2024 Pre-Rulemaking Measure Review
Preliminary Assessment

MUC ID	Title
MUC2024-101	Parkinson's Syndromes, Multiple Sclerosis (MS), and Amyotrophic Lateral Sclerosis (ALS)
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): Parkinson's disease, other degenerative diseases of basal ganglia, multiple sclerosis (MS), and amyotrophic lateral sclerosis (ALS) affect nearly half a million of Medicare beneficiaries, and patients with these disorders have higher utilization of health care services. There are many improvement opportunities to advance patient care and reduce health care costs for patients with Parkinson's syndromes, MS, or ALS. The Parkinson's Syndromes, MS, and ALS 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 as addressing a gap in clinician coverage of cost measures as other existing episode-based cost measures are not applicable to neurologists providing chronic care and outpatient care management. 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 Parkinson's Syndromes, Multiple Sclerosis (MS), and Amyotrophic Lateral Sclerosis (ALS) episode-based cost measure to the MIPS measure set. The Parkinson's Syndromes, Multiple Sclerosis (MS), and Amyotrophic Lateral Sclerosis (ALS) measure impacts a large patient population and represents significant costs to Medicare for managing these conditions and their complications. Literature and testing suggest that there are opportunities for improvement in addressing the high costs associated with fall-related treatment. Additionally, the measure will fill a measurement gap in the MIPS measure set by capturing chronic condition care provided by neurologists, a specialty with limited applicability of existing cost measures in MIPS.
Description: The Parkinson's Syndromes, MS, and ALS 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 Parkinson's and related conditions, MS, or ALS. This chronic condition measure includes the Medicare Parts A, B, and D costs for services that are clinically related to managing and treating Parkinson's Syndromes, MS, or ALS episode.

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

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 Parkinson's Syndromes, MS, and ALS 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 Parkinson's Syndromes, MS, and ALS 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 spinal cord injury.
- Patients with microvascular decompression.
- Patients with stereotactic radiosurgery.

Exceptions: N/A

Measure type: Cost/Resource Use	**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
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

Measure Overview	
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 [Source: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) Submission Form]
Importance: Parkinson's disease, other degenerative diseases of basal ganglia, multiple sclerosis (MS), and amyotrophic lateral sclerosis (ALS) affect nearly half a million Medicare beneficiaries, and these patients have higher health care utilization, including higher rates of emergency department (ED) admissions, inpatient stays, skilled nursing facility (SNF) stays, and home health utilization. Economic burden is high: the measure captures approximately $2.48 billion in Medicare spending. Areas of possible improvement in care for these conditions include improving fall-related education and treatment, screening patients for additional comorbidities not related to physical complications, and mitigating drug interactions or use of inappropriate medications. The developer did not evaluate 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 in an iterative process from persons (i.e., patients and family) with lived experience and that input was shared with the clinician workgroup to inform their discussion of measure specifications.	
Rating: Met	

Measure Performance

For Tables 1a and 1b, the developer provided the mean score and number of entities for each performance score decile along with the minimum and maximum performance scores observed.

Interpretation: The mean score for the 2,930 entities described in the testing submission for this measure was 14645.70 and 14425.28, respectively. The mean score for the 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. MUC2024-101 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)	14645.70 (4130.33)	2014.41	8339.16	10713.04	12014.84	12996.85	13901.50	14689.67	15596.01	16716.66	18387.15	23102.13	39313.90
Number of Entities	2,930	1	293	293	293	293	293	293	293	293	293	293	1

Table 1b. MUC2024-101 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)	14425.28 (4801.49)	2014.41	7485.54	9939.40	11154.53	12193.55	13255.58	14369.17	15521.06	16907.97	19073.89	24352.10	40684.17
Number of Entities	2,930	1	293	293	293	293	293	293	293	293	293	293	1

Conformance
Measure alignment with conceptual intent: A submission attachment provides a comprehensive, detailed list of codes associated with the measure 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 provides steps for calculating the measure score [Source: Methodology August 2024]. Specification is aligned with conceptual intent.
Rating: Met

Feasibility	
eCQM feasibility testing/analysis conducted:	No [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	

Validity

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, physical/occupational/speech therapy, 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, such as emergency department visits, hospitalizations, and post-acute care. The treatment choices and adverse events were collectively linked to risk-adjusted 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 (i.e., higher cost) were costs for major procedures, outpatient physical/occupational/speech and language pathology therapy ("OT/PT/speech"), imaging services, laboratory tests, and Part B-covered drugs (Model 1). These same factors were also usually associated with lower adverse events costs (Model 2), which the developer interpreted as evidence that such services are beneficial to patient outcomes but may be prone to overuse. Outpatient evaluation and management (E/M) services and durable medical equipment (DME) were associated with modestly better performance scores at both levels (Model 1) but substantially higher costs of adverse events (Model 2); the developer states that reduction of adverse events could also reduce costs for E/M and DME services. Part D costs are associated with a worse measure score at both reporting levels (Model 1) but do not have a statistically significant association with the cost of adverse events at the group level (Model 2), which the developer interpreted as potential to reduce medication costs without increasing the occurrence of adverse events [Source: MERIT Submission Form; Measure Justification Form].

The developer also provided testing showing that episodes with adverse events have higher risk-adjusted costs compared to the average risk-adjusted episode cost ($14,565). Episodes with clinically related hospitalizations have more than two times higher risk-adjusted episode costs ($37,769) and episodes with clinically related emergency department visits have approximately 40% higher risk-adjusted episode costs ($20,614) [Source: Episode-Based Cost Measure (EBCM) At-A-Glance].

The developers stated that these findings support the measure's validity because they indicate that the measure assesses the intended costs, which include costs associated with the treatment choices and the consequences of those treatment choices.

The developer also analyzed if there was an association between social risk and performance by examining the coefficient of patient-level dual Medicare and Medicaid status when added into the risk model. Results showed there was a statistically significant association between a patient's dual status and episode costs for the Parkinson's and Related Conditions subgroups, and the Multiple Sclerosis with Part D enrollment subgroups. Additionally, clinicians and groups tended to perform worse on

Validity
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]. 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 and that there is adequate consistency in these results?
Threats to validity: The developer considered potential threats to validity of the measure and developed a risk-adjustment model to address this. The risk-adjustment model was developed in collaboration with the technical expert panel (TEP) and clinical workgroup. Variables included in the risk-adjustment model were "standard" risk adjusters (hierarchical condition codes, disability status, age category, disability status, end-stage renal disease status, dual-eligibility status, and types of clinician specialties from which the patient has received care), and condition-specific clinical risk factors (frailty; wheelchair dependence; history of falling; difficulty swallowing; cognitive status impairment, decline, or deficit; deep brain stimulation; dysphonia; dysarthria and anarthria; other degenerative diseases of basal ganglia; past contracture diagnoses; sleep apnea; bowel or bladder incontinence; dependence on respirator; and intrathecal pump during the episode). Risk models are stratified by each subgroup and Part D enrollment status combination. The measure subgroups are: Parkinson's and Related Conditions, Multiple Sclerosis (MS), and Amyotrophic Lateral Sclerosis (ALS). The model shows acceptable calibration and reports the amount of variance in model due to risk factors versus provider performance.
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 2,930 TINs and 2,930 TIN-NPIs. The median reliability (at a 20-episode threshold) for the TINs and TIN-NPIs is 0.611 and 0.571, respectively. This indicates that roughly 50% of TINs in the testing data had reliability >0.6 and were capable of distinguishing between poor and good quality care. However, both exceed the 0.4 reliability required for MIPS. 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 4-week public comment period to determine measure concepts for development, a TEP (20 members: clinicians, administrators, patients), a clinical expert panel ("workgroup": 15 members representing 18 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; providers were predominantly neurologists [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. They indicated that the proposed measure aligns with several quality measures in the Supportive Care for Neurodegenerative Conditions MIPS Value Pathway. They identified process measures focused on patient assessments, referrals, end-of-life planning, prescribing, health-related social needs, and plan of care for falls as potentially relevant MIPS measures [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, proposed CMS 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 proposed CMS program?	