2024 Pre-Rulemaking Measure Review
Preliminary Assessment

MUC ID	Title
MUC2024-074	Median Time to Pain Medication for Patients with a Diagnosis of Sickle Cell Disease (SCD) with Vaso-Occlusive Episode (VOE)
Measure Steward & Developer	**Proposed CMS Programs**
American Society of Hematology/ Health Services Advisory Group, Inc. (HSAG)	Hospital Outpatient Quality Reporting Program; Rural Emergency Hospital Quality Reporting Program

Measure Overview
Rationale (excerpt from submission): Sickle cell disease (SCD) is the most common inherited blood disorder and is estimated to affect approximately 100,000 individuals in the United States. SCD is also most prominent among Black or African American patients—affecting 1 out of 365 Black or African American births—and the average life expectancy of publicly insured individuals with SCD is reported to be approximately 52.6 years of age. Based on a 2022 systematic review, total annual costs (medical and non-medical) were estimated to range from $14,012 to $80,842 per patient per year.
CMS-provided program rationale: CMS is considering adding this measure to the Rural Emergency Hospital and Hospital Outpatient Quality Reporting Programs. We believe the adoption of this measure can assist in the rapid identification and treatment of pain related to vaso-occlusive episodic pain related to sickle cell disease and complications in the ED. Identification and treatment of SCD effects can provide patient satisfaction and pain relief as well as decrease potential costs if prolonged hospitalization is not required to treat the symptoms.
Description: Median time (in minutes) from ED arrival to initial administration of pain medication for all patients, regardless of age, with a principal encounter diagnosis of SCD with VOE.
Measure background: New measure, never reviewed by Measure Applications Partnership (MAP) Workgroup or Pre-Rulemaking Measure Review (PRMR) or used in a Medicare program.
Numerator: Time (in minutes) from Emergency Department (ED) arrival to initial administration of pain medication. **Exclusions:** None

The analyses upon which this publication is based were performed under Contract Number 75FCMC23C0010, entitled, "National Consensus Development and Strategic Planning for Health Care Quality Measurement," sponsored by the Department of Health and Human Services, Centers for Medicare & Medicaid Services.

Measure Overview	
Denominator: Emergency department (ED) encounters for all patients, regardless of age, who have a principal encounter diagnosis of SCD with VOE and who have at least one qualifying pain medication administered during the ED encounter. **Exclusions:** None **Exceptions:** None	
Measure type: Process	**Measure has multiple scores:** No **Measure is a composite:** No **Measure is digital and/or an eCQM:** Yes **Measure is a paired or group measure:** No
Level of analysis: Facility	**Data source(s):** Digital-Electronic Health Record (EHR) Data
Care setting(s): Emergency Department	**Risk adjustment or stratification:** Yes, stratified by medication route
CBE endorsement status: Never submitted	**CBE endorsement history:** N/A
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** No

Meaningfulness

Importance	
Type of evidence:	Clinical Guidelines or USPSTF (U.S. Preventive Services Task Force) Guidelines [Source: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) Submission Form]

Importance: This measure addresses timing to the administration of pain medication for adult and pediatric patients with SCD presenting to the ED. Implementation of this measure may enhance pain management and improve other aspects such as hospital admission rates. Performance results indicate that the average time for administering medication to patients with SCD experiencing vaso-occlusive episodes is significantly higher than the recommended guidelines. This suggests a potential for improvement in the timeliness of care for these patients. During the measure development process, the developer sought input from a technical expert panel (TEP) including clinical experts in hematology and emergency medicine, along with a patient representative. Additionally, during a public comment period from April 15 to April 29, 2024, 85% of the 48 respondents supported the measure, highlighting its potential to improve care and reduce hospital stays for these patients.

Two guidelines support this measure:

1) The American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Recommendation 1A. For adults and children with SCD presenting to an acute care setting with acute pain related to SCD, the ASH guideline panel recommends rapid (within 1 hour of emergency department [ED] arrival) assessment and administration of analgesia with frequent reassessments (every 30-60 minutes) to optimize pain control (strong recommendation based on low certainty in the evidence about effects).

2) The 2014 National Heart, Lung and Blood Institute (NHLBI) Evidence-Based Management of Sickle Cell Disease Expert Panel Report. In adults and children with SCD and a vaso-occlusive crisis (VOC): Rapidly initiate treatment with parenteral opioids associated with severe pain (Strong Recommendation, High-Quality Evidence) OR Rapidly initiate analgesic therapy within 30 minutes of triage or within 60 minutes of registration. (Consensus–Panel Expertise – Expert Opinion)

This measure aims to address significant health inequities experienced by SCD patients, particularly in pain management, where delays in treatment contribute to poor outcomes. This measure is valuable given the significant racial and socioeconomic inequities faced by individuals with SCD.

Rating: Met

Measure Performance

Table 1 includes performance score decile averages, calculated from the testing data. This table reflects performance data for adult populations provided in the original submission as well as testing data obtained where available for pediatric populations (N=3).

Table 1. MUC2024-074 Performance Score Deciles

	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean Score	87.3 (45.7)	42.0	44.3	54.5	61.2	66.5	70.0	76.7	89.7	92.5	120.2	206.8	268.0
Entities	25	1	2	2	3	2	3	3	3	2	3	2	1

Conformance
Measure alignment with conceptual intent: This measure aims to address significant health inequities experienced by SCD patients, particularly in pain management, where delays in treatment contribute to poor outcomes. The measure specifications are consistent with the measure focus (time from arrival to administration of pain medication in the ED) for all patients, regardless of age, who have a principal encounter diagnosis of SCD with VOE and who have at least one qualifying pain medication administered during the ED encounter.
Rating: Met

Feasibility	
eCQM feasibility testing conducted:	Yes [Sources: Bonnie Testing; Feasibility Scorecard]
Feasibility: As this measure is an electronic clinical quality measure (eCQM), the measure developers conducted Bonnie testing and submitted a feasibility scorecard. The feasibility scorecard addresses the following domains: • Data availability: Is the data readily available in a structured format, i.e., resides in fixed fields in EHR? • Data accuracy: What is the accuracy of the data element in EHRs under normal operating conditions? Are the data source and recorder specified? • Data standards: Is the data element coded using a nationally accepted terminology standard? • Workflow: Is the data captured during the course of care? And how does it impact workflow for the user? Across two Epic EHR sites and one Meditech site, the testing found no data element feasibility concerns.	
Rating: Met	

Validity	
Validity testing:	Face Validity [Source: MERIT Submission Form]
Testing level(s):	Patient-/Encounter-Level Testing
Validity: The developer conducted face validity via a survey among experts on the Technical Expert Panel (TEP), including hematologists, emergency medicine physicians, and a patient/caregiver representative. All respondents agreed that the measure accurately reflects its intended purpose, and supported inclusion of the pediatric population following review of the additional testing data. This indicates support for the measure's relevance and applicability across adult and pediatric populations.	
Threats to validity: The measure is recommended to be stratified by route of medication administered to monitor for potential unintended consequences.	
Rating: Met	

Reliability	
Reliability testing method(s):	Random Split-Half Correlation [Source: MERIT Submission Form]
Testing level:	Facility
Reliability discussion: The numerator and denominator for this measure are well defined. The developer calculated the reliability results from data consisting of 23 facilities. The split-half reliability, using the Pearson correlation coefficient with Spearman-Brown correction, was 0.95 with a confidence interval of [0.89, 0.99] based on bootstrap samples. The high correlation score combined with a narrow confidence interval suggests strong reliability. However, without sufficient information to report reliability by deciles, we cannot assess the extent to which facility size impacts reliability scores.	
Additional reliability analyses: Only a single estimate for reliability is required; therefore, interpolated decile averages of the reliability data were not generated.	
Rating: Met	

Usability	
Usability considered in application:	Yes, the submission materials document and examine the measure's usability, indicating that an expert panel and public feedback support the measure, highlighting its potential to improve care and reduce disparities.
Usability discussion: The developer did not identify unintended consequences from the testing of this new measure. However, concerns raised during the public comment suggest there is potential to meet the measure criteria by administering a qualifying oral medication prior to the patient being fully evaluated. The developer notes that the medication list has been left intentionally broad to allow for individualized patient-centered treatment plans (e.g., opioid vs non-opioid). Stratification of measure scores by medication route is recommended to monitor for potential unintended consequences. In considering the potential variation in measure usability across adult and pediatric populations within the selected CMS programs, the developer provided additional testing in combined adult and pediatric populations [Source: Addendum Sensitivity Analysis Report]. This testing found similar	

Usability
median times to pain medication compared to the adult-only variation of this measure, consistent with findings from the literature.
Rating: Met

External Validity	
Was this measure tested in the same target population as the CMS program?	Yes
External validity discussion: The developer tested this measure among ED encounters for all patients, regardless of age, who have a principal encounter diagnosis of SCD with VOE and who have at least one qualifying pain medication administered during the ED encounter. Measure testing included both adult and pediatric populations (6% of sample), supporting external validity of the measure to the selected CMS programs.	
Rating: Met	

Appropriateness of Scale

Similar or related measures in program(s):	The developer did not identify similar or related measures in the proposed programs.
Measure appropriateness, equity, and value across target populations/measured entities: The measure developer reviewed existing quality measures and found no competing measures specifically evaluating the timing of pain medication administration for SCD with VOE patients. Regarding equity of this measure's performance and benefit across populations, the developer's literature review and analysis do not provide sufficient information to assess the potential for differential benefit or harm to specific subgroups of participating entities or their patient populations. The committee should consider the distribution of benefit and risks/burdens of the measure within the proposed program population.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	Expected outcomes include reduction in time to pain management, improvement in the overall patient experience, and more timely treatment for adult and pediatric patients with SCD. Implementation of this measure has the potential to improve other aspects such as hospital admission rates.

Measure implementation impacts over time: While the measure developer briefly mentions potential outcomes for their measure on patient populations, there may be a need for further examination of near- and long-term impacts of this eCQM for measured entities and patients after implementation.
Questions for the committee to consider:

- What are the potential near- and long-term impacts of this measure on measured entities, proposed CMS programs, and patient populations?
- Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame?
- How will this measure mature through revisions in the future if added to proposed CMS programs?