

## 2024 MIPS Peer-Reviewed Journal Article Requirement Template

Section 101(c)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires submission of new measures for publication in applicable specialty-appropriate, peer-reviewed journals prior to implementing in the Merit-based Incentive Payment System (MIPS). Such measures will be submitted by the Centers for Medicare & Medicaid Services (CMS), to a journal(s), before including any new measure on the MIPS Quality Measures List. The measure submitter shall provide the required information for article submission under the MACRA per the MIPS Annual Call for Quality Measures submission process.

Interested parties submitting measures for consideration through the MIPS Annual Call for Quality Measures must complete the required information by the CMS Annual Call for Measures deadline (8 p.m. ET on May 10, 2024). Some of the information requested below may be listed in specific fields in the CMS Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT); however, to ensure that CMS has all of the necessary information and avoid delays in the evaluation of your submission, please fully complete this form as an attached Word document. The information in MERIT must be consistent with the information below, including the following, but not limited to:

- **Non-Pressure Ulcers**
- **Affordability and Efficiency**

**Measure Steward:** *Centers for Medicare & Medicaid Services*

**Measure Developer:** *Acumen, LLC*

**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 measure includes the costs of services that are clinically related to the attributed clinician's role in managing care during a non-pressure ulcer episode.*

### I. Statement

- Background (Why is this measure important?).

Chronic non-pressure ulcers are highly prevalent in the US Medicare population. In 2019, 16.3% of Medicare beneficiaries were affected by chronic ulcers, up from 14.5% in 2014.<sup>1</sup> Venous ulcers affect nearly 5% of individuals aged 65 and older, and about 15% to 25% of patients with diabetes develop foot ulcers.<sup>2</sup> Chronic ulcers can last over a year, are recurring in up to 70% of patients, and can lead to loss of function, decreased quality of life (QOL), and poor health outcomes.<sup>3</sup> Ulcers can heavily impact QOL for patients, as more than 85% of lower limb amputations are preceded by foot or ankle ulcers.<sup>4</sup>

Chronic non-pressure ulcers are also costly to the U.S. healthcare system. Total Medicare spending for all wound types is \$28.1 billion annually. Including noninfected and infected wound costs, the estimated cost of care for diabetic foot ulcers ranges from \$6.2 billion to \$18.7 billion, and \$0.7

<sup>1</sup> Sen CK. Human Wound and Its Burden: Updated 2022 Compendium of Estimates. *Adv Wound Care (New Rochelle)*. 2023;12(12):657-670. doi:10.1089/wound.2023.0150.

<sup>2</sup> Greer N, Foman N, Dorrian J, et al. *Advanced Wound Care Therapies for Non-Healing Diabetic, Venous, and Arterial Ulcers: A Systematic Review*. Washington (DC): Department of Veterans Affairs (US); November 2012.

<sup>3</sup> *Optimal Care of Chronic, Non-Healing, Lower Extremity Wounds: A Review of Clinical Evidence and Guidelines*. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; December 17, 2013.

<sup>4</sup> Suthar M, Gupta S, Bukhari S, Ponemone V. Treatment of chronic non-healing ulcers using autologous platelet rich plasma: a case series. *J Biomed Sci*. 2017 Feb 27;24(1):16. doi: 10.1186/s12929-017-0324-1. PMID: 28241824; PMCID: PMC5327512.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5327512/>

billion to \$1.5 billion for venous leg ulcers,<sup>5</sup> with the total cost for wounds ranging from \$31.7 to \$96.8 billion when they are included as a secondary diagnosis.<sup>6</sup>

- Environmental scan (Are there existing measures in this area?)

Based on a search of the CMS Measure Inventory Tool (CMIT), no related or competing measures are currently used in the MIPS Cost performance category. However, we found key quality measures that are related to non-pressure ulcer care. These MIPS and QCDR quality measures (listed in Table 1 and 2 below, respectively) may include metrics focused on similar patient cohorts, clinically related to the care provided for the episode group, or complementary care.

**Table 1. MIPS Quality Measures Potentially Relevant for the Non-Pressure Ulcers Measure**

Measure Title	Measure ID	Measure Description	Measure Type
Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy Neurological Evaluation	126	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	Process
Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear	127	This measure examines the percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	Process
Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments	219	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.	Patient Reported Outcome

**Table 2. QCDR Quality Measures Potentially Relevant for the Non-Pressure Ulcers Measure**

Measure Title	Measure ID	Measure Description	Measure Type
Patient Reported Nutritional Assessment and Intervention Plan in Patients with Wounds and Ulcers	USWR22	The percentage of patients who have a visit for a wound(s) and/or ulcer(s) and who self-report a validated nutritional assessment for whom an appropriate intervention plan is recommended by the practitioner based on the assessment results.	Process
Non-Invasive Arterial Assessment of Patients with Lower Extremity Wounds or Ulcers for Determination of Healing Potential	USWR30	Percentage of patients aged 18 years or older with a non-healing lower extremity wound or ulcer that undergo a non-invasive arterial assessment at the initial visit for the wound or ulcer, once in a 12-month period.	Process
Adequate Compression at Each Visit for Patients with Venous Leg Ulcers Appropriate to Arterial Supply	USWR32	Percentage of venous leg ulcer visits among patients aged 18 years and older in which adequate compression is provided at each visit within the 12-month reporting period.	Intermediate Outcome
Diabetic Foot Ulcer (DFU) Healing or Closure	USWR33	Percentage of diabetic foot ulcers among patients aged 18 or older that have achieved healing or closure within 6 months, stratified by the Wound Healing Index.	Process

<sup>5</sup> Agency for Healthcare Research and Quality (2018). Skin Substitutes for Treating Chronic Wounds. <https://effectivehealthcare.ahrq.gov/products/skin-substitutes/protocol>

<sup>6</sup> Nussbaum SR, Carter MJ, Fife CE, et al. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. *Value Health*. 2018;21(1):27-32. doi:10.1016/j.jval.2017.07.007

Venous Leg Ulcer (VLU) Healing or Closure	USWR34	Percentage of venous leg ulcers among patients aged 18 or older that have achieved healing or closure within 12 months, stratified by the Wound Healing Index.	Process
Adequate Off-loading of Diabetic Foot Ulcers (DFUs) Performed at Each Visit, Appropriate to Location of Ulcer	USWR35	Percentage of visits in which diabetic foot ulcers among patients aged 18 years and received adequate off-loading during a 12-month reporting period, stratified by location of the ulcer.	Process
Offloading with Remote Monitoring	REGCLR5	Percentage of patients with a plantar foot ulcer who were treated with an off-loading device enabling doctor to remotely monitor for use of the device and were compliant with offloading and healed their ulcer in 10 weeks.	Outcome
Monitor and Improve Treatment Outcomes in Chronic Wound Healing	REGCLR8	Percentage of patients presenting with a non-healing (chronic) wound (present for 6 weeks with no or limited response to treatment) who are currently visiting a provider responsible for their wound care, who performs a re-assessment of the wound (The use of digital imaging to monitor the wound is encouraged) , and has used the information learned from that re-assessment to implement a change in treatment plan, and whose wound healing rate has accelerated since implementation of the updated treatment plan.	Outcome
Functional Status Change for Patients with Upper or Lower Quadrant Edema	FOTO4	This is a patient-reported outcome performance measure (PRO-PM) consisting of a PROM of risk-adjusted change in FS for patients aged 14 years+ with lymphedema or other causes of edema. For patients with such conditions affecting the leg, foot, groin, or lower trunk regions, the change in FS is assessed using the FOTO Lower Quadrant Edema (LQE) FS PROM. For patients with such conditions affecting the arm, hand, chest, or breast body regions, the change in FS is assessed using the FOTO Upper Quadrant Edema (UQE) FS PROM.	Patient Reported Outcome
Appropriate non-invasive arterial testing for patients with intermittent claudication who are undergoing a Lower Extremity peripheral vascular intervention	OEIS6	Proportion of patients who completed a structured walking program of a duration not less than 12 weeks prior to undergoing peripheral arterial intervention in patients with claudication.	Process
Use of ultrasound guidance for vascular access	OEIS8	Proportion of vascular access using ultrasound guidance for vessel puncture during endovascular procedures.	Patient-Reported Outcome-based Performance Measure (PRO-PM)

**II. Gap Analysis**

- Provide evidence for the measure (What are the gaps and opportunities to improve care?).

The Non-Pressure Ulcers episode-based cost measure assesses costs related to non-pressure ulcer care, a current measurement gap in the MIPS cost performance category. Furthermore, an environmental scan of the literature identified two critical areas for improving care and reducing costs, including:

1. Reducing recurring ulcers as well as lower limb amputations caused by non-healing wounds
2. Creating a care management plan to coordinate appropriate treatment technologies

It is estimated that more than 85% of lower limb amputations are preceded by foot or ankle ulcers.<sup>7</sup> Methods to correctly identify ulcer types and severity, such as color-flow duplex ultrasounds and plain radiographs,<sup>8,9</sup> as well as continuous care of already identified wounds are vital components to preventing amputations. Certain compression systems, such as multi-component bandage systems, also promote faster healing and are more cost-effective than single-component systems.<sup>10</sup> Additionally, clinicians should administer the presence of swelling, as the complication has shown to reduce the efficacy of medications used to treat venous ulcers.<sup>11</sup>

The wide variety of existing technologies to treat ulcers raises the need to create care management plans tailored to specific patient needs. For instance, unless a diabetic wound has not healed by at least 50% in four weeks, clinicians should not consider skin grafts, as they have shown to slow healing time for neuropathic and arterial ulcers.<sup>12,13</sup> Wound debridement and compression therapy should also be limited for arterial ulcers and only performed if adequate blood supply to the wound has been established.<sup>14</sup> Finally, the use of oral antibiotics to treat stasis dermatitis ulcers has not shown to improve healing rates, unless an infection is detected. A more accurate furnishing of these services to the patients who need them would represent significant opportunities for cost savings and improved health outcomes.

- Expected outcome (patient care/patient health improvements, cost savings).

Focusing on specific care patterns that decrease the recurrence of ulcers and incidence of lower limb amputations has the potential of reducing major downstream costs and increasing quality of care. Proper wound care of diabetic ulcers is done by following standard of care guidelines including offloading pressure from the wound, ensuring circulation for healing, treating present infections, and performing regular wound debridement.<sup>15</sup> Likewise, offloading treatments for neuropathic ulcers, such as total contact casting, removable cast walkers, and forefoot casting provided during a four-to-six-week period has shown to promote healing and reduce the risk of reoccurrence.<sup>16,17</sup>

Improving care coordination for patients with non-pressure ulcers is also important for follow-up care and management of comorbidities. Effective management of venous ulcers has previously included patient education for diet and lifestyle modification, progressive resistance exercise, managing cardiac comorbidities, and psychosocial support. Clinicians must also follow clinical practice guidelines when using novel, advanced wound therapies such as stem cell therapy and

<sup>7</sup> Suthar M, Gupta S, Bukhari S, Ponemone V. Treatment of chronic non-healing ulcers using autologous platelet rich plasma: a case series. *J Biomed Sci.* 2017 Feb 27;24(1):16. doi: 10.1186/s12929-017-0324-1. PMID: 28241824; PMCID: PMC5327512.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5327512/>

<sup>8</sup> Schneider C, Stratman S, Kirsner RS. Lower Extremity Ulcers. *Med Clin North Am.* 2021;105(4):663-679. doi:10.1016/j.mcna.2021.04.006

<sup>9</sup> Eastman DM, Dreyer MA. Neuropathic Ulcer. In: StatPearls. Treasure Island (FL): StatPearls Publishing; September 28, 2022.

<sup>10</sup> O'Meara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. *Cochrane Database Syst Rev.* 2012;11(11):CD000265. Published 2012 Nov 14. doi:10.1002/14651858.CD000265.pub3

<sup>11</sup> Collins L, Seraj S. Diagnosis and treatment of venous ulcers. *Am Fam Physician.* 2010;81(8):989-996.

<sup>12</sup> Agency for Healthcare Research and Quality (2018). Skin Substitutes for Treating Chronic Wounds.

<https://effectivehealthcare.ahrq.gov/products/skin-substitutes/protocol>

<sup>13</sup> Eastman DM, Dreyer MA. Neuropathic Ulcer. In: StatPearls. Treasure Island (FL): StatPearls Publishing; September 28, 2022.

<sup>14</sup> Schneider C, Stratman S, Kirsner RS. Lower Extremity Ulcers. *Med Clin North Am.* 2021;105(4):663-679. doi:10.1016/j.mcna.2021.04.006

<sup>15</sup> Wounds International (2013). Best practice guidelines: Wound management in diabetic foot ulcers.

<https://www.woundsinternational.com/resources/details/best-practice-guidelines-wound-management-diabetic-foot-ulcers>

<sup>16</sup> Eastman DM, Dreyer MA. Neuropathic Ulcer. In: StatPearls. Treasure Island (FL): StatPearls Publishing; September 28, 2022.

<sup>17</sup> Urso B, Ghias M, John A, Khachemoune A. Neuropathic ulcers: a focused review. *Int J Dermatol.* 2021;60(10):e383-e389.

doi:10.1111/ijd.15362

negative pressure wound therapy,<sup>18</sup> and conduct follow-up care to reduce the risk of recurrence after healing.<sup>19</sup>

- Recommendation for the measure (Is it based on a study, consensus opinion, USPSTF recommendation etc.?).

This measure is based on input from a Technical Expert Panel (TEP), Clinical Expert Workgroup, and other interested parties' feedback on the measure concept and the measure specifications.

### III. Reliability/Validity

- What testing has been performed at the level of implementation? (MIPS requires full measure testing at the individual clinician level (and may also need to be tested at the group level) for MIPS Clinical Quality Measures (CQMs) and Electronic Clinical Quality Measures (eCQMs) collection types. Administrative claims measures tested at the group level require a reliability threshold to be implemented at the group level.)

Please provide testing results including the N value, Bonnie test case results, correlation coefficient and any other pertinent information or values to be considered.

- Reliability Testing Results at the accountable entity level

Reliability evaluates a measure's ability to differentiate the performance of one clinician from another consistently. The signal-to-noise ratio is used to estimate reliability, which indicates how much of the variation in the measure score is explained by differences among clinicians' performance (i.e., signal) instead of differences within each clinician's performance (i.e., noise). Specifically, noise is the variation from one episode to another during the performance period for a particular clinician.

The table below shows reliability metrics at various testing volume thresholds. While higher thresholds yield higher reliability results, it is at the cost of further reducing the number of clinicians and clinician groups eligible for the measure, which would reduce the potential impact of the measure. We used a 20-episode volume threshold; for simplicity, we use this threshold across all measures. If the measure is implemented in MIPS in the future, CMS will establish a case minimum through notice-and-comment rulemaking.

CMS generally considers 0.4 as the threshold indicating 'moderate' reliability, which is supported by previous work into reliability and the threshold was finalized in the CY 2022 Physician Fee Schedule final rule<sup>20</sup>. At the 20-episode volume threshold, testing indicates that the mean reliability for the Non-Pressure Ulcers measure is 0.805 at the TIN level and 0.794 at the TIN-NPI level, indicating high levels of reliability for the measure. Additionally, 97.39% and 96.65% of TINs and TIN-NPIs, respectively, meet or exceed the moderate reliability threshold of 0.4.

**Table 3. Sample Size, Mean Reliability, and Proportion of Clinicians above Moderate Reliability at Various Testing Volume Thresholds**

Volume Threshold	TIN			TIN-NPI		
	Number of TINs	Mean Reliability	Percent Above 0.4	Number TIN-NPIs	Mean Reliability	Percent Above 0.4
10	6,755	0.741	90.16%	9,174	0.721	88.23%

<sup>18</sup> Aleksandrowicz H, Owczarczyk-Saczonek A, Placek W. Venous Leg Ulcers: Advanced Therapies and New Technologies. *Biomedicines*. 2021 Oct 29;9(11):1569. doi: 10.3390/biomedicines9111569. PMID: 34829797; PMCID: PMC8615583. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8615583/>

<sup>19</sup> Jindal R, Dekiwadia DB, Krishna PR, Khanna AK, Patel MD, Padaria S, Varghese R. Evidence-Based Clinical Practice Points for the Management of Venous Ulcers. *Indian J Surg*. 2018 Apr;80(2):171-182. doi: 10.1007/s12262-018-1726-3. Epub 2018 Jan 27. Erratum in: *Indian J Surg*. 2018 Apr;80(2):183. PMID: 29915484; PMCID: PMC5991028. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5991028/>

<sup>20</sup> CMS, "Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements," 86 FR 64996-66031.

Volume Threshold	TIN			TIN-NPI		
	Number of TINs	Mean Reliability	Percent Above 0.4	Number TIN-NPIs	Mean Reliability	Percent Above 0.4
20	4,174	0.805	97.39%	4,060	0.794	96.65%
30	2,903	0.847	99.48%	2,111	0.839	98.91%

- Face Validity Testing Results, Clinician Sites

Face validity testing was not conducted for the Non-Pressure Ulcers measure.

- Empiric Validity Testing Results at the accountable entity level

Validity is a criterion used to assess whether the cost measure can quantify the construct it aims to measure, which is the cost directly related to treatment choices and the cost of adverse outcomes resulting from care. Validity is evaluated empirically by estimating the effect of relevant treatment choices on the measure score. This analysis first estimates the correlation between treatment choices and the measure score while controlling for adverse outcomes. Then the correlation between treatment choices and related adverse outcomes is calculated to demonstrate the indirect effect. Generally, adverse outcomes are non-trigger inpatient hospitalizations, non-trigger emergency room visits, and post-acute care. The remaining service categories are typically considered treatment.

Overall, the results demonstrate that the cost measure is reflective of both the cost directly related to treatment choices, as well as cost of adverse outcomes as a result of care (Table 4). Therefore, there's evidence that the measure is capturing what it purports to measure.

Model 1 demonstrates that adverse events are associated with worse clinician performance at the group and individual reporting levels. Ambulatory/minor procedures, imaging services, and durable medical equipment are also associated with a worse measure score at the TIN and TIN-NPI levels. Part D Drugs are associated with worse performance at the TIN-NPI reporting level only. Moreover, these services are associated with a higher cost of adverse events in Model 2, suggesting that the opportunities to reduce these costs are linked to the reduction of adverse events.

Laboratory, pathology, and other test services as well as major procedures are associated with worse clinician performance at the TIN and TIN-NPI levels in Model 1, but not associated with the cost of adverse events in Model 2. This suggests that there is a potential for overuse of these services.

Lastly, the cost of outpatient evaluation and management services, Part B drugs, and Part D drugs is shown to not be a significant driver of the measure score.

**Table 4: Estimated Effect of Treatment Choices on the Measure Score**

Service Categories	Coefficient in Thousands [95% Confidence Interval] (p-value)			
	TIN		TIN-NPI	
	Model 1: Mean O/E = Mean Cost of Treatment Choices + Mean Cost of Adverse Events	Model 2: Mean Cost of Adverse Events = Mean Cost of Treatment Choices	Model 1: Mean O/E = Mean Cost of Treatment Choices + Mean Cost of Adverse Events	Model 2: Mean Cost of Adverse Events = Mean Cost of Treatment Choices
Adverse Events	0.07 [0.06,0.08] (p < 0.01)	-	0.06 [0.06,0.07] (p < 0.01)	-
Outpatient Evaluation & Management Services	0.01 [-0.03,0.04] (p = 0.73)	1.62 [1.46,1.78] (p < 0.01)	-0.03 [-0.08,0.01] (p = 0.13)	1.93 [1.74,2.12] (p < 0.01)
Major Procedures	0.36 [0.16,0.56] (p < 0.01)	0.71 [-0.21,1.63] (p = 0.13)	0.24 [0.04,0.44] (p = 0.02)	0.83 [-0.06,1.71] (p = 0.07)

Ambulatory/Minor Procedures	0.06 [0.05,0.06] (p < 0.01)	0.28 [0.24,0.32] (p < 0.01)	0.06 [0.05,0.07] (p < 0.01)	0.28 [0.24,0.32] (p < 0.01)
Outpatient Physical, Occupational, or Speech and Language Pathology Therapy	0.06 [-0.13,0.24] (p = 0.55)	0.48 [-0.38,1.33] (p = 0.27)	0.09 [-0.08,0.27] (p = 0.31)	0.85 [0.06,1.64] (p = 0.03)
Laboratory, Pathology, and Other Tests	0.96 [0.74,1.18] (p < 0.01)	0.06 [-0.97,1.09] (p = 0.91)	0.90 [0.72,1.08] (p < 0.01)	-0.24 [-1.04,0.56] (p = 0.56)
Imaging Services	0.34 [0.23,0.44] (p < 0.01)	1.78 [1.28,2.27] (p < 0.01)	0.34 [0.21,0.46] (p < 0.01)	1.53 [0.98,2.09] (p < 0.01)
Durable Medical Equipment and Supplies	0.02 [0.02,0.02] (p < 0.01)	0.04 [0.03,0.05] (p < 0.01)	0.02 [0.02,0.02] (p < 0.01)	0.03 [0.02,0.04] (p < 0.01)
Chemotherapy and Other Part B Covered Drugs	0.00 [-0.01,0.00] (p = 0.34)	0.05 [0.04,0.07] (p < 0.01)	0.00 [0.00,0.00] (p = 0.95)	0.03 [0.01,0.05] (p < 0.01)
Part D Drugs	-0.02 [-0.07,0.03] (p = 0.47)	1.10 [0.85,1.35] (p < 0.01)	0.05 [0.00,0.11] (p = 0.05)	0.99 [0.74,1.23] (p < 0.01)

- Data Element/Patient Encounter Level Testing

This is not applicable to the Non-Pressure Ulcers measure.

- Exclusion Frequency

Exclusions specific to the Non-Pressure Ulcers measure are developed with input from the Non-Pressure Ulcers Clinician Expert Workgroup. These exclusion criteria ensure that the reportable episode populations are more homogenous and comparable than all episodes meeting the triggering logic for the measure. The table below displays descriptive statistics of all episodes meeting the measure's triggering logic, excluded episodes, and final reportable episodes at both TIN and TIN-NPI levels.

**Table 5: Frequency of Measure Exclusions**

Exclusion Criteria	Episodes	
	Count	% of All Episodes Meeting Trigger Logic
All Episodes Meeting Triggering Logic	650,065	100.00%
Beneficiary Death in Episode	109,007	21.10%
Outlier	7,785	1.51%
Calciphylaxis	1,947	0.38%
Hidradenitis Suppurativa	739	0.14%
Recent Hospice	7,410	1.43%
Pyoderma Gangrenosum	1,909	0.37%
Scleroderma	1,757	0.34%
Sickle Cell Anemia	497	0.10%
Vasculitis	5,185	1.00%
TIN does not Meet Testing Volume Threshold	112,738	21.83%
TIN-NPI does not Meet Testing Volume Threshold	278,654	53.95%
<b>Reportable Episodes</b> (if all clinicians reported as TIN at the testing volume threshold)	296,588	57.42%
<b>Reportable Episodes</b> (if all clinicians reported as TIN-NPI at the testing volume threshold)	153,129	29.64%

- What were the minimum sample sizes used for reliability results?

Please refer to table 2 for the breakdown of TINs and TIN-NPIs that meet the 10, 20, and 30 case volume thresholds used to assess reliability

- Other Information
  - Is it risk adjusted? If so, how?

The Non-Pressure Ulcers episode-based cost measure is a risk-adjusted measure. The risk adjustment model for this measure uses a log-linear regression model, which utilizes variables from the CMS Hierarchical Condition Code Version 24 (CMS-HCC V24) 2021 Risk Adjustment Model. This includes comorbidities captured by 86 HCC codes that map with thousands of ICD-10-CM codes, and other standard risk adjustors, including interaction variables accounting for a range of comorbidities, patient level demographics (i.e., age) and health status (i.e., disability status, end-stage renal disease [ESRD] status, recent use of long-term care), dual eligibility, and types of clinician specialties from which the patient has received care. Additional risk adjustors that are clinically relevant to this measure were developed with input from the Non-Pressure Ulcers Clinician Expert Workgroup. The measure is further stratified by sub-group and Part D enrollment status (i.e., arterial ulcer type with/without Part D enrollment, diabetic ulcer type with/without Part D enrollment, venous ulcer type with/without Part D enrollment, non-specific ulcer with/without Part D enrollment, and multiple ulcer types with/without Part D enrollment); risk adjustment is performed separately for episodes within each combination to allow for comparisons within more clinically homogenous cohorts.

As background for the risk adjustment approach, Acumen received generalized feedback on risk adjustment in episode-based cost measure calculation during a previous TEP meeting. This input informed the way in which the Clinician Expert Workgroup’s feedback on risk adjustors and exclusions was sought and incorporated. The draft measure also underwent a national field testing period and public comment periods, where interested parties were able to provide feedback on the measure specifications including the risk adjustment model. The Clinician

Expert Workgroup had an opportunity to further refine the measure specifications after considering feedback collected during field testing.

- What benchmarking information is available?

This measure provides a score evaluating clinician's risk-adjusted resource use as a dollar amount which can be compared with the scores for other clinicians, as well as relevant national averages.

- Collection Type: Specify the data collection type.

This measure uses administrative Medicare claims data.

- Specify measure stage of development.

This measure is fully developed.

- For Patient Reported Outcome Performance Measures:
  - The survey or tool has been tested and does not require modifications based on results?
  - Patient/encounter level testing for each critical data element does not require changes to the tool base on the results?

This is not applicable to the Non-Pressure Ulcers measure.

#### **IV. Endorsement**

- Provide the Consensus-Based Entity (CBE) (i.e., Partnership for Quality Measures (PQM)) endorsement status (and CBE ID) and/or other endorsing body. If the measure is only endorsed for paper records, please note endorsement for only the data source being submitted.

This measure is not currently endorsed by the CBE and has never been submitted for endorsement.

#### **V. Summary**

- Alignment with CMS Meaningful Measures Initiative or MACRA (if applicable).

This cost measure aligns with CMS's Meaningful Measures 2.0 domain of Affordability and Efficiency. Through this measure, we aim to improve care by optimizing health outcomes and resource use associated with treating and managing non-pressure ulcers. The development of episode groups for resource use analysis is also required by section 101(f) of MACRA.

- Relevance to MIPS or other CMS programs.

This measure would be proposed in future rulemaking for inclusion in the Cost performance category for MIPS. If finalized through rulemaking, the measure would assess clinician performance in the Cost performance category, and could count toward the overall MIPS final score.

- Rationale: Use of measure for inclusion in program (specialty society, regional collaborative, other).

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, and assesses costs for a condition not captured by other cost measures, as well addressing a gap in clinician coverage of cost measures for specialists such as podiatrists.<sup>21</sup> 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. The measure's development is aligned with episode-based cost measures currently used in the program.

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<sup>21</sup> CMS, 2023 Call for Cost Measures, <https://mmshub.cms.gov/sites/default/files/2022-Call-for-Cost-Measures-Fact-Sheet.pdf>

- Public reporting (if applicable).

This is not applicable to the Non-Pressure Ulcers measure.

- Preferable relevant peer-reviewed journal for publication.

*International Wounds Journal* and *Wounds*

- Rationale as to how the measure correlates to existing cost measures and improvement activities, as applicable and feasible.

This episode-based cost measure correlates with episode-based cost measures currently used in the Cost performance category of MIPS, as they were developed under the same comprehensive framework and systematic process that account for the roles and responsibilities of individual clinicians in the care of patients experiencing specific health conditions. Compared to the two population-based cost measures used in MIPS, Medicare Spending Per Beneficiary (MSPB) clinician and TPCC, episode-based cost measures only include items and services related to the episode for a clinical condition or procedure as opposed to all services provided to a patient over a given timeframe. While the two population-based measures may capture some of the same costs as episode-based cost measures, there is no risk of double counting as the measures are calculated separately and averaged into a single score for the MIPS Cost performance category. Across the different episode-based cost measures, each measure is tailored to assess the clinician's role in performing a particular procedure or managing a specific condition adjusted by specialty for the defined scope of the measure.

There are no improvement activities in MIPS specific to non-pressure ulcers. However, there are improvement activities related to diabetic care, which is the underlying condition for diabetic ulcers captured by this measure. These include Glycemic Management Services (IA\_PM\_4), Glycemic Referring Services (IA\_PM\_20), and Glycemic Screening Services (IA\_PM\_19). Additionally, there are improvement activities related to chronic care and care transition, including Chronic Care and Preventative Care Management for Empowered Patients (IA\_PM\_13), Care Transition Documentation Practice Improvements (IA\_CC\_10), Care Transition Standard Operational Improvements (IA\_CC\_11), which may correlate with the Non-Pressure Ulcers measure as it aims to improve outcomes for patients that have chronic conditions or diseases and care transition.