2024 Pre-Rulemaking Measure Review
Preliminary Assessment

MUC ID	Title
MUC2024-025	Diagnostic Delay of Venous Thromboembolism (DOVE) in Primary Care
Measure Steward & Developer	**Proposed CMS Programs**
Brigham and Women's Hospital	Merit-based Incentive Payment System (MIPS)–Quality

Measure Overview
Developer-provided rationale (excerpt from submission): The lack of a standard definition of venous thromboembolism (VTE), as well as the low performance of existing identification algorithms, points to a need for the novel, data-driven DOVE electronic clinical quality measure (eCQM). Measuring and reporting delayed VTE diagnosis rates will inform health care providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by patients. This measure has the potential to lower health care costs associated with VTE by providing ongoing intermediate patient outcome data that can be used to improve VTE diagnostic performance and to reduce complications associated with delayed diagnosis and treatment.
CMS-provided program rationale: CMS may add the Diagnostic Delay of Venous Thromboembolism (DOVE) in Primary Care measure to the MIPS quality measure inventory as a new electronic clinical quality measure. This measure addresses the commonly missed or delayed diagnosis of VTE in primary care, which results in requiring timely and adequate treatment to decrease mortality and morbidity. Improved performance on this measure will have a significant impact on the patient population served by MIPS as well as for clinical practice provided by clinicians enrolled in the program. This measure's specification is appropriate and aligned with the measure target (the rate of delayed diagnosis of lower-limb VTE) among patients aged 18 and older seen in primary care. The risk of mortality and morbidity associated with delayed or missed VTE diagnosis is high, which affirms the potential value of this measure to be included in MIPS. This measure is fully tested, developed, and CBE endorsed. This measure fulfills a gap in MIPS for treatment of patients with VTE and may be a potential future addition to the Primary Care MIPS Value Pathway (MVP).
Description: The DOVE eCQM assesses the rate of delayed diagnosis of VTE in adults aged 18 years and older in the primary care setting. Delayed diagnosis is defined as diagnosis of a lower limb VTE that occurs >24 hours following the index primary care visit where symptoms for the VTE were first present (within 30 days). The target population for this measure is all patients, 18 years and older, across all payers.

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Measure Overview

Measure background: Submitted previously, but not included on Measures Under Consideration (MUC) List.

Numerator: A patient is included in the numerator if they are included in the denominator population and their VTE diagnosis occurs >24 hours following their primary care visit (within 30 days).

Denominator: All adult patients (age 18 years and older) presenting in primary care with VTE-related symptoms with an eligible lower limb VTE event (see below) are included in the measure denominator. VTE-related symptoms are identified in the EHR either as structured data (using the VTE-related symptoms value set, OID 2.16.840.1.113762.1.4.1206.51) or identified in unstructured data in clinical notes by a natural language processing (NLP) algorithm.

Criteria for an eligible VTE event:

1. Aged 18 years or older on the date of the primary care visit

2. All PCP visits in this measure must be performed by a provider with the following specialties: Nurse Practitioner (occupation), Physician (occupation), Medical practitioner (occupation), Technical healthcare occupation (occupation), Family medicine specialist (occupation), General practitioner assistant (occupation), General practitioner principal (occupation), Associate general practitioner (occupation).

3. Receive a diagnosis of a lower limb Venous Thromboembolism within 30 days of their primary care visit. For a patient to have a VTE diagnosis, they must have all of the following VTE-related codes within the same encounter: ICD-10 CM code for VTE, CPT codes for an imaging scan for VTE linked to the same encounter as the ICD-10 CM code, RxNorm order for therapeutic anticoagulants placed in the same encounter as the imaging scan.

4. Have no eligible VTE events within 6 months of the qualifying VTE event

A VTE diagnosis is defined using ICD billing codes, CPT imaging codes, and RxNorm medication codes for therapeutic anticoagulants, all three codes must be present for an eligible VTE encounter.

The following symptoms in the provider clinical notes are defined as VTE symptoms: cough, hypotension, lightheadedness, syncope, tachycardia, hemoptysis, shortness of breath, calf pain, leg pain, foot pain, calf numbness, leg numbness, foot numbness, calf tingling, leg tingling, foot tingling, calf redness, leg redness, foot redness, calf swelling, leg swelling, foot swelling, calf tenderness, leg tenderness, foot tenderness, calf warmth, leg warmth, and foot warmth.

Exclusions: This measure excludes patients who have a hospice or palliative care encounter within 90 days of the eligible VTE encounter. The rationale for this exclusion is that these patients have different care goals than non-hospice or palliative care which may affect their VTE diagnosis.

Measure Overview	
Measure type: Intermediate Outcome	**Measure has multiple scores:** No **Measure is a composite:** No **Measure is digital and/or an eCQM:** Yes **Paired or group measure:** No
Level of analysis: Clinician Group	**Data source(s):** EHR
Care setting: Clinician office/clinic, hospital, outpatient, primary care	**Risk adjustment or stratification:** None
CBE endorsement status: Endorsed, CBE ID 3749e	**CBE endorsement history:** Endorsed 2023
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** No

Meaningfulness

Importance	
Type of evidence:	Empirical data [Source(s): Measure Information Form (MIF); MUC Entry/Review Information Tool (MERIT) Submission Form; MIPS Peer-Reviewed Journal Article Form]
Importance: This measure addresses the commonly missed or delayed diagnosis of VTE in primary care, requiring timely and adequate treatment to decrease mortality and morbidity. Improved performance on this measure will have significant impact on the clinical practice of providers enrolled and the patient population served by providers participating in MIPS. During CBE endorsement in 2023, the committee found the importance of this measure sufficient.	
Rating: Met, Prior CBE Endorsement	

Measure Performance

Table 1 show performance score deciles (i.e., the data sorted and broken into ten equal parts) based on the information provided for the 15 clinician groups described in the testing submission.

Interpretation: The mean score for the 15 clinician groups described in the testing submission was 73. For this measure, a lower score represents better quality of care.

Table 1. MUC2024-025 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 (SD)	73 (9)	55	57	63	72	72	73	77	78	79	81	85	85
Number of Entities	15	1	2	1	2	1	2	1	2	1	2	1	1

Conformance
Measure alignment with conceptual intent: As outlined in the MIF and MIPS Peer-Reviewed Journal Article Form submitted, this measure's specification is appropriate and aligned with the measure target (the rate of delayed diagnosis of lower-limb VTE) among patients aged 18 and older seen in primary care.
Rating: Met, Prior CBE Endorsement

Feasibility	
eCQM Feasibility testing conducted:	Yes [Source(s): Bonnie Testing, Feasibility Final Scorecard; MERIT Submission Form; MIF]
Feasibility: 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. No data element feasibility challenges were identified across the 3 testing sites using Epic, Allscripts and Sunrise Client Manager EHRs. During CBE endorsement in 2023, the committee found the feasibility of this measure sufficient.	
Rating: Met, Prior CBE Endorsement	

Validity	
Validity testing:	Face Validity & Empiric Validity [Source(s): MIPS Peer-Reviewed Journal Article Form]
Testing level(s):	Accountable entity level & data element/patient encounter level
Validity: A panel of experts established face validity by agreeing this measure was an accurate reflection of quality and could be used to distinguish between good and poor-quality care. The developer conducted random split half correlation at the clinician group level, demonstrating strong positive correlation between test and validation samples. The developer compared the eCQM to manual chart review at identifying numerator, denominator, and exclusion encounters and found 100% agreement, indicating accuracy in ability to define eligible VTE events. During CBE endorsement in 2023, the committee found the validity of this measure sufficient.	
Threats to validity: A sub-analysis found no significant differences across patients by race, ethnicity, sex, insurance, and age, indicating no significant differences in the delayed VTE diagnosis rate by patient characteristic and supporting the lack of risk adjustment or stratification.	
Rating: Met, Prior CBE Endorsement	

Reliability	
Reliability testing method(s):	Signal-to-noise analysis & inter-rater reliability (NLP algorithm and VTE phenotyping) [Source(s): MIPS Peer-Reviewed Journal Article Form]
Testing level:	Individual clinician and clinician group level & VTE event level
Reliability discussion: The numerator and denominator for this measure are well defined. The developer performed multiple levels of reliability testing for this measure. The developer calculated signal-to-noise (SNR) reliability for a dataset consisting of 43 clinician groups. (The submission does not describe the total number of patients.) At the clinician group level, 43 groups from Site 1 and Site 3 were sampled and the median signal-to-noise statistical result was 0.3958 (95% CI; 0.3385, 0.4532). The minimum SNR was 0.2474 and the maximum was 0.95. The mean reliability is 0.3958, and the majority of clinician groups have a reliability <0.6. This indicates that for roughly 60% of measured entities, the measure has reliability below the acceptable threshold. The PRMR PAs use a threshold of 0.6 to indicate that a measure is capable of differentiating entities by quality of performance. While this measure's median SNR reliability is below that, it does exceed the 0.4 required by MIPS The developer also calculated random split half correlation for a dataset consisting of 2,344 patients across 15 clinician groups. This analysis was conducted at the clinician group level due to sample size limitations at the individual clinician level. The Spearman rank correlation is 0.782, a sufficiently high correlation to consider the measure reliable within this subset of clinician groups.	

Reliability
Note: The developer also calculated reliability at the individual clinician level, but they state that this measure is specified for use at the clinician group level, so those results are not discussed here.
Additional reliability analyses: Battelle calculated SNR and intraclass correlation coefficient (ICC) reliability for the 15 clinician groups described in the article *Testing of an Electronic Clinical Quality Measure for Diagnostic Delay of Venous Thromboembolism (DOVE) in Primary Care.* Table 2 shows reliability calculations in two ways: SNR and ICC adjusted by the denominator size based on the 15 sites that had both performance data and contributed to reliability calculations.
Rating: Met, Prior CBE Endorsement

Reliability Tables

Table 2 show reliability deciles based on the information provided for the 15 clinician groups described in the testing submission. Battelle creates these tables to provide reviewers with a standardized format to assess reliability.

Interpretation: In both calculations (SNR and ICC), the reliability is less than 0.6 for 11 of the 15 (73%) of the clinician groups. This indicates that the measure may not perform with acceptable reliability to distinguish quality of care in the majority of entities tested.

Table 2. MUC2024-025 Mean Reliability (by Reliability Decile)

	Mean	SD	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max	IQR
Signal to Noise (SNR)	58	17	38	40	44	45	50	53	56	57	70	83	95	95	25
ICC	50	18	34	35	35	36	37	44	46	51	60	74	93	93	23

Usability
Usability of measure within MIPS: Based on discussion of the measure on the MUC List submission documents, there is an opportunity for improvement on the measure target among clinician and clinician groups participating in MIPS. No external program-level factors that may present barriers to measure use were identified during review. During discussions with technical expert panel (TEP) members, developers identified one potential unintended consequence of measure use: "measure to quantify delayed diagnosis of VTE within a CMS payment program may motivate primary care clinicians to overuse VTE diagnostic resources to avoid a high DOVE rate." The developer suggests both promoting the use of low-cost tools such as D-dimer tests to rule out a VTE prior to ordering imaging and using a clinical decision support tool currently in development.
Rating: Met, Prior CBE Submission

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 clinician and clinician group primary care settings and the same population (patients aged 18 and older) as the intended MIPS population.	
Rating: Met	

Appropriateness of Scale

Related or competing measures in MIPS:	None
Measure appropriateness, equity, and value across target populations/measured entities: A review of active MIPS measures did not identify any similar or competing measures, suggesting that this measure would fill a gap within the current MIPS quality measure inventory. In their submission, the measure developer suggests that this measure correlates to existing cost measures and improvement activities, indicating that delayed or missed VTE diagnosis is related to increased hospitalization and health care spending. The focus and target population of this measure align with the intent and population of MIPS and would be an appropriate addition. With regard to equity of this measure's performance and benefit across populations, the literature review and sub-analysis provided by the developer in submission materials does not suggest differential benefit or harm to specific subgroups of MIPS-participating clinicians or their patients. Given the risk of mortality and morbidity associated with delayed or missed VTE diagnosis, the potential value of this measure, once implemented in MIPS, is high. The committee should consider if, based on their professional and patient experience, there is a chance for variation in distribution of benefit or burden across provider and patient populations.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	Expected outcomes of measure implementation include “reduction in delayed diagnosis of VTEs in the primary care setting by providing clinician groups with their quantified DOVE rates” and promotion of “patient safety and outcomes as well as reduce[d] healthcare costs associated with the increased morbidity and mortality of delayed diagnoses” [Source(s): MIPS Peer-Reviewed Journal Article Form]
Measure implementation impacts over time: The measure developer mentions potential outcomes for their measure on clinician and patient populations. There is a need for further examination of near- and long-term impacts of this measure after implementation across patient and provider populations. Questions for the committee to consider include: • What are the potential near- and long-term impacts of this measure on measured entities, MIPS, and patient populations? • Will benefits and burdens associated with this measure be realized within an appropriate implementation timeframe? • How will this measure mature through revisions in the future if added to the MIPS quality measure inventory?	