2024 Pre-Rulemaking Measure Review
Preliminary Assessment

MUC ID	Title
MUC2024-100	Non-Pressure Ulcers
Measure Steward & Developer	**Proposed CMS Programs**
Centers for Medicare & Medicaid Services (CMS)	Merit-based Incentive Payment System-Cost (MIPS)

Measure Overview
Developer-provided rationale (excerpt from submission): Chronic non-pressure ulcers are highly prevalent in older adults. For instance, venous ulcers affect nearly 5% of older adults and 15% to 25% of patients with diabetes develop foot ulcers. Furthermore, chronic leg and foot ulcers can reoccur in up to 70% of patients leading to loss of function, decreased quality of life, and poor health outcomes. There are many improvement opportunities to advance patient care and reduce health care costs for patients with non-pressure ulcers, with appropriate treatment and management opportunities depending on the ulcer type. For instance, providing offloading treatments (e.g., total contact casting, removable cast walkers) for diabetic ulcers, limiting wound debridement for arterial ulcers, incorporating compression systems for venous ulcers, improving patient wound care education, and considering advanced wound care therapies for higher stage diabetic ulcers. The Non-Pressure Ulcers episode-based cost measure was selected for development because of its impact in terms of patient population, clinician coverage, and Medicare spending; because it assesses costs for a condition not captured by other cost measures; and because it addresses a gap in clinician coverage of cost measures for specialists such as podiatrists. Following measure selection based on prior public comments and feedback, initial empirical analyses, and CMS priority areas, the subsequent measure-specific clinician expert workgroup provided extensive, detailed input on this measure.
CMS-provided program rationale: CMS is considering adding the Non-Pressure Ulcers measure to the MIPS measure set. The prevalence and costs of non-pressure ulcers are high, capturing affecting a large patient population and percentage of Medicare spending. Literature and testing suggest that there are opportunities for improvement in performance, such as providing appropriate wound care, debridement, supportive durable medical equipment (DME), and minimizing complications related to care. Additionally, the measure will fill a measurement gap area in care and management of ulcers in the MIPS cost performance category and it will assess the podiatry specialty, which did not previously have an applicable episode-based cost measure in MIPS.
Description: The Non-Pressure Ulcers episode-based cost measure evaluates a clinician's or clinician group's risk-adjusted and specialty-adjusted cost to Medicare for patients who receive medical care to manage and treat non-pressure ulcers. This chronic condition

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Measure Overview	
measure includes Medicare Parts A, B, and D costs for services that are clinically related to managing and treating non-pressure ulcers.	
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: The measure numerator is the average ratio of the observed costs to the expected cost for all Non-Pressure Ulcers episodes attributed to a clinician. This sum is then multiplied by the national average observed episode cost to generate a dollar figure. **Exclusions:** None	
Denominator: The measure denominator is the total number of days from Non-Pressure Ulcers episodes assigned to the clinician across all patients. **Exclusions:** The following standard exclusions are applied to ensure data completeness: • Patient has a primary payer other than Medicare for any time overlapping the episode window or 120-day lookback period prior to the episode window. • Patient was not enrolled in Medicare Parts A and B for the entirety of the lookback period plus episode window or was enrolled in Part C for any part of the lookback plus episode window. • Patient was not found in the Medicare Enrollment Database (EDB). • Patient's death date occurred before the episode end date. • Patient has an episode window shorter than 1 year. • Patients with extremely low episode costs. • Patient's residence is outside the United States or its territories during the episode window, as indicated in the EDB. The following measure exclusions are applied to account for patient heterogeneity: • Patients with calciphylaxis. • Patients with pyoderma gangrenosum. • Patients with scleroderma. • Patients with sickle cell anemia • Patients with vasculitis. • Patients with hidradenitis suppurativa. • Patients with prior hospice use. **Exceptions:** N/A	
Measure type: Cost/Resource Use	**Measure has multiple scores:** No **Measure is a composite:** No **Measure is digital and/or an eCQM:** No **Measure is a paired or group measure:** No
Level of analysis: Clinician: Individual and Group	**Data source(s):** Digital-Administrative systems: Administrative Data (non-claims); Digital-Administrative systems: Claims Data

Measure Overview	
Care setting(s): Ambulatory/office-based care; Hospital outpatient department (HOD); Nursing home; Skilled nursing facility	**Risk adjustment or stratification:** Risk adjustment
CBE endorsement status: Never submitted	**CBE endorsement history:** N/A
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** The development and implementation of cost measures in MIPS is required by Section 101(f) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Meaningfulness

Importance	
Type of evidence:	Peer-Reviewed Systematic Review; Empirical Data [Sources: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) final submission form; Methodology Testing August 2024; Episode-Based Cost Measure (EBCM) At-A-Glance]
Importance: Chronic non-pressure ulcers are very common in the Medicare population. In 2019, chronic ulcers affected 16.3% of beneficiaries. In addition, foot or ankle ulcers precede more than 85% of lower-limb amputations. This measure captures an estimated $1.9 billion in Medicare spending. Treating ulcers appropriately depends in large part on the type of ulcer, and correct treatment is key for preventing amputations. Appropriate treatments vary considerably between ulcer types (i.e., venous, diabetic, or arterial).Adherence to clinical guidelines specific to each ulcer type is key to preventing the recurrence of ulcers and lower-limb amputations and, thus, ultimately reducing major downstream costs and increasing quality of care. The developer did not evaluate the measure's meaningfulness to patients; however, the developer states that stakeholder input continues to stress the importance of this measure focus and described how input was collected from persons with lived experience (i.e., patients and family) in an iterative process and shared with the clinician workgroup to inform their discussion of measure specifications. The submission reported performance scores for 4,174 clinician groups ("TINs") and 4,060 individual clinicians ("TIN-NPIs") with at least 20 attributed episodes each. Performance scores demonstrate substantial variance at each level. The developer analyzed statistically significant associations in episode cost and patients with enrollment in both Medicare and Medicaid (i.e., dual-eligible patients) for each measure subgroup at the clinician group (TIN) and individual clinician (TIN-NPI) level of analysis. Several subgroups showed a statistically significant association between patient dual-eligibility status and episode cost (venous ulcer type, multiple ulcer type, and diabetic ulcer type subgroups with Part D enrollment). Additionally, clinicians and groups tended to perform worse on episodes with dual-eligibility status prior to applying risk adjustment for dual-eligibility status. The measure risk adjusts for patient dual-eligibility status to account for social risk factors outside a clinician's control that may be influencing their performance. [Source: Measure Justification Form].	
Rating: Met	

Measure Performance

For Tables 1a and 1b, the developer provided the mean score and number of entities for each performance score decile (i.e., the data sorted and broken into 10 equal parts) along with the minimum and maximum performance scores observed.

Interpretation: The mean score for the 4,174 TIN entities described in the testing submission for this measure was 9,108.90. The mean score for the 4,060 TIN-NPI entities described in the testing submission for this measure was 8,480.14. For this ratio measure, a lower score indicates better quality of care.

Table 1a. MUC2024-100 Performance Score Deciles – TIN (Taxpayer Identification Number)

	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)	9,108.90 (4,398.51)	594.88	3,158.30	5,216.41	6,374.92	7,280.83	8,093.31	8,945.47	9,897.82	11,072.83	12,813.31	18,234.08	72,857.77
Number of Entities	4,174	1	417	417	418	417	418	417	418	417	418	417	1

Table 1b. MUC2024-100 Performance Score Deciles – TIN-NPI (Taxpayer Identification Number-National Provider Identifier)

	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)	8,480.14 (4,669.90)	594.88	2,709.63	4,432.67	5,494.47	6,388.11	7,305.66	8,181.56	9,223.77	10,485.29	12,438.97	18,141.25	87,295.15
Number of Entities	4,060	1	406	406	406	406	406	406	406	406	406	406	1

Conformance
Measure alignment with conceptual intent: A submission attachment provided a comprehensive, detailed list of codes associated with the measure specifications and includes codes to define the numerator, denominator, exclusions, episode triggers, codes for attribution to a clinician, and risk factors for the risk-adjustment model [Source: Methodology Measure Codes]. Another attachment provided steps for calculating the measure score [Source: Methodology August 2024]. Specification is aligned with conceptual intent.
Rating: Met

Feasibility	
eCQM feasibility testing/analysis conducted:	Yes [Source: MERIT Submission Form]
Feasibility: All data elements exist in defined fields in electronic sources; the developer did not assess alignment with United States Core Data for Interoperability (USCDI)/USCDI+ quality guidelines. Aligning with USCDI standards for data elements can promote interoperability and improve feasibility. Because data are derived from claims, modifications to the provider workflow do not apply.	
Rating: Met	

Validity	
Validity testing:	Empiric Validity [Source: MERIT Submission Form, Peer-Reviewed Article, Measure Justification Form, Episode-Based Cost Measure (EBCM) At-A-Glance].
Testing level(s):	Clinician – Group; Individual Clinician
Validity: The developer provided a conceptual model that outlines ways in which a clinician or group can impact their risk-adjusted measure score. The developer also used regression models to evaluate validity at each level of analysis: Model 1) the effects of categories of costs (i.e., treatment choices) on the mean observed-to-expected cost ratio (i.e., the measure score), controlling for the costs of adverse events; Model 2) the effects of categories of treatment costs on the costs of adverse outcomes. Finally, the developer presented testing on whether episodes with adverse events are more expensive than the average episode cost, as would be expected for a cost measure. The conceptual model provided examples of treatment choices (e.g., physician visits, skin and vascular procedures, medications, following clinical guidelines, providing patient education, coordinating with care teams, etc.). These treatment choices were linked to the likelihood and severity of adverse events, like emergency department visits, hospitalizations, and post-acute care. The treatment choices and adverse events were collectively linked to measure scores [Source: Measure Justification Form]. At both levels of analysis (group, individual clinician), increased costs from adverse events were associated with worse measure performance (i.e., higher costs) (Model 1). Drivers of worse performance were costs for ambulatory/minor procedures, imaging services, durable medical equipment (Model 1). These same factors were also associated with higher adverse events costs, which the developers interpreted as evidence that reducing such costs may be linked with reducing adverse events, (Model 2). At both levels, costs for laboratory, pathology, and other test services and major procedures were not associated with increased cost of adverse events (Model 2), despite being associated with worse measure performance (Model 1), and the developers interpreted these findings as evidence that these services may be overused [Source: Peer-Reviewed Article].	

Validity
The developer also provided testing showing that episodes with adverse events have higher risk-adjusted costs compared to the average risk-adjusted episode cost ($8,293). Episodes with major procedures, like amputations, have more than two times higher risk-adjusted episode costs ($17,257) and episodes with clinically related emergency department visits have approximately 120% higher risk-adjusted episode costs ($19,457) [Source: Episode-Based Cost Measures (EBCM) At-A-Glance]. The developer stated that these findings support the measure's validity because they indicate that the measure assesses the intended costs, which include costs associated with treatment choices and the consequences of those treatment choices. The committee should consider if these models are adequate for establishing validity of the measure. Do committee members find that results are consistent with their expectations?
Threats to validity: The developer developed the risk-adjustment model in collaboration with the technical expert panel (TEP) and clinical workgroup. The risk-adjustment model includes variables with factors specific to the condition (frailty, smoking, lymphedema, sleep apnea, and place of service/the main practice location type of the attributed clinician group) and "standard" risk adjusters (hierarchical condition codes, disability status, age category, disability status, end-stage renal disease status, dual-eligibility status, number and types of clinician specialties from which the patient has received care, and recent use of institutional long-term care). Risk models are stratified by each subgroup and Part D enrollment status combination. The measure subgroups are: diabetic ulcers, arterial ulcers, venous ulcers, multiple ulcer types, and non-specific ulcers. The model shows acceptable calibration and reports the amount of variance in model due to risk factors versus provider performance [Source: Peer-Reviewed Article].
Rating: Met

Reliability	
Reliability testing method(s):	Signal-to-Noise [source: MERIT Submission Form, Methodology Testing]
Testing level:	Clinician – Group; Individual Clinician
Reliability discussion: The numerator and denominator for this measure are well defined. The dataset consists of 4,174 TINs (i.e., clinician groups) and 4,060 TIN-NPIs (i.e., individual clinicians). The median reliability for the TINs and TIN-NPIs is 0.85 and 0.841, respectively, at a 20-episode volume threshold, which are both >0.60, indicating that 20% of entities have a higher risk of misclassification. If the measure is implemented in the Merit-based Incentive Payment System (MIPS) in the future, CMS will establish a case minimum through notice-and-comment rulemaking.	
Additional reliability analyses: Only a single estimate was required for reliability, therefore interpolated decile averages of the reliability data were not generated.	
Rating: Met	

Usability	
Usability considered in application:	Yes
Usability discussion: The developer described the processes used for collecting input from several sources, including a TEP (20 members: clinicians, administrators, patients), a clinical expert panel ("workgroup": 19 members representing 21 professional societies), persons with lived experience (i.e., patients and family), and a 6-week national field testing period in which MIPS-eligible clinicians and clinician groups meeting a minimum threshold of 20 episodes could review reports and submit feedback. The TEP provided input on cross-measure topics such as methodology and testing, while the workgroup provided input on measure specification. Input from persons with lived experience was also presented to the clinical expert panel to inform measure specification. Developer reports that no unintended consequences have been identified.	
Rating: Met	

External Validity	
Was this measure tested in the same target population as the CMS program?	Yes
External validity discussion: The measure's target population is Medicare fee-for-service beneficiaries, and the developer tested it in ambulatory/office-based care settings, hospital outpatient departments (HODs), nursing homes, and skilled nursing facilities. Participating entities show diversity in terms of geographic region, provider specialty, and volume [Source: Measure Justification Form].	
Rating: Met	

Appropriateness of Scale

Similar or related measures in program(s):	None
Measure appropriateness, equity, and value across target populations/measured entities: The developers identified no related or competing measures in this program. The developer identified several potentially relevant MIPS and qualified clinical data registry (QCDR) measures, including process measures focused on patient assessments for patients with diabetes, offloading for patients with diabetic foot ulcers, and arterial and nutrition assessments for patients with ulcers or wounds; an intermediate outcome measure focused on provision of compression treatment for venous leg ulcers; and outcome measures addressing functional status, vascular ultrasounds, ulcer and chronic wound healing, and patient compliance [Source: Measure Justification Form]. The committee should consider if, based on their professional and patient experience, there is a chance for variation on distribution of benefit or burden across provider and patient populations.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	The developer identified impacts from the measure, including reduced cost, improved health status, and improved quality of life.
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 measure 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, MIPS, 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 the MIPS measure set?	