2024 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2024-085	Hospital Harm – Anticoagulant-Related Major Bleeding
Measure Steward & Developer	**Proposed CMS Programs**
Centers for Medicare & Medicaid Services (CMS); Mathematica	Hospital Inpatient Quality Reporting Program; Hospital-Acquired Condition Reduction Program; Medicare Promoting Interoperability Program;

Measure Overview
Developer-provided rationale (excerpt from submission): While many medication classes can increase a patient's risk of bleeding, anticoagulant and thrombolytic bleeding events in particular are the most common, preventable, and measurable adverse drug events (ADEs). Unfractionated heparin and warfarin have been found to be the most commonly implicated medications in anticoagulant-associated adverse drug events (ADEs). However, newer anticoagulants (i.e., direct acting oral anticoagulants (DOACs) such as apixaban and rivaroxaban) are now routinely in use, and risks of adverse bleeding events and other negative outcomes from these newer anticoagulants have been identified. Thrombolytics are also high-alert medications that have a narrow therapeutic window, may not be used routinely, and are, therefore, less familiar to staff and yet must be used rapidly for the patient to benefit (e.g., thrombolysis for acute stroke) leading to time pressure and increased risk of error.
CMS-provided program rationale: CMS is considering including this quality measure in its quality reporting programs because the measure supports CMS's long-standing effort to link Medicare payments to health care quality in the inpatient hospital setting. The Anticoagulant-Related Major Bleeding quality measure targets the issue of preventable, adverse drug outcomes, a patient safety issue that can lead to poor patient outcomes. The inclusion of this quality measure into a quality reporting program will help the agency move one step closer to achieving its strategic quality initiatives of improving quality and health outcomes across the care journey and achieving zero preventable harm.
Description: The proportion of inpatient hospitalizations for patients aged 18 and older who were administered at least one anticoagulant medication within the first 24 hours of admission and had a subsequent bleeding event. Bleeding events must occur during the encounter.
Measure background: New measure, never reviewed by Measure Applications Partnership (MAP) Workgroup or Pre-Rulemaking Measure Review (PRMR) or used in a Medicare program.

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

Numerator: Inpatient hospitalizations that include bleeding events during the encounter following an anticoagulant medication administration during the same encounter.

A bleeding event is defined as the presence of one of the following:

- Criterion A: A diagnosis of acute bleeding at/into a critical anatomic site, with the bleeding diagnosis not present on admission, i.e., a bleeding diagnosis Present on Admission indicator = N (Diagnosis was not present at time of inpatient admission) or U (Documentation insufficient to determine if the condition was present at the time of inpatient admission)
- OR Criterion B: One evidence factor of a bleeding event and a diagnosis of acute bleeding at/into a non-critical anatomic site, with the bleeding diagnosis not present on admission, i.e., a bleeding diagnosis Present on Admission indicator = N (Diagnosis was not present at time of inpatient admission) or U (Documentation insufficient to determine if the condition was present at the time of inpatient admission)
- Evidence of Criterion B bleeding event is determined by EITHER:
    - An absolute decrease in hemoglobin results of 2 g/dL within a 48-hour period, excluding the first 24 hours of arrival, and within 5 days of the anticoagulation administration. An absolute decrease is determined when a confirmatory decrease is identified using the highest hemoglobin within 24 hours of the initial hemoglobin drop OR
    - Transfusion of whole or red blood cells, excluding the first 48 hours of arrival in the hospital (including the emergency department and observation) and within 5 days of the anticoagulation administration

A full list of anticoagulants included in the measure can be found on the Value Set Authority Center website:
https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1248.22/expansion/Latest

Exclusions: N/A

Denominator: Inpatient hospitalizations for patients aged 18 and older with a length of stay of 48 hours or longer, without a diagnosis of obstetrics, and at least one anticoagulant medication was administered within the first 24 hours of the hospitalization.

Exclusions: Inpatient hospitalizations for:

- Patients who had a critical or non-critical site bleeding diagnosis present on admission
- Patients who received dialysis during the hospitalization
- Patients who had a diagnosis of a coagulation disorder during the encounter
- Patients who had extracorporeal membrane oxygenation (ECMO) during the hospitalization

Exceptions: N/A

Measure type: Outcome	**Measure has multiple scores:** No **Measure is a composite:** No

Measure Overview	
	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): Hospital inpatient acute care facility	**Risk adjustment or stratification:** No
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; Grey Literature
Importance: The developer reported performance scores for five inpatient hospital sites as the mean rate of Anticoagulant-Related Major Bleeding (ARMB) per 100 encounters; mean scores range from 0.41 [standard deviation (SD) 6.38] to 1.43 [SD 11.88]. The developer did not evaluate differences in measure score performance between subgroups by social risk factors. Developers summarize research showing that patients treated with anticoagulants are at increased risk of bleeding, with substantially increased morbidity and mortality, and that adverse drug events (ADEs) associated with anticoagulants and thrombolytics are preventable through monitoring and careful dosing of these medications. Developers provide an extensive summary of applicable clinical guidelines [Source: Evidence Attachment] and focus their attention on the set of guidelines from the eight sources cited in the Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) submission form. These guidelines include recommendations for the therapeutic range for INR, use of reversal agents, patients undergoing major orthopedic procedures, prevention of venous thromboembolism (VTE) in nonsurgical patients, avoidance of antithrombotic and thrombolytic therapy for ischemic stroke, antithrombotic therapy for VTE, and management of VTE. Developers also provide findings from five grey literature sources, which focus on developing protocols and implementation strategies for health care organizations to support safe and effective use of anticoagulants. Finally, developers report that consulted patients and caregivers agreed the measure is meaningful, indicating their technical expert panel (TEP) includes four patient representatives.	
Rating: Met	

Measure Performance

Table 1 shows performance scores based on the information provided for the five entities described in the testing submission.

Interpretation: The mean score for the five entities described in the testing submission for this measure was 0.678. For this proportion measure, a lower score indicates better quality of care.

Table 1. MUC2024-085 Performance Scores

	Overall	Min	Score #2	Median	Score #4	Max
Mean Score (SD)	0.678 (0.43)	0.41	0.43	0.50	0.63	1.43
Number of Entities	5	1	1	1	1	1

Conformance
Measure alignment with conceptual intent: The measure specification aligns with the measure focus (bleeding events during the encounter following an anticoagulant medication administration during the same encounter) among inpatient hospitalizations for patients aged 18 and older with a length of stay of 48 hours or longer, without a diagnosis of obstetrics, and at least one anticoagulant medication was administered within the first 24 hours of the hospitalization. The numerous, diverse guidelines cited generally support a measure specification and overall intent of monitoring ARMB events.
Rating: Met

Feasibility	
eCQM feasibility testing/analysis conducted:	Yes [source: MERIT Submission Form, Feasibility Scorecard]
Feasibility: Developers report that all data elements are available in defined fields in electronic sources, that some fields align with USCDI/USCDI+ quality standard definitions, and that the provider workflow did not require modification to report the data. As this measure is an eCQM, the measure developers conducted eCQM testing and submitted a feasibility scorecard. Results in this scorecard address the following domains: • Data Availability: Data element exists in a structured format in this electronic health record (EHR). • Data Accuracy: Information is from authoritative source and/or is highly likely to be correct. • Data Standards: Data element is coded in a nationally accepted terminology standard or can be mapped to that terminology standard. • Workflow: The data element is routinely collected during clinical care and requires no, or limited, additional data entry from a clinician or other provider, and no EHR interface changes. The feasibility scorecard reported that one data element (ECMO) was not available at four of the 13 sites, indicating a challenge to feasibility that was accounted for in the feasibility plan. The committee should consider if this represents an acceptable level of feasibility for implementation in the program.	
Rating: Met	

Validity	
Validity testing method(s):	Face Validity [Source: MERIT Submission Form]
Testing level(s)	N/A
Validity: Developer reported that two out of two experts consulted agreed that the measure as specified is an accurate reflection of quality and can distinguish between good and poor quality of care. While only face validity testing is required for submission, the committee should consider if a sample size of 2 experts is sufficient for establishing face validity.	
Threats to validity: During discussions in development of the PA, the developer shared that they are currently testing risk adjustment and stratification approaches to assess whether to make this change in future years.	
Rating: Not met but addressable	

Reliability	
Reliability testing method(s):	Random Split-Half Correlation [Source: MERIT Submission Form]
Testing level:	Facility
Reliability discussion: The numerator and denominator for the measure are well defined. The developer calculated random split-half reliability on a dataset consisting of 11,892 patients across five entities. The mean bootstrapped reliability value is 0.846, indicating acceptable reliability across the five entities tested. When data for additional facilities becomes available, signal-to-noise reliability can be calculated to provide reliability estimates for each facility.	
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
Usability discussion: Developers indicated that the measure included input from 13 clinician members of their TEP; the submission did not describe the content of their input. The developer notes potential unintended consequences, including underdosing of anticoagulants and thrombolytics, leading to an increase in blood clots. Developers also note that the measure is intended to be partnered with the Hospital Harm: Postoperative Venous Thromboembolism (VTE) measure. The grey literature cited provides recommendations for how hospitals can build anticoagulant stewardship programs to implement evidence-based system improvements that improve safety and quality of anticoagulant use.	
Rating: Met	

External validity	
Was this measure tested in the same target population as the CMS program?	Yes
External validity discussion: This measure is specified to address a broad, all-payer population getting care at hospital inpatient acute care facilities. Discussion with the developer indicates that the testing sites represented a mix of predominantly urban teaching hospitals and one rural facility with a diversity of EHR vendors.	
Rating: Met	

Appropriateness of Scale

Similar or related measures in program(s):	None
Measure appropriateness, equity, and value across target populations/measured entities: The developer did not identify any related or competing measures in the proposed programs. Developer notes that the measure will be partnered with the Hospital Harm: Postoperative Venous Thromboembolism (VTE) measure. Regarding equity of this measure's performance and benefit across populations, the literature review and analysis provided by the developer in submission materials do not provide sufficient information to assess the potential for differential benefit or harm to specific subgroups of selected CMS program-participating clinicians or their patients. The committee should consider if this measure may have variation in benefit or burden to different populations.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	Measure impacts cited include reduced risk of bleeding and death [Source: MERIT Form].
Measure implementation impacts over time: While the measure developer briefly mentions potential outcomes for their measure on patient populations, there may be need for further examination of near- and long-term impacts of this measure after implementation across provider and patient populations. Questions for the committee to consider: • What are the potential near- and long-term impacts of this measure on measured entities, the programs the measure has been submitted for (Hospital Inpatient Quality Reporting Program; Hospital-Acquired Condition Reduction Program; Medicare Promoting Interoperability Program), 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 these programs' measure sets?	