breast, patients who have not been diagnosed with breast cancer (who are having prophylactic mastectomies), and males with breast cancer are excluded.

Respondents who are missing one or more responses to the SDM Process measure do not receive a total score and thus, are excluded.

Adjustment/Stratification: None

Level of Analysis: Clinician: Group/Practice

Setting of Care: Ambulatory Care, Inpatient/Hospital, Outpatient Services

Type of Measure: Outcome: PRO-PM

Data Source: Instrument-Based Data

Measure Steward: Massachusetts General Hospital

STANDING COMMITTEE EVALUATION

Table A.1-2.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-12; Pass-11; No Pass-1 (11/12 – 91.7%, Pass)	• The standing committee recognized that the developer described the process of shared decision making (SDM), wherein clinicians meaningfully engage patients in medical decisions. The developer posited that the goal of SDM is to improve decision quality, ensuring that decisions are well-informed and reflect patient goals, concerns, and preferences as has been associated with lower decisional conflict as well as less decision regret.

Criterion	Total Votes	Rationale
		• The developer also provided a study on hip and knee replacement and spine surgery decisions in which researchers found that SDM process scores were related to less regret and higher patient satisfaction. • The standing committee had no major concerns and passed the measure on evidence.

1b. Performance Gap	• Total Votes-12; H-3; M-7; L-1; I-1 (10/12 – 83.3%, Pass)	• The standing committee recognized that the developer provided gap data, including mean scores regarding disparities, from three sources: Sample 4, Sample 5, and Sample 6.
		  • Mean scores were provided in each sample, ranging from 2.4 to 3.3 with standard deviations ranging from 1.0 to 1.2.
		  • The developer reported that younger respondents and males appear to have slightly higher scores, though most results are neither statistically nor clinically significant.
		  • The developer concluded that the calculated rates do show disparities by education or race/ethnicity but noted that the samples were small for race/ethnicity.
		• The standing committee acknowledged the differences in performance gap.
		• A standing committee member asked the developer whether it reviewed income disparities. Another standing committee member noted that many of the procedures were moved to different settings of care, such as ambulatory surgical centers. The developer stated that income data were not available, and because this measure was tested in Massachusetts, almost all (98%) of the data were insured, making the data less meaningful to test by insurance status.
		• The standing committee had no other questions and passed the measure on performance gap.

Table A.1-2.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale
2a. Reliability	• Total Votes-12; Yes-10, No-2 (10/12 – 83.3%, Pass) • SMP Total Votes-10; H-0; M-8; L-0; I-2	• The standing committee reviewed the reliability testing, which was conducted at the accountable entity level. The average signal-to-noise estimate for reliability was 0.69 (95% CI = [0.685, 0.69]). The developers also reported an ICC of 0.96. • The standing committee noted that reliability testing was also conducted at the patient/encounter level in the 2016 submission, where the developer noted that Cronbach alpha may not be an appropriate measure of reliability due to the nature of the measure. However, the developer calculated the alphas for some decisions, noting that they were in the 0.5 to 0.7 range. The short-term, test-retest data resulted in ICC values ranging from 0.7 to 0.8. • Several standing committee members had similar concerns with the SMP, in that the accountable entity-level testing did not demonstrate adequate reliability for all surgical procedures (namely prostate surgery, PCI, and mastectomy). The developer clarified that there were more data in some areas than others, which may have led to the lower scores. However, it provided a videotape recording to facilitate the assessment, which strengthened reliability.

Criterion	Total Votes	Rationale
		• The committee acknowledged that the SMP passed the measure on reliability. • The standing committee had no further questions and accepted the SMP's passing rating for reliability.

2b. Validity	• Total Votes-12; Yes-8, No-4 (8/12 – 66.7%, Pass)
	• SMP Total Votes-10; H-3; M-4; L-1; I-2
		• The standing committee noted that for the patient/encounter-level testing, the developer provided evidence from three published studies, which showed correlations in the predicted direction with other decision-making outcomes (e.g., higher confidence; higher satisfaction; less regret; and higher rates of informed, patient-centered surgery).
		• The standing committee recognized that the validity testing was also conducted at the accountable entity level. The developer tested whether clinical practices that implemented shared decision making had higher SDM scores than sites practicing usual care.
		  • For osteoarthritis of the knee and hip, patients in practices where decision aids were used reported significantly better decision processes (2.9 versus 2.5, p <0.001 and 2.9 versus 2.1, p <0.001, respectively). The difference in the SDM process scores for spine practices that did and did not use decision support (3.0 versus 2.75, p=0.12) was in the expected direction but was not large enough to reach statistical significance.
		  • Regarding breast cancer practices, those that had formal decision support had significantly better scores than cancer practices without any decision support interventions (2.7 versus 2.3, p <0.05).
		• The committee acknowledged that the SMP passed the measure on validity.
		• However, some standing committee members raised some concerns regarding the lack of risk adjustment. One standing committee member agreed with the choice to not risk-adjust the measure, stating that shared decision making is a fundamental process and that any differences should not be risk-adjusted. Additionally, the developer further clarified that risk adjustment is not needed because disparities were not being observed.
		• The standing committee accepted the developer's responses and accepted the SMP's passing rating for validity.

Table A.1-2.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-13; H-0; M-10; L-1; I-2 (10/13 – 76.9%, Pass	• The standing committee recognized that the developer reported that data for this measure are generated online or via paper. Patient surveys administered via paper are required to be entered into an online database by staff for reporting. The only difficulty regarding the data collection was obtaining sufficient response rates due to the administrative burden on clinic staff. Electronic patient surveys can be captured via the patient reported outcomes registries or online survey platforms.

Criterion	Total Votes	Rationale
		• The standing committee raised a concern about whether people who do not speak English or Spanish or those with developmental disabilities are able to respond to the survey. • The standing committee also had concerns about the cost of the infrastructure to administer surveys by practice and whether proxy surveys could be used in patients with cognitive impairment. The developer replied that data were collected from older adults who showed mild or moderate cognitive impairments to see how the surveys performed and hope to have more data to review in the future; however, nothing had become definitive yet. The developer clarified that other entities (e.g., insurance companies) could administer the survey, which would reduce the financial and measurement burden on practices. • The standing committee passed the measure on feasibility.

Table A.1-2.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-14; Pass-12; No Pass-2 (12/14 – 85.7%, Pass)	• The standing committee recognized that the Alliance Quality Path Program, similar to CBE #2958, specifies the measurement of decision quality and shared decision making as part of its criteria for recognition. The developer noted that this measure can be used for this recognition. The Shared Decision-Making Program at the Massachusetts General Brigham Health System incorporates items from the SDM measure into the Patient-Reported Outcomes registry. • The standing committee did not raise any questions and passed the measure on use.
4b. Usability	• Total Votes-14; H-0; M-9; L-1; I-3 (9/13 – 69.2%, Pass)	• The standing committee recognized that the developer did not provide trend data but does state that higher scores have also been associated with less decisional conflict and less decision regret reported by patients and that scores improve after the introduction of formal decision support programs. • The standing committee had questions and concerns regarding when to ask the survey questions and what practices can do with low scores. The standing committee also raised questions about the temporality of receiving the scores. The developer stated that there was an average score for a practice, and survey questions would ideally be asked right after the surgery to reduce recall bias. • The standing committee did not raise any additional concerns and passed the measure on usability.

Table A.1-2.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• CBE #0005 CAHPS Clinician & Group Surveys (CG-CAHPS) Version 3.0 - Adult, Child • CBE #3227 CollaboRATE Shared Decision Making Score	• This measure was identified as related to the following measures: CBE #0005 CAHPS Clinician & Group Surveys (CG-CAHPS) Version 3.0 – Adult, Child and CBE #3227 CollaboRATE Shared Decision-Making Score • The developer stated that CBE #0005 has an optional supplement of the shared decision-making items that are adaptations of the items used in CBE #2962. The developer explained that the problem with integrating CBE #2962 into CBE #0005 pertained to both the sample sizes required and sampling strategies. CBE #2962 refers to more specific procedures. In addition, the developer noted that CBE #2962 focuses more on detail and has a larger sample size to assess a focused group of procedures. • The developed noted that CBE #3227 assesses the perceptions of shared decision making but does not target specific decisions or concrete behaviors during the clinical encounter. The developer noted that shared decision-making quality can vary by type. Therefore, it was important to collect data on specific procedures and medications. A standing committee member stated that the key data element is assessing the time spent with the doctor. However, none of the measures capture this. The standing committee member also noted that this key data element could be integrated into future iterations of the measure. Another standing committee member again mentioned the heterogeneity of CBE #2962 and how it might work operationally when there are so many different types of procedures assessed. • The standing committee did not raise any major concerns with the developer's rationale regarding the differences with the related measures.

Table A.1-2.6. Standing Committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-13; Yes-10; No-3 (10/13 – 76.9%, Pass)	• The standing committee recommended the measure for continued endorsement.

Table A.1-2.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	• None
Non-supportive comments	• N/A	• None

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-2.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0 (13/13 – 100%, Endorsed)	• The lead discussant and other CSAC members found no major concerns with the process for the measure.

APPEALS BOARD EVALUATION

Table A.1-2.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3720 Patient-Reported Fatigue Following Chemotherapy among Adults with Breast Cancer

Staff Assessment | Specifications

Numerator Statement: The PRO-PM numerator is the group-level PROMIS Fatigue score at the follow-up survey.

Denominator Statement: Adult patients with stages I-III female breast cancer receiving an initial chemotherapy regimen within the measurement window.

Exclusions: Patients on a therapeutic clinical trial, patients with recurrence/disease progression, patients who leave the practice, patients who die

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician: Group/Practice

Setting of Care: Ambulatory Care, Outpatient Services

Type of Measure: Outcome: PRO-PM

Data Source: Instrument-Based Data, Paper Medical Records, Electronic Health Records

Measure Steward: Purchaser Business Group on Health

STANDING COMMITTEE EVALUATION

Table A.1-3.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-12; Pass-9; No Pass-3 (9/12 – 75.0%, Pass)	• The standing committee recognized that this new outcome PRO-PM measure measures fatigue following chemotherapy for adult patients with breast cancer. It is based on the PROMOnc premise that medical oncologists who provide the highest quality care, in particular medical and non-medical support to patients with curative-intent cytotox therapy, will be able to reduce symptom burden and therefore improve patient transition into the cancer survivorship period. • The standing committee noted that that there are randomized trials showing a clear link between process and the PRO-PM. • During the pre-evaluation review, a standing committee member commented that the evidence was low in the National Comprehensive Cancer Network (NCCN) guidelines regarding the impact of interventions on fatigue. • A standing committee member asked about how fatigue should be tracked in different stages of cancer treatment. Another question was asked about whether males should be included because men can be treated for breast cancer in rare cases. The developer replied that the practices that perform well are the ones that address fatigue while treatment is ongoing. Regarding males with breast cancer, the developer explained that only one male was in the sample, and therefore, the numbers were not high enough to include males in the measure. • A standing committee member asked about the treatability of fatigue. The developer explained that there are meaningful interventions to evaluate the intensity of fatigue, nutritional

Criterion	Total Votes	Rationale
		imbalances, and anemia and to perform interventions such as diet, exercise, and medication review. • The standing committee voted to pass the measure on evidence.
1b. Performance Gap	• Total Votes-12; H-0; M-10; L-0; I-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that in 10 clinician groups that participated in the field test, there were 744 follow-up surveys, and 323 were used for analysis. The average adjusted measure score was 48.51, with a range from 42.13 to 53.07 and standard deviation of 3.13. The confidence intervals for the highest and lowest groups did not overlap. • The standing committee also noted that in the measure submission, the developer stated that the measure was adjusted for race and ethnicity, marital status, and insurance status; however, none of these variables were significant in the relationship with the measure. The developer reported the presence of outliers and a meaningful distribution in the scores. • The standing committee passed the measure on performance gap.

Table A.1-3.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale
2a. Reliability	• Total Votes-12; Yes-10; No-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that reliability testing was conducted at the encounter level and accountable entity level. The standing committee noted that the mean estimate of the reliability for the measure score was 0.77, with a range from 0.38 to 0.88 across clinician group practices. • The standing committee noted that the SMP passed the measure on reliability with a rating of moderate (H-0; M-9; L-1; I-0). • The standing committee had no questions or concerns and accepted the SMP's passing rating on reliability.

2b. Validity	• Total Votes-12; H-0; M-8; L-1; I-3 (8/12 – 66.7%, Pass)	• The standing committee recognized that validity testing of the measure score was conducted through a systematic assessment of face validity using a panel of 12 oncologist advisors. The following survey question was asked: "Rate your agreement with the following statement: The scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality."
		  • Eight of the 12 advisors participated in the survey. The four oncologists who declined to participate in the face validity voting expressed concerns regarding the impact of COVID-19 on sample size, and thus performance scores. They requested additional data prior to voting.
		  • All eight indicated "moderate agreement," "agreement," or "strong agreement" to the above question. Three agreed or strongly agreed that the fatigue measure could differentiate good versus poor quality. Participants who did not rate the measure as 4 or 5 (i.e., agree or strongly agree) felt that fatigue was more susceptible to pandemic-related issues.

Criterion	Total Votes	Rationale
		• The standing committee recognized that both survey nonresponsive and missing data were assessed and that across the 10 sites, 896 patients were eligible for follow-up and 19 met the exclusion criteria. The total number of follow-up surveys was 744, making up a survey administration rate of 85%. Among those surveys, 323 were completed and nine were ineligible. No statistical significance was identified, except that the respondents and nonrespondents differed on marital status and insurance. • The standing committee noted that the SMP did not reach consensus on validity (H-0; M-6; L-3; I-1) due to concerns with the face validity testing, the lack of meaningful differences in performance, and concerns with missing response rates. • During the discussion, the standing committee asked for clarification on how much an improvement in fatigue is really about the quality of care in this population. A comment was also made about understanding what sorts of interventions had been done and what had been effective to reduce fatigue. The developer explained that practices that performed well on the measure assessed and intervened on fatigue early. The developer also noted that they risk-adjusted for baseline fatigue, which would be a proxy for prior interventions. Stage IV cancer patients were excluded because the goal was to address patients with curative cancer, considering there are measures for Stage IV patients that are separate. • The standing committee discussed the face validity testing and the SMP's concern regarding four of the 12 oncologists and noted that the fatigue may not be due to cancer but to fatigue related to the COVID-19 pandemic. The developer stated that COVID-19 may have been a confounding factor. However, the guidelines recommend assessing stressors like the COVID-19 pandemic. The developer also stated that meaningful differences were present between the test sites, which were tested in part during the COVID-19 pandemic. • The standing committee did not have any further questions passed the measure on validity during offline voting.

Table A.1-3.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-12; H-0; M-8; L-3; I-1 (8/12 – 66.7%, Pass)	• The standing committee recognized that the developer fielded a questionnaire during the testing period to assess the burden and feasibility related to data abstraction and implementation and patient related activities. Seven ADCC sites and two MOQC sites responded to the burden questionnaire. Most of the implementation burden was associated with administering the survey rather than collecting the clinical and demographic data elements; patient identification was also a challenge, which test sites mitigated by building EHR reports to facilitate patient identification. • The standing committee noted that measures from the Patient-Reported Outcomes Measurement Information System (PROMIS) originate from a survey that must be collected by

Criterion	Total Votes	Rationale
		staff, then entered into the electronic health record (EHR) in structured fields. Some EHRs (e.g., Epic and Cerner) now include PROMIS surveys. The developer stated that collecting the baseline survey with the originally defined time frame from patients taking oral chemotherapy was challenging. According to the feedback, 75% of respondents reported that it took them less than 10 minutes to complete the PROMOnc survey; 92% reported that they understood the survey instructions; 83%reported that they did not have any technical issues completing the survey; and 83% felt that the time that it took to complete the survey was reasonable. • One concern mentioned by the standing committee was having staff enter the data. The developer stated that many of the test sites programmed the survey into the EHR or on an iPad. Some of the sites programmed it into the Research Electronic Data Capture (RedCAP). The Michigan practices also had a centralized vendor. Health plans could also potentially collect the data. Regarding clinical trials, patients were excluded because including them could potentially alter the data for the measure. • During offline voting, the standing committee passed the measure on feasibility.

Table A.1-3.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-12; Pass-8; No Pass-4 (8/12 – 66.7%, Pass)	• The standing committee stated that the measure will be submitted to the Measures Under Consideration (MUC) List for potential inclusion the CMS Quality Payment Program. • A standing committee member further stated that the measure information could also be given to the patient. The developer stated that the measure could be used for quality improvement. • The developer stated that PRO-PM data are being provided to patients. • During offline voting, the standing committee passed the measure on use.
4b. Usability	• Total Votes-12; H-1; M-5; L-3; I-3 (6/12 – 50.0%, No Pass)	• The standing committee recognized that the developer stated that the measure just completed testing and has not been used for performance improvement at the time for submission of endorsement. The developer stated that there were no unexpected findings during implementation and no potential harms were identified. • The standing committee noted concerns about potential harm or unintended consequences if the measure was used for accountability, and many standing committee members expressed that the measure would be more appropriate for use as a quality improvement measure. The general concern was that it may incentivize a pharmacological solution. • A standing committee member expressed that they would not like to see this measure in a value-based payment program. The developer explained that the measure was developed iteratively with the technical expert panel (TEP) to facilitate its usability.

Criterion	Total Votes	Rationale
		• During offline voting, the standing committee did not reach consensus on usability, which is not a must-pass criterion. This was primarily due to the concern regarding the potential unintended consequences of the measure's use in public programs versus quality improvement.

Table A.1-3.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• CBE #0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer • CBE #0387e Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/ Progesterone Receptor (ER/PR) Positive Breast Cancer	• This measure was identified as related to the following measures: CBE #0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer and CBE #0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer • The committee noted that these endorsed measures are assessing use of hormonal therapy in the numerator, and therefore limit the denominator to tumors that are estrogen receptor positive or progesterone receptor positive, which is not relevant to the PROMOnc PRO-PM target population. The committee also noted that CBE #3720 looks at fatigue as a symptom, rather than a treatment, so the differences are justified.

Table A.1-3.6. Standing committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-12; Pass-8; No Pass-4 (8/12 – 66.7%, Pass)	• The standing committee recommended the measure for overall suitability for endorsement during offline voting.

Table A.1-3.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	• None
Non-supportive comments	• One	Pre-evaluation comments: • None Post-evaluation comments: *Testing of the measure during COVID-19* • The commenter emphasized the devastating impact of COVID-19 on physician practices and patient care. The commenter also raised concerns about the pandemic's effect on sample size and performance scores and urged for additional testing outside of the PHE before considering these measures for endorsement. • The developer acknowledged the impact of the COVID-19 pandemic and reassured the committee that it had sufficient testing data for analyses and will continue to refine testing analyses during implementation for maintenance submission. • A standing committee member asked about the use of the measure, to which the developer stated the measure had been submitted to CMS' Measures Under Consideration (MUC) list. • The standing committee considered the comment and maintained their decision to endorse the measure.

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-3.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0 (13/13 - 100%, Endorsed)	• The CSAC lead discussant summarized the public comment that was received during the public comment period from the American Medical Association (AMA) on the impact of COVID-19 on some patient visits and that treatments were postponed during the early months of COVID-19. The AMA agreed with the four oncologists that did not participate in face validity assessments, given concerns and that additional testing outside the pandemic is necessary. • The lead discussant believed that the concern is not that fatigue comes from COVID, but that chemotherapy causes fatigue, and patients may be getting suboptimal chemotherapy if it is delayed due to the pandemic. • The co-chair noted that the concerns were correct about some fatigue issues and noted that there was a robust discussion about this during the post-comment meeting. The overall sense of the PEF committee was that this is an important concept to measure and that measuring of the concept outweighs the problems with the measure. • Another CSAC member commented that the PEF committee appeared to discuss these areas of concern in-depth. She noted that COVID is not going away and that this measure was important in acknowledging fatigue, which has a huge impact on the quality of life for people. She further stated that some fatigue is expected, but there are ways to manage it. • In response to the CSAC lead discussant's comment, it was noted that the developer responded to the comment from AMA, stating that the test sites communicated with the developer throughout the testing period including during the public health emergency (PHE). The test sites paused testing while they responded to the PHE and adjusted clinical workflows. These test sites remained engaged and created additional approaches to administer surveys to patients during the PHE. • The CSAC upheld the standing committee's decision to endorse the measure.

APPEALS BOARD EVALUATION

Table A.1-3.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3734 Alignment of Person-Centered Service Plan (PCSP) with Functional Assessment Standardized Items (FASI) Needs

Staff Assessment | Specifications

Numerator Statement: The number of HCBS recipients aged 18 years or older with documented needs in the areas of self-care, mobility, or IADL as determined by the most recent FASI assessment within the previous 12 months and with documentation that the subsequent PCSP addresses the FASI-based functional needs in self-care, mobility, and IADL.

Denominator Statement: The number of HCBS recipients aged 18 years or older with documented needs in the areas of self-care, mobility, or IADL as determined by the most recent FASI assessment within the previous 12 months.

Exclusions: Exclusions inherent in the denominator definition include individuals younger than 18 years, individuals who have not had a FASI assessment within the previous 12 months, and individuals who have had a FASI assessment, but no functional needs were identified in the areas of self-care, mobility, or IADL. In addition, individuals without three months of continuous HCBS enrollment are excluded.

Adjustment/Stratification: None

Level of Analysis: Other, population: regional and state

Setting of Care: Ambulatory Care, Outpatient Services, Post-Acute Care

Type of Measure: Process

Data Source: Assessment Data, Instrument-Based Data, Electronic Health Records, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE EVALUATION

Table A.1-5.1. Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-13; H-0; M-10; L-3; I-0 (10/13 – 76.9%, Pass)	• The standing committee recognized that the developer provided a logic model that depicts that if self-care, mobility, and IADL (instrumental activities of daily living) needs are addressed by an individual's PCSP, then it can lead to short-term outcomes such as facilitation of responsivity to unmet needs, increased standardization of assessing functional needs, and accurate alignment between needs and PCSP and long-term outcomes such as address unmet needs to prevent poor outcomes, set goals to benchmark progress on quality measure, and facilitate increased service satisfaction for individuals served and their families. • The standing committee noted that the developer did not provide a systematic review but did conduct a literature review. • A standing committee member commented on the importance of these measures to people in Medicaid and in home-based services. One standing committee member stated that a plan of care does improve outcomes in this population.

Criterion	Total Votes	Rationale
		• Another standing committee member described the evidence as not particularly strong for people with intellectual disabilities. The developer replied that they had cited publications showing that building services plans are important for people with intellectual disabilities. Additionally, the developer clarified that group homes are included in the measure. • The standing committee did not raise any additional discussion and passed the measure on evidence during offline voting.

1b. Performance Gap	• Total Votes-13; H-1; M-9; L-2; I-1 (10/13 – 76.9%, Pass)	• The standing committee recognized that the developer examined data from June and July 2018 from nine organizations across four different states and found performance measure scores ranging from 42.5% for individuals with an intellectual or developmental disability to 85.5% for individuals with an acquired brain injury. The overall mean of the performance scores was 66.3%.
		• The developer presented descriptive statistics for the total FASI-based needs for individuals in the denominator of the performance measure and conducted a one-way ANOVA to compare the program type on the summed total number of FASI-based needs identified across all programs.
		  • The developer determined that there was a significant effect of program type on the summed total of all FASI-based needs identified (F equals 22.97, p less than 0.0001).
		  • The developer further noted that comparison using Tukey's honestly significant difference (HSD) test found that the mean number of needs for the older adult and physical disability groups were significantly different from each other and the other three groups, but that the mean number of needs for the other three programs were not statistically different from each other.
		• A standing committee member asked whether the data were divided by home or group home, to which the developer replied that the data were not analyzed in that way.
		• The standing committee also asked why the performance gap may have been higher in the population with intellectual disabilities; however, the developer did not have an explanation for this occurrence. The developer clarified that they also had groups in the sample with an acquired brain injury and older adults with Alzheimer's disease and the rates were not lower in those groups. There was no further discussion on performance gap.
		• During offline voting, the standing committee passed the measure on this criterion.

Table A.3-5.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale
2a. Reliability	• Total Votes-13; H-0; M-7; L-4; I-2 (7/13 – 53.8%, Consensus Not Reached) • Post-comment Use Revote: Total Votes-16; H-0; M-11; L-3; I-2 (11/16 – 69%, Pass)	• The standing committee recognized that reliability testing was done at the patient/encounter level, and that additional analysis was run to determine agreement by program type. The kappa values ranged from 0.02 to 0.78. • The standing committee noted that the SMP did not review this measure. • The standing committee also noted that the data elements are clearly defined but that high quality services are subjective and may lead to variation in the reliability of the results. • The standing committee asked for clarification on the elements used for the survey score. The developer clarified that the survey looks at three areas: alignment of self-care, mobility, and activities of daily living (ADLs). • The standing committee also asked about the kappa value of 0.2, which was low, for people with intellectual disabilities. The developer confirmed that the low kappa value was accurate and that they did not have an explanation as to why it was low. Regarding the three areas listed above, the developer noted that if all the areas of intervention were missing, the survey results would have been removed from the analysis. To be included in the measure, at least one of the areas needed to be captured in the survey. The developer noted that only a small percentage was removed for this reason. • During offline voting, the standing committee did not reach consensus on the reliability criterion. • During the post-comment meeting, some standing committee members expressed concern about the survey responses, specifically about consent being given by individuals with intellectual disabilities. The developer responded noting the varying levels of function among those being surveyed, and assured the committee that having support from caregivers is acceptable, emphasizing the importance of having the individual present and actively engaged in the conversation. • A standing committee member acknowledged the robust performance of the measure's reliability in other subgroups but questioned the appropriateness of excluding a suboptimal subgroup due to low reliability. In response to this suggestion, the developer confirmed that due to contractual obligations with the steward of the measure (CMS), it could not remove the IDD (intellectual and developmental disability) population from the measure. • Another committee member suggested that the measure might be better constructed as a composite, as it is a measure of five different domains. This committee member also questioned the accuracy of responses from IDDs. The developer shared that individuals were included in the assessment process regardless of their cognitive and communicative abilities. The developer further stated that the forms were completed in a manner consistent with usual practice, involving the person if they were able to participate independently or with the presence of a caregiver if that was the norm.

Criterion	Total Votes	Rationale
		• One committee member expressed concern about repeatedly discussing the same issue and expressed a desire to understand why there was a lack of data, specifically if the data were deliberately withheld from the committee as it could have substantiated their concerns. In response, the developer highlighted the challenges associated with gathering additional data, including time and financial constraints, and reiterated that data were not withheld from the committee. • The committee recognized the importance of the measure and its performance within other subpopulations and requested to document that while it agrees that the instrument is very important, there are still some areas that are critical to address. If endorsed, the committee would like to see additional data supporting the IDD population at the time of endorsement maintenance review. • The standing committee passed the measure on reliability during the post-comment meeting.

2b. Validity	• Total Votes-13; H-0; M-8; L-3; I-2 (8/13 – 61.5%, Pass)	• The standing committee recognized that validity testing had been conducted at the accountable entity level.
		  • The developers conducted face validity for the measure by surveying a technical expert panel (TEP) as well as the reviewers who participated in the reliability testing.
		  • The developers also convened a TEP consisting of 22 subject matter experts and stakeholders where preliminary results were shared and the TEP members were asked to provide feedback in an online form. Twelve provided feedback including seven potential FASI PM users, two advocacy group representatives, two self-advocates, and one potential FAFSI PM user.
		  • For the critical data elements the reviewers consistently gave the elements a 90% 'agree' or 'strongly agree' rating.
		• The standing committee questioned the developer regarding how difficult it is for people with intellectual disabilities to adequately answer the questions. The developer replied that there is a low risk of collecting survey information; in the field test, there were only 36 missing data abstractions forms, which was 7.8% of the sample.
		• A standing committee member asked whether any patients or family members served on the TEP. The developer confirmed that four participants consisting of patients and family members served on the TEP.
		• Another standing committee member asked staff how to vote on validity if there were an issue with a subset of the validity (e.g., the intellectual disabilities population). Staff explained that since the number of missing data was minimal, it did not cause any major concern and is reflected in the preliminary rating for validity.
		• Another question was asked about whether the functional assessment standardized items (FASI) measure cognitive features (e.g., depression) rather than functional features. The developer replied that they discussed this subject in depth when they were developing the FASI and decided to focus fully on functional measures.

Criterion	Total Votes	Rationale
		• A standing committee member mentioned that this is an important area that should be addressed in the future. • During offline voting, the standing committee passed the measure on validity.

Table A.3-5.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-13; H-0; M-7; L-6; I-0 (7/13 – 53.8%, Consensus Not Reached)	• The standing committee recognized that the data elements are abstracted from a record by someone other than the person obtaining original information and that some data elements are in defined fields in electronic sources. The developer stated that the measure requires two sources of data, the FASI and the PCSP, and that the data-entry process depends on the provider organization's resources. • The standing committee recognized that the developer offered a solution for the amount of time to gather data by suggesting the creation of a streamlined data abstraction form by removing unnecessary items used for the testing and modifying the FASI to an electronic system. The developer further suggested that the organizations may consider developing a standardized PCSP form. • A standing committee member commented about whether measures of social determinants of health are captured in this measure. • There were also significant concerns with the amount of time and effort required to implement the survey, as well as the large variety of organizations that needed to gather the data. • The developer stated that the FASI is available with Logical Observation Identifier Names and Codes (LOINC) codes; therefore, it can be captured using EHR data. The developer also explained that by using standardized templates, they could improve the feasibility of the data collection for sites. This is particularly true for patients with intellectual disabilities, where service planning is even more important. • During offline voting, the standing committee was unable to reach consensus on feasibility.

Table A.3-5.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-13; Pass-10; No Pass-3 (10/13 – 76.9%, Pass)	• A standing committee member noted that the measure is in use or is being considered for use in three states. It was being used by VHA, particularly for its Program of Comprehensive Assistance for Family Caregivers as part of its VFAI. • A standing committee member asked whether the measure can be used for value-based purchasing. The developer replied that some of the states use fee-for-service delivery. However, it could also be used to gather data for value-based purchasing, assuming enough data are gathered in enough states to make comparisons. • A standing committee member suggested avoiding using the measure for accountability until data collection could be streamlined. The developer replied that this measure captures the voice of the individual in the PCSP. The developer also stated that the measure could also be stratified by different types of individuals within a state. Based on this information, the standing committee member thought that because the measure was at the state level, it would be difficult to hold entities who are providing the service accountable for the measure. • During offline voting, the standing committee passed the measure on the use criterion.
4b. Usability	• Total Votes-13; H-0; M-9; L-3; I-1 (9/13 – 69.2%, Pass)	• The standing committee recognized that the performance measure was not measured over time and therefore changes because of implementation could not be determined. • The developer stated in their submission that they were surprised by the extent of the TEP and reviewer agreement on the importance of the measure for aligning functional needs with service planning. • A standing committee member provided a supportive comment, stating that the benefits of this measure outweigh any potential harm. • Another standing committee member questioned whether the measure would be usable to truly measure quality at the state level because it may be difficult to understand how performance is improving and how the end user may use the information. • A question was asked about whether the measure is being used at the state level for quality improvement. The developer noted that the measure is expected to be used in states for the HCBS quality improvement projects and public reporting. The developer further stated that they are hoping to identify best practices and potentially stratify by groups (e.g., brain injury) at some point. • During offline voting, the standing committee passed the measure on usability.

Table A.3-5.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• CBE #2624 Functional Outcome Assessment • CBE #2631 Percent of Long-Term Care Hospital (LTCH) Patients With an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function • CBE #2967 Home and Community-Based Services (HCBS) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Measures	• The standing committee recognized that for CBE #2624, it also requires a standardized functional assessment to specify the numerator. • The standing committee noted that CBE #3734 relies specifically on the FASI assessment, while CBE #2624 specifies use of any standardized assessment tool that has been normalized and validated. • One standing committee member mentioned that even though CBE #2624 is more specific to the instrument used, there still may be opportunity for further harmonization. • The standing committee did not have any recommendations for harmonization for CBE #2631 and recognized that CBE #2967 has a similar population and is justified as it is targeting a different intervention. • There were no further comments from the committee on these related measures.

Table A.3-5.6. Standing committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-16; Yes-12; No-4	• The standing committee recommended the measure for overall suitability for endorsement.

Table A.3-5.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	• None
Non-supportive comments	• N/A	• None

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-5.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-5.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

CBE #3718 Patient-Reported Pain Interference Following Chemotherapy among Adults with Breast Cancer

Staff Assessment | Specifications

Numerator Statement: The PRO-PM numerator is the group-level PROMIS Pain Interference score at the follow-up survey.

Denominator Statement: Adult patients with stages I-III female breast cancer receiving an initial chemotherapy regimen within the measurement window.

Exclusions: Patients on a therapeutic clinical trial. Patients with recurrence/disease progression. Patients who leave the practice. Patients who die.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Clinician: Group/Practice

Setting of Care: Ambulatory Care, Outpatient Services

Type of Measure: Outcome: PRO-PM

Data Source: Based Data, Paper Medical Records, Electronic Health Records

Measure Steward: Purchaser Business Group on Health

STANDING COMMITTEE EVALUATION

Table A.1-4.1 Importance to Measure and Report (MUST PASS)

Criterion	Total Votes	Rationale
1a. Evidence	• Total Votes-12; Pass-10; No Pass-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that the developer provided a logic model that depicts that patients who are undergoing chemotherapy with curative intent experience persistent symptoms following treatment, such as pain, fatigue, and other issues impacting health-related quality of life. The model states that specific evidence-based practices, if delivered by the group practice and clinician, will experience lower symptom burden during the survivorship period. • The developer referenced the 2022 National Comprehensive Cancer Network (NCCN) Adult Cancer Pain Guideline and 2022 NCCN Survivorship Guideline recommendations to demonstrate relationships between the PRO-PM and healthcare actions that can be utilized to achieve the desired outcome. • One standing committee member expressed a favorable view of the measure, particularly with respect to addressing pain through both pharmacologic and non-pharmacologic methods. • Another standing committee member mentioned that the evidence was graded as a low-quality level of evidence for the interventions. The standing committee did not have any additional discussion on this concern. • During offline voting, the standing committee passed the measure on evidence.

Criterion	Total Votes	Rationale
1b. Performance Gap	• Total Votes-12; H-1; M-7; L-1; I-3 (8/12 – 66.7%, Pass)	• The standing committee recognized that from the ten clinician groups that participated in the beta field test, there were 744 follow-up surveys and 323 were used for analysis. The average adjusted measure score was 50.51. The range was 43.92 to 54.11 with a standard deviation of 2.83. The confidence intervals from the lowest group to the highest group did not overlap. • The standing committee recognized that during testing, administrative data were collected on race or ethnicity, marital status, and insurance status (Medicaid or dual eligible). Race and ethnicity were also collected via the survey instrument. The developer stated that after adjustment for multiple comparisons, none of these variables were significant in their relationship with the measure but did not provide the data to support this conclusion. • A standing committee member asked about the ethnicity distribution, particularly ensuring equal proportions of race and ethnicity in the sample, given the potential differences in pain perception. Another standing committee member stated that this is not the case regarding perception of pain; rather, it is more about differences in treatment by racial disparities. • Another standing committee member asked about whether test sites were representative of different types of practices. The developer stated that a wide variety of practices exists across several states. • The standing committee did have any further discussion and passed the measure on performance gap during offline voting.

Table A.1-4.2. Scientific Acceptability of Measure Properties (MUST PASS)

Criterion	Total Votes	Rationale

2a. Reliability	• Total Votes-12; Pass-10; No Pass-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that reliability testing was conducted at the patient/encounter and accountable-entity levels.
		  • The developer noted that PROMIS measures, including the pain interference scale, have undergone rigorous development and validation and provided several references. Reliability testing from the literature demonstrates that for the PROMIS Pain interference, the Cronbach's alpha is 0.99.
		  • To test the reliability of the measure score, a signal-to-noise analysis was performed. The estimate of the adjusted ICC was 0.097. The estimate of the reliability at the average sample size for a group (32 patients per group) was 0.77. Using the Spearman-Brown prophecy formula, the developer estimates that in order to obtain a nominal reliability of 0.7, a minimum sample size of 22 patient respondents would be required. Group-specific reliability ranged from 0.39 to 0.88, with a mean of 0.66 (SD=0.20) and a median reliability of 0.68. The proportion of groups in the sample that had sufficient reliability using a reliability threshold of 0.70 was 50%.

Criterion	Total Votes	Rationale
		• The standing committee noted that the SMP passed the measure on reliability (H-0; M-9; L-1; I-0). • The standing committee did not have any concerns about the reliability testing and accepted the SMP's rating for reliability during offline voting.

2b. Validity	• Total Votes-12; Pass-10; No Pass-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that reliability testing was conducted at the patient/encounter and accountable entity levels.
		  • Critical data elements were evaluated by comparing the Patient-Reported Outcomes in Oncology (PROMOnc) and cancer registry datasets. A total of 570 patients were included in the analysis. The percentage agreement by data element ranged from 71.63 to 100%. Reported kappas ranged from 0.64 to 0.67. Reported sensitivity ranged from 33.33 to 89.52%. Specificity ranged from 60 to 99.80%.
		  • The developer assessed face validity using a panel of 12 oncologist advisors with eight of the 12 advisors participating in the survey. The four oncologists who declined to participate in the face validity voting expressed concerns regarding the impact of coronavirus disease 2019 (COVID-19) on sample size, and thus, performance scores. They requested additional data prior to voting.
		• The standing committee noted that the SMP passed the measure on validity (H-2; M-5; L-1; I-2).
		• A standing committee member commented on understanding the upstream management of pain, particularly whether patients are opioid naïve or whether they had chronic pain prior to treatment. The developer stated that they did not want to incentivize the overuse of opioids because they can be unsafe and cause adverse effects.
		• The standing committee did not have any additional discussion on validity and accepted the SMP's rating on validity during offline voting.

Table A.1-4.3. Feasibility

Criterion	Total Votes	Rationale
3. Feasibility	• Total Votes-12; H-0; M-10; L-1; I-1 (10/12 – 83.3%, Pass)	• The standing committee recognized that PROMIS measures emanate from a survey that must be collected by staff and entered into the EHR in structured fields. The developer noted that during testing, documentation is gathered in some provider notes, instead of in structured fields, but noted that this practice is changing. Some EHRs (Epic and Cerner), now include PROMIS surveys. However, this is not an eCQM. • A standing committee member stated that because EHRs can be non-standardized, they would need to be integrated into diverse systems (e.g., Cerner systems tend to differ, while Epic systems seem to be more standardized). The developer explained that it would be feasible in terms of implementing the measure in rural areas due to less resources for measure collection.

Criterion	Total Votes	Rationale
		• During offline voting, the standing committee passed the measure on feasibility.

Table A.1-4.4. Use and Usability (USE IS MUST PASS FOR MAINTENANCE MEASURES)

Criterion	Total Votes	Rationale
4a. Use	• Total Votes-12; Pass-10; No Pass-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that the developer stated that the measure will be submitted to the Measures Under Consideration (MUC) List for potential inclusion the CMS Quality Payment Program. • The standing committee did not have any concerns or questions and passed the measure on use during offline voting.
4b. Usability	• Total Votes-12; H-1; M-9; L-0; I-2 (10/12 – 83.3%, Pass)	• The standing committee recognized that the measure just completed testing and has not been used for performance improvement at the time for submission of endorsement. • The standing committee noted that the measure is similar to CBE #3720, which the standing committee did not reach consensus on usability for. This was due to some standing committee members expressing concern with the measure's use in public programs where the standing committee agreed that pain was more addressable than fatigue. Therefore, the measure may be more appropriate in public programs. • The standing committee did not have any major concerns and passed the measure on usability during offline voting.

Table A.1-4.5. Related and Competing Measures

Criterion	Related and/or Competing Measure(s)	Rationale
5. Related and Competing	• CBE #0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0	• This measure was identified as related to the following measures: CBE #0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer and CBE #0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer • The committee noted that these endorsed measures are assessing use of hormonal therapy in the numerator, and therefore limit the denominator to tumors that are estrogen receptor positive or progesterone receptor positive, which is not relevant to the PROMOnc PRO-PM target population. The committee also noted that CBE #3718 looks at fatigue as a symptom, rather than a treatment, so the differences are justified.

Criterion	Related and/or Competing Measure(s)	Rationale
	or Stage IB – Stage III hormone receptor positive breast cancer • CBE #0387e Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/ Progesterone Receptor (ER/PR) Positive Breast Cancer	

Table A.1-4.6. Standing committee Recommendation for Endorsement

Committee Endorsement Recommendation	Total Votes	Rationale
Recommended for Endorsement	• Total Votes-12; Yes-10; No-2 (10/12 – 83.3% Pass)	• During offline voting, the standing committee recommended the measure for overall suitability for endorsement.

Table A.1-4.7. Public and Member Comment

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Supportive comments	• N/A	• None

Supportive/Non-supportive Comments	Number of Comments Received	Comment Summary
Non-supportive comments	• One	Post-evaluation comment *Testing of the measure during COVID-19* • The commenter emphasized the devastating impact of COVID-19 on physician practices and patient care. The commenter also raised concerns about the pandemic's effect on sample size and performance scores and urged additional testing outside of the PHE before considering these measures for endorsement. • The developer acknowledged the impact of the COVID-19 pandemic and reassured the committee that it had sufficient testing data for analyses and will continue to refine testing analyses during implementation for maintenance submission. • A standing committee member asked about the use of the measures, to which the developer stated that the measure had been submitted to the CMS Measures Under Consideration (MUC) list. • The standing committee considered the comment and maintained their decision to endorse the measure.

CONSENSUS STANDARDS APPROVAL COMMITTEE (CSAC) EVALUATION

Table A.1-4.8. CSAC Endorsement Decision

CSAC Endorsement Decision	Total Votes	Rationale
Endorsed	• Total Votes-13; Yes-13; No-0	• Unanimous approval to endorse the measure via a consent calendar.

APPEALS BOARD EVALUATION

Table A.1-4.9. Appeals

Appeal Received (Yes/No)	Appellant Organization	Summary of Appeal and Its Review
No	• N/A	• N/A

Appendix B: Patient Experience and Function Standing Committee and Battelle Staff

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