2024 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2024-079	Assessment of Autonomic Dysfunction and Follow-Up
Measure Steward & Developer	**Proposed CMS Programs**
American Academy of Neurology (AAN)	Merit-based Incentive Payment System (MIPS)–Quality

Measure Overview
Developer-provided rationale (excerpt from submission): Autonomic dysfunction is directly related to the quality of life of people with Parkinson's disease (PD). Autonomic dysfunction was found to be the most prevalent non-motor symptom of PD, affecting more than 70% of patients in all stages of PD. The desired outcome is to address and eliminate autonomic dysfunction in people with PD. This measure will provide an incentive for providers to identify autonomic dysfunction and offer available treatments to improve quality of life.
CMS-provided program rationale: CMS may add the Assessment of Autonomic Dysfunction and Follow-Up measure to the MIPS quality measure inventory as a new clinical quality measure. The measure fills a gap within MIPS for patients with PD. The intent of this measure is to improve screening rates for autonomic dysfunction in PD patients receiving care in ambulatory or office-based care settings. This process measure includes assessment and follow-up and will provide an incentive for providers to identify autonomic dysfunction while offering available treatments to improve quality of life. This measure is currently a MIPS qualified clinical data registry (QCDR) measure, and it was in the Neurodegenerative Conditions MIPS Value Pathway (MVP) with potential for future inclusion in the proposed Quality Care for Patients with Neurologic Conditions MVP. This measure is fully tested and developed, and the testing data provided demonstrates room for improvement with a median performance rate of 20.6% and mean performance rate of 37%.
Description: Percentage of patients with a diagnosis of PD (or caregivers as appropriate) who were assessed for symptoms of autonomic dysfunction in the past 12 months, and if autonomic dysfunction was identified, patient had appropriate follow-up.
Measure background: New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or Pre-Rulemaking Measure Review (PRMR) or used in a Medicare program.

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Measure Overview	
Numerator: Patients (or care partners as appropriate) who were assessed(i) for symptoms or signs of autonomic dysfunction(ii) once in the past 12 months and if autonomic dysfunction identified, patient had appropriate follow-up (iii) i) Assessed is defined as use of a screening tool or discussion with the patient or care partner ii) Symptoms of autonomic dysfunction is defined as including at least one of the following: - orthostatic hypotension or intolerance - constipation - urinary urgency - incontinence or nocturia - fecal incontinence - urinary retention requiring catheterization - delayed gastric emptying - dysphagia - drooling or sialorrhea - hyperhidrosis - sexual dysfunction or erectile dysfunction - syncope, lightheadedness, or dizziness Signs of autonomic dysfunction: - orthostatic vital signs iii) Follow-up actions: - Orthostatic hypertension: stop antihypertensives, add midodrine or droxidopa, or home monitoring - Constipation: recommended/use PEG 3350, senokot, or Dulcolax - Urinary urgency or incontinence: recommended/use oxybutynin, refer to incontinence clinic, have urodynamics, add mirabegron - Urinary retention: catheterization inserted/placed\Dysphagia: may require speech language pathologist\Drooling: botulinum toxin injection, atropine drops - Sexual dysfunction: referral to PCP **Exclusions:** N/A	
Denominator: All patients with a diagnosis of Parkinson's disease **Exclusions:** N/A **Exceptions:** N/A	
Measure type: Process	**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	**Data source(s):** Digital-Clinical Registries; Digital-Electronic Health Record (EHR) Data

Measure Overview	
Care setting(s): Ambulatory/office-based care	**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:	Peer-reviewed literature [source: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) Submission Form]
Importance: Screening for autonomic dysfunction is consistent with National Institute for Health and Care Excellence (NICE) PD in adults clinical practice guidelines (NICE guideline 71). Autonomic dysfunction is directly related to the quality of life of people with PD, affecting more than 70% of patients in all stages of PD. A 2013 study by Baek et al. noted that provider compliance rate for annual review of autonomic dysfunction was 22.8%. Pilot testing data for the measure, which was conducted in 2023 and used 7 months of performance data for 258 clinicians, found the average performance rate was 42.02%, with a range of 0.92-100%, suggesting there is significant room for improvement.	
Rating: Met	

Measure Performance

Table 1 shows deciles (i.e., the data sorted and broken into 10 equal parts) based on the data provided in the testing submission for the 163 entities.

Interpretation: The mean score for the 163 entities described in the testing submission for this measure was 20.5. For this proportion measure, a higher score indicates better quality of care.

Table 1. MUC2024-079 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)	20.5 (29.3)	0	0	5	7.5	10	17	24	50	60	70	80	100
Number of Entities	163	20	17	16	16	17	16	16	17	16	16	16	2

Conformance
Measure alignment with conceptual intent: The purpose of this measure is to improve screening rates for autonomic dysfunction in PD patients receiving care in ambulatory or office-based care settings. The denominator includes all patients diagnosed with PD. There are no denominator exclusions or exceptions, suggesting the measure captures the population of interest as specified.
Rating: Met

Feasibility	
eCQM feasibility testing conducted:	No [Source: MERIT Submission Form]
Feasibility: The measure relies on a combination of standardized fields and manually abstracted data elements. Some data elements are in defined fields in electronic sources and align with USCDI/USCDI+ Quality standard definitions. The submission materials indicate that no workflow changes are needed for this measure. The committee should consider the feasibility and benefit/burden tradeoff for manually abstracted data elements of this measure.	
Rating: Met	

Validity	
Validity testing method(s):	Face Validity, Data Element Validity, Convergent Validity [Source: MERIT Submission Form]
Testing level(s)	Provider
Validity: A technical expert panel (TEP) established face validity, with 83% of the panel voting in favor of the measure's face validity. Data element validity was established by comparing eight patient encounter records for the measure being tested to an authoritative source. Convergent validity for the measure was assessed by examining correlations between the measure and a measure of screening for risk in patients with dementia or their caregivers in a sample of 149 providers. As expected, the measures were positively correlated ($r = 0.38$, p.001, $r^2 = 0.15$). While statistically significant, these correlations are weak and may indicate lack of alignment between this measure and the one selected for comparison. The committee should consider if this level of empiric validity is sufficient to demonstrate measure validity.	
Threats to validity: The measure developer could strengthen this measure submission through the interpretation of those correlations with a logic model or concept model that specifies the mechanisms in common among the measures that could be responsible for that correlation.	
Rating: Met	

Reliability	
Reliability testing method(s):	Signal-to-Noise [Source: MERIT Submission Form]
Testing level:	Individual Clinician
Reliability discussion: The numerator and denominator for this measure are well defined. Reliability is calculated from a dataset consisting of 8,261 patients across 163 providers. The median reliability is 0.96, the lower 25th percentile is 0.90, and the minimum is 0.35. Nearly all the entities have a reliability >0.6, suggesting that this measure is capable of differentiating entities by quality of performance. The reliability could be lower for facilities with small denominators or if the measure is calculated with data for a shorter time-period.	
Additional reliability analyses: For Tables 1 and 2, Battelle used the performance and reliability data provided to approximate decile averages by interpolation.	
Rating: Met	

Reliability Tables

Tables 1 and 2, respectively, show deciles for reliability based on the data provided in the testing submission for the 163 entities. Battelle created these tables to provide reviewers with a standardized format to assess reliability.

Interpretation: Nearly all the entities have a reliability >0.6, suggesting that this measure is capable of differentiating entities by quality of performance.

Table 2. MUC2024-079 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
0.93	0.14	0.35	0.67	0.75	0.90	0.91	0.94	0.97	0.98	1.0	1.0	1.0	1.0	0.1

Usability	
Usability considered in application:	No
Usability discussion: Based on discussion of the measure in 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. No unintended consequences were indicated in the submission.	
Rating: Met	

External Validity	
Was this measure tested in the same target population as the CMS program?	Not determined
External validity discussion: This measure has been used for MIPS reporting since 2017 as Qualified Clinical Data Registry (QCDR) measure AAN 9 for the Quality component; however, the Axon QCDR is being phased out in 2024. The revised measure was tested with 7 months of performance data from 258 clinicians in 2023 that represented the broad MIPS clinician population.	
Rating: Met	

Appropriateness of Scale

Similar or related measures in program(s):	None identified
Measure appropriateness, equity, and value across target populations/measured entities: AAN seated a multidisciplinary TEP to create the Parkinson's measure. AAN conducted a public comment period where members of AAN and associations that participated on the TEP were invited to review the measure and provide comment. In a focus group of three Parkinson's patients and three care partners, two individuals found this measure very important, three found it fairly important, and one found it important. The feedback from the focus group indicated that autonomic dysfunction issues are the top concern for patients with Parkinson's as they address quality-of-life issues. These issues affect patients every day and hinder their ability to leave the house. This measure may lead to an emphasis on screening for and addressing autonomic dysfunction over aspects of care not specifically named. However, because this area has been deemed important by patients, caregivers, and provider stakeholders, the adverse consequences of such an emphasis are likely minimal. 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:	No
Measure implementation impacts over time: The measure developer does not articulate a relationship between the measure and patient benefits or harm over time.	

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 clinicians, 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?