2024 Pre-Rulemaking Measure Review
Preliminary Assessment

MUC ID	Title
MUC2024-031	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)
Measure Steward & Developer	**Proposed CMS Programs**
American Gastroenterological Association (AGA)	Merit-based Incentive Payment System (MIPS)–Quality

Measure Overview
Developer-provided rationale (excerpt from submission): Achieving SVR is the first step toward reducing future HCV morbidity and mortality. Once achieved, SVR is associated with long-term clearance of HCV infection, which is regarded as a virologic "cure," as well as with improved morbidity and mortality. Patients who achieve SVR usually have improvement in liver histology and clinical outcomes.
CMS-provided program rationale: CMS may add the Hepatitis C Virus (HCV): Sustained Virological Response (SVR) measure to the MIPS quality measure inventory as a new clinical quality measure. MIPS does not have any related measures that examine achieving SVR and improvement in HCV infection, which could benefit quality of patient care by reducing future HCV morbidity and mortality and generating cost savings. This measure is fully tested and developed. This outcome measure represents a gap in the MIPS/CMS priority area of the Chronic Conditions' Goal: Improved Disease-Specific Outcomes plus has potential for inclusion in two MIPS Value Pathways (MVPs): Gastroenterology and the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV.
Description: Percentage of patients aged greater than or equal to 18 years with active HCV with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.
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: All patients aged greater than or equal to 18 years at the time of the eligible encounter with an eligible encounter and positive/detectable HCV RNA test result in the denominator identification period who have a subsequent negative/undetectable HCV RNA test result 20 weeks to 12 months after first positive/detectable HCV RNA test result identified in the denominator identification period. **Performance Met:** The patient achieved sustained virological response as identified by an HCV RNA test (CPT 87522) or (CPT 87521) with a negative/undetectable HCV RNA result

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Measure Overview	
that occurred 20 weeks to 12 months after the first positive/detectable HCV RNA test result within the denominator identification period. OR Denominator Exception: Repeat HCV RNA labs not performed for medical reasons documented by clinician (e.g., delay in treatment of HCV related to treatment of HIV, HBV, hepatocellular carcinoma, decompensated cirrhosis) OR Performance Not Met: Patient did not achieve sustained virological response. Sustained virological response is identified by an HCV RNA test (CPT 87522) or (CPT 87521) with a negative/undetectable HCV RNA result that occurred 20 weeks to 12 months after the first positive/detectable HCV RNA test result within the denominator identification period.	
Denominator: All patients aged greater than or equal to 18 years at the time of the eligible encounter within the denominator identification period AND Patient encounter during the denominator identification period (CPT): 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215 WITH Hepatitis C Virus Quantitative or Qualitative RNA Test Completed (CPT 87522) or (CPT 87521) within the denominator identification period AND Positive/Detectable Hepatitis C Virus Quantitative or Qualitative RNA Test Result within the denominator identification period. **Exclusions:** Medical reasons for not receiving Hepatitis C testing or treatment documented by clinician (e.g., patients with limited life expectancy, hospice, palliative care, death)	
Measure type: Outcome	**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: Claims Data; Digital-Electronic Health Record (EHR) Data; Non-Digital-Other: Some elements in chart notes
Care setting(s): Ambulatory/office-based care; Other: Practices including both academic and private	**Risk adjustment or stratification:** No
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:	Clinical Guidelines or U.S. Preventive Services Task Force (USPSTF) Guidelines; Peer-Reviewed Original Research [Sources: Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT) Submission Form, MIPS Peer-Reviewed Journal Article Form]
Importance: This measure is aligned with the Hepatitis C Guidance 2023 Update: American Association for the Study of Liver Diseases–Infectious Diseases Society of America Recommendations for Testing, Managing, and Treating Hepatitis C Virus Infection. The literature review and gap analysis submitted indicate that there is both a benefit to quality of patient care to reduce future HCV morbidity and mortality and cost savings supporting the importance of this measure.	
Rating: Met	

Measure Performance

Table 1 shows performance score deciles (i.e., the data sorted and broken into ten equal parts) based on the information provided for the 15 entities described in the testing submission.

Interpretation: The mean score for the 15 entities described in the testing submission for this measure was 48. For this proportion score, a higher score indicates better quality of care.

Table 1. MUC2024-031 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)	48 (11)	23	25	40	42	45	49.5	54	55	56	57	63	63
Entities	15	1	2	1	2	1	2	1	2	1	2	1	1

Conformance
Measure alignment with conceptual intent: As outlined in the MIPS Peer-Reviewed Journal Article Form and MERIT submission, this measure's specification is appropriate and aligned with the measure target (Percentage of patients with negative/undetectable HCV RNA) among adult patients with HCV seen in ambulatory/office-based care. Numerator and denominator populations are appropriate and exclusions align with clinical evidence.
Rating: Met

Feasibility	
eCQM Feasibility testing conducted:	No [Source: MERIT Submission Form]
Feasibility: Some data elements are in defined fields in electronic sources and align with United States Core Data for Interoperability (USCDI)/USCDI+ quality standard definitions. The submission did not indicate any additional changes to provider workflow for the implementation of this measure. The submission materials for this measure indicate that the measure has undergone feasibility testing and communication with the developer affirms that data element feasibility was conducted across four sites. Additionally, risk factors for SVR were collected as part of standard workflow and appeared in structured fields.	
Rating: Met	

Validity	
Validity testing:	Face Validity & Empiric Validity [sources: MERIT Submission Form, Attachment of Additional Results, MIPS Peer-Reviewed Journal Article Form]
Testing level(s):	Individual and Group Clinician Level
Validity: Face validity was established through interviews with a group of seven experts and patients as well as a public comment period during measure development that received favorable clinician responses. All clinicians/experts agreed that measures scores would distinguish between good and poor care and identify care quality gaps. The developer conducted empiric hypothesis-based validity testing at the clinician and clinician group levels to assess the ability of the measure to distinguish measure scores among distinct patient groups. This was assessed through Cohen's effect sizes of differences in performance scores by clinical-level and patient-level groups and assessed in 2021 and 2022 samples stratified by sex, insurance status, and the presence of a comorbidity such as HBV or HIV. In the 2022 clinician-level analysis, there was a small Cohen's D effect (0.21) for differences in the SVR rates by sex, with females having slightly higher rates of SVR than males. In the 2021 clinician-level analysis, there was medium Cohen's effect (0.71) with males having higher rates of SVR than females. In the patient-level 2021+2022 analysis, there was no significant effect by sex	

Validity
(Cohen's 0.04). In the 2022 clinician-level analysis, there was not a significant effect on SVR rates by insurance status (Cohen's 0.10). In the 2021 clinician-level analysis, there was a very large effect (Cohen's 3.14) with insured patients having higher rates of SVR. In the 2021 and 2022 patient-level analysis, there was a large effect (Cohen's 0.81) with insured patients having higher rates of SVR.
Threats to validity: Results of stratified analyses suggest that there may be meaningful differences at the patient level for factors including insurance status and comorbidities. However, the measure submission indicates that the potential for low numbers of patients with comorbidities per clinician could reduce the benefit of stratification by this particular patient-level factor**.**
Rating: Met

Reliability	
Reliability testing method(s):	Random Split-Half Correlation [sources: MERIT Submission Form, Attachment of Additional Results, MIPS Peer-Reviewed Journal Article Form]
Testing level:	Individual Clinician
Reliability discussion: The numerator and denominator for this measure are well defined. Random split-half correlation is calculated from a full year of data (2022) consisting of 253 patients across 15 clinicians. The intraclass correlation (ICC) calculated from 1,000 bootstrapped pairs of samples is 0.52, which is less than the threshold of 0.6. The PRMR PA threshold is 0.6 to indicate that a measure is capable of differentiating entities by quality of performance; while this measure's reliability is lower than that, it does exceed the 0.4 required by MIPS.	
Additional reliability analyses: See Table 2 below.	
Rating: Met	

Reliability Tables

Table 2 shows reliability deciles (approximated from submission materials) based on the information provided for the 15 entities described in the testing submission. Battelle creates these tables to provide reviewers with a standardized format to assess reliability.

Interpretation: To obtain a rough estimate of the possible signal-to-noise reliability at the clinician level, Battelle performed a simulation based on the performance data provided in the submission; Table 2 shows the results. Without the raw data, it is not possible to know the actual reliability values, but these results suggest that the reliability of the measure is less than the threshold of 0.6 for most of the entities.

Table 2. MUC2024-031 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
0.3	0.11	0.23	0.23	0.24	0.25	0.25	0.26	0.27	0.28	0.33	0.41	0.62	0.62	0.09

Usability	
Usability considered in application:	Yes [Sources: MERIT submission form, MIPS Peer-Reviewed Journal Article Form]
Usability discussion: Based on the discussion of the measure in the submission documents, there is an opportunity for improvement on the measure target among clinician and clinician groups participating in MIPS. The developer did not identify external program-level factors that may present barriers to measure use. The measure submission provides a thoughtful discussion of potential unintended consequences of the measure within MIPS, including: clinicians may exclude patients who are less likely to adhere to HCV care, treatment for patients with a low detectable viral load may not allow for spontaneous viral clearance, and that SVR may be more difficult to test and document in disadvantaged groups, with these patients experiencing more barriers to treating HCV.	
Rating: Met	

External validity	
Was this measure tested in the same target population as the CMS program?	Yes
External validity discussion: The developer conducted the validity and reliability testing for this measure in clinician populations and care sites representative of the MIPS population; the testing indicates that this measure has suitable external validity.	
Rating: Met	

Appropriateness of Scale

Similar or related measures in program(s):	• 00476-05-E-MIPS One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation • 00319-01-C-MIPS Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis

	• 00058-01-C-MIPS Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users [Source: MIPS Peer-Reviewed Journal Article Form]
Measure appropriateness, equity, and value across target populations/measured entities: The developer identified several active MIPS measures as related to the proposed measure. However, these measures address different measure targets and populations than the proposed measure. These measures within MIPS indicate that the proposed measure focus is of interest and value to MIPS and that this measure is aligned with broader MIPS objectives. Regarding equity of this measure's performance and benefit across populations, the literature review and sub-analysis provided by the developer in submission materials does not suggest differential benefit or harm to specific subgroups of MIPS-participating clinicians or their patients beyond consideration of measure performance for patients with comorbidities. The committee should consider if there is equity in distribution of benefits and burdens related to this measure.	

Time to Value Realization

Plan for near- and long-term impacts after implementation:	No
Measure implementation impacts over time: While the measure developer briefly mentions potential outcomes for their measure on clinician and patient populations, there is a need for further examination of near- and long-term impacts of this measure after implementation across provider and patient 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?	