2024 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2024-084	Quality of Life Outcome for Patients with Neurologic Conditions
Measure Steward & Developer	**Proposed CMS Programs**
American Academy of Neurology (AAN)	Merit-based Incentive Payment System (MIPS)–Quality

Measure Overview
Developer-provided rationale: Measuring quality of life allows patients and providers to identify areas of concern and develop appropriate treatment plan adjustments as needed. Assessing the quality of life for patients with neurologic conditions allows clinicians to address patient concerns and intervene, when possible, to reduce certain symptoms or address situations that may reduce the patient's feeling of well-being. Collecting quality of life data in a neurology ambulatory setting is feasible and found to be meaningful.
CMS-provided program rationale: CMS may add the Quality of Life Outcome for Patients with Neurologic Conditions measure to the MIPS quality measure inventory as a new clinical quality measure. It addresses a CMS priority for patient experience of care assessing patient-reported quality-of-life outcomes for patients with neurologic conditions using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health tool. Measuring quality of life allows patients and providers to identify areas of concern and develop appropriate treatment plan adjustments as needed. This measure is currently in use as a qualified clinical data registry (QCDR) measure and is in the CMS Innovation Center Dementia Care Model. The QCDR measure is also in two MIPS Value Pathways (MVPs): Supportive Care for Neurodegenerative Conditions and Optimal Care for Patients with Episodic and Neurological Conditions (such MVPs are proposed to be combined into one MVP: Quality Care for Patients with Neurologic Conditions). There is potential for future inclusion in the proposed combined Quality Care for Patients with Neurologic Conditions MVP.
Description: Percentage of patients whose quality of life assessment results are maintained or improved during the measurement period.
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 whose Patient-Reported Outcomes Measurement Information System (PROMIS) Global Health 10 score at 12 months (+/- 60 days) was maintained or improved from the index score. For patients with more than 2 scores present at twelve months (+/- 60 days) the last score recorded shall be compared to the index visit score. **Exclusions:** N/A	
Denominator: Patients aged 18 years and older diagnosed with a neurologic condition. Denominator identification period: The period in which eligible patients can have an index event. The denominator identification period occurs prior to the measurement period and is defined as 14 months to two months prior to the start of the measurement period. For example, the denominator identification period for the 2019 calendar year is from 11/1/2017 to 10/31/2018. For patients with an index event, there needs to be enough time following index for the patients to have the opportunity to reach comparison twelve months +/- 60 days after the index event date. **Exclusions:** • Patients who died • Second PROMIS Global Health 10 score not collected at 12 months (+/- 60 days) **Exceptions:** N/A	
Measure type: Patient-Reported Outcome Performance Measure (PRO-PM) or Patient Experience of Care	**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-Applications: Patient-Reported Health Data or Survey Data (electronic); Digital-Clinical Registries; Digital-Electronic Health Record (EHR) Data; Digital-Patient Portal Data; Non-Digital-Patient-Reported Health Data or Survey Data (telephonic or paper-based)
Care setting(s): Ambulatory Care	**Risk adjustment or stratification:** None
CBE endorsement status: Never submitted	**CBE endorsement history:** Never submitted
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** No

Meaningfulness

Importance	
Type of evidence:	Empirical data [source: MERIT Submission Form]
Importance: The submission did not report performance scores for this new measure. For assessment of any performance gap, the developer stated in the submission, "There is no non-zero performance data from the Axon Registry." The developer did not present any clinical guidelines or systematic reviews. Empirical data focused on performance of the PROMIS global health items and feasibility of implementation of the instrument in ambulatory care settings. One study evaluated the psychometric properties of PROMIS-10 for patients with ischemic stroke and intracerebral hemorrhage and found acceptable performance, recommending its use in outcome measures for patients with stroke. The submission did not discuss studies linking processes, structures, or interventions with quality of life in this population. In terms of meaningfulness to patients, the developer noted their technical expert panel (TEP) included a patient and a caregiver who advocated for the measure despite clinician disapproval. Discussion with the developer provided context that clinicians on the work group were concerned about being held responsible for the quality of life of patients with neurodegenerative disorders with the consideration stated that, more often than not, neurology patients' health and quality of life gets worse over time due to the disease course, regardless of treatments. The committee should consider requesting clarification regarding existence of a performance gap and should explore the concerns that clinicians on the TEP expressed regarding this measure.	
Rating: Not Met but Addressable	

Conformance
Measure alignment with conceptual intent: The measure specifications align with the focus (patient-reported quality of life for patients with neurologic conditions) among patients aged 18 years and older diagnosed with a neurologic condition.
Rating: Met

Feasibility	
eCQM feasibility testing conducted:	Yes
Feasibility: According to the Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) submission form for this measure**,** all data elements are defined in electronic fields and align with United States Core Data for Interoperability (USCDI)/USCDI+ quality standard definitions. The provider workflow did not need to be modified to collect measure data. Collecting patient-reported outcomes, including using the PROMIS tool, has been shown to be feasible in neurological ambulatory care settings.	
Rating: Met	

Validity	
Validity testing method(s):	Face Validity [Sources: MERIT Submission Form, Methodology Measure Specs]
Testing level(s):	N/A
Validity: The developer reported that 12 out of 17 TEP members (71%) voted in favor of the measure's face validity; the submission did not provide any discussion details. The developer did not evaluate empiric validity; the developer also indicates there are no plans to test at this time. Additional assessment of empiric validity or face validity in a sample more representative of the CMS program population could strengthen the scientific acceptability of this measure. The developer also reported the results of an analysis of patient/encounter-level testing that evaluated percent agreement between a manual reviewer and another in-use measure for numerator, denominator, and exclusions criteria. The initial sample was eight patient encounter records, with the plan to sample an additional 30 records if an error was found. The evaluation compared findings from an audit of the Axon Registry clinical data with manual abstraction from the same data source. The results for each data element were in 100% agreement within the initial sample of eight records. Committee members could consider whether a sample size of eight for data element testing is sufficient for this population and whether the results will be applicable beyond the Axon Registry.	
Threats to validity: The developer did not risk adjust but provided a list of potential data elements developed by their work group. These include comorbidities, cognitive impairments, trauma exposure, resource utilization, duration of neurological disease, polypharmacy, physical function, and use of interpreter [Source: Methodology Measure Specs]. Stratification has not been recommended.	
Rating: Met	

Reliability	
Reliability testing method(s):	None
Testing level:	N/A
Reliability discussion: Reliability testing was not performed; developer indicates there are no plans to test at this time.	
Additional reliability analyses: N/A	
Rating: Not Met	

Usability	
Usability considered in application:	Yes [Source: MERIT Submission Template, MIPS Peer-Reviewed Journal Article Form]
Usability discussion: Developer notes that they utilized a multidisciplinary TEP and public comment periods to collect input about the measure; they do not provide details regarding the content of the input collected. A potential unintended consequence is the possibility that clinicians who treat patients with chronic degenerative diseases may be penalized. This measure is currently in use in the AAN's Axon Registry as AAN 22 and was approved for this use by CMS in 2019. Developer also states the measure is currently in use in the CMS Innovation Center (CMMI) Dementia Care Model and in two MVPS Value Pathways: Supportive Care for Neurodegenerative Conditions and Optimal Care for Patients with Episodic Neurological Conditions. The developer cited several MIPS improvement activities, such as engagement of patients, family, and caregivers in developing a plan of care and use of certified EHR to capture patient-reported outcomes, among others [Source: MIPS Peer-Reviewed Journal Article Form].	
Rating: Met	

External Validity	
Was this measure tested in the same target population as the CMS program?	N/A
External validity discussion: This measure has not been tested in populations generalizable to the proposed CMS program population to indicate external validity of the measure.	
Rating: Not Met	

Appropriateness of Scale

Similar or related measures in program(s):	None
Measure appropriateness, equity, and value across target populations/measured entities: This criterion cannot be evaluated for this measure based on the information provided in the submission. The committee may consider these potential questions as more information becomes available: • How might different populations see different benefit from use? • Do the focus and target population align with the proposed program to make it an appropriate addition? • Will the measure have the same impact in rural or low-resource settings? • Does the developer address barriers to use of measure for specific populations? • Is the measure more appropriate for some care settings than others within MIPS?	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	The developer cited some measure impacts, including patient health improvements and patient-centered care by promoting the identification areas of concern and development of treatment plans. [Source: MIPS Peer-Reviewed Journal Article Form, MERIT Submission Form]
Measure implementation impacts over time: While the measure developer briefly mentions potential outcomes for their measure on 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?	