# **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:

* **Hepatitis C Virus (HCV): Sustained Virological Response (SVR)**
* **[Meaningful Measures 2.0 Framework Domain]**

**Measure Steward:** American Gastroenterological Association

**Measure Developer:** American Gastroenterological Association

**Description:**  Percentage of patients aged >= 18 years with active hepatitis C (HCV) with negative/undetectable HCV ribonucleic acid (RNA) at least 20 weeks to 12 months after positive/detectable HCV RNA test result.

1. **Statement**

* Background (Why is this measure important?).

Achieving Sustained virological response (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.

Nineteen cohort studies (n=105 to 16,864) evaluated the association between SVR after antiviral therapy and mortality or complications of chronic HCV infection.

SVR was associated with decreased risk for all-cause mortality (adjusted hazard rations, 0.07 to 0.39)(60, 6169, 72, 73, 75-78), liver-related mortality (adjusted hazard rations, 0.12 to 0.46, and other complications of end-stage liver disease versus no SVR. The subgroup of studies that focused on patients with advanced fibrosis or cirrhosis at baseline reported similar risk estimates. (Chou et. al., 2013)

Chou R, Dana T, Fu R, Zakher B, Wagner J, Ramirez S, Grusing S, Jou JH. Screening for Hepatitis C Virus Infection in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA. 2020 Mar 2. doi: 10.1001/jama.2019.20788. Epub ahead of print. Erratum in: JAMA. 2020 Apr 7;323(13):1318. PMID: 32119034.

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

There are no known competing measures. The following measures are HCV-related measures that are currently CBE endorsed, but do not address Sustained Virological Response:

0387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

0395: Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment (retired)

0396: Hepatitis C: HCV Genotype Testing Prior to Treatment (retired)

0398: Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment (retired)

0399: Hepatitis C: Hepatitis A Vaccination (retired)

0400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation

0401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis

1. **Gap Analysis**

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

With the advent of new direct acting antiviral treatments, SVR can be as high as 90-95% for most patients. However, adherence to recommended treatment and follow-up to ensure response to treatment are crucial to ensure high a rate of response. Emerging data from clinical practice show variation in SVR rate across different institutions, ranging from 65 to 87% for the most widely used combination in 2014. This wide variation provides an opportunity to improve the care of HCV patients. (Yehia B, Schranz A, Umscheid C, and Lo Re V. The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United Stated: A Systematic Review and Meta-Analysis. PLoS ONE 9(7), July 2014.)

Testing results for gap:

2022 clinician-level results

Mean: 48

Min: 23

Max: 63

Theoretical upper limit score: 100

Theoretical lower limit score: 0

2022 clinician group-level results

Mean: 44

Min: 35

Max: 57

Theoretical upper limit score: 100

Theoretical lower limit score: 0

Highly effective direct-acting antiviral (DAA) therapy for the treatment of HCV results in high rates of SVR if treatment is completed. Mean performance scores of 48% have substantial room for improvement and can be improved via treatment initiation, treatment completion, patient follow-up, and care coordination.

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

1. Reduce mortality of patients with chronic hepatitis C.

2. Reduce the risk of hepatic decompensation and liver cancer in patients with chronic hepatitis C

3. Improve health related quality of life of patients with chronic hepatitis C

4. Reduce the cost of hepatitis C care by minimizing the need for re-treatment as well as reducing the risk of long-term adverse outcomes.

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

The recommendation is based on the following studies:

• AASLD Practice Guidelines: Hepatitis C. https://www.aasld.org/practice-guidelines/hepatitis-c

• Backus LI, Boothroyd DB, Phillips BR, Belperio P, Halloran J, Mole LA. A sustained virologic response reduces risk of all-cause mortality in patients with hepatitis C. Clin Gastroenterol Hepatol. 2011;9(6):509-516.

• Berenguer J, Álvarez-Pellicer J, Martin PM, et al. Sustained virological response to interferon plus ribavirin reduces liver-related complications and mortality in patients coinfected with human immunodeficiency virus and hepatitis C virus. Hepatology. 2009;50(2):407-413.

• Bruneau J, Zang G, Abrahamowicz M, Jutras-Aswad D, Daniel M, Roy E. Sustained drug use changes after hepatitis C screening and counseling among recently infected persons who inject drugs: a longitudinal study. Clin Infect Dis. 2014;58(6):755-761.

• Chou R, Hartung D, Rahman B, Wasson N, Cottrell EB, Fu R. Comparative Effectiveness of Antiviral Treatment for Hepatitis C Virus Infection in Adults: A Systematic Review. Ann Intern Med. 2013;158:114-123. doi:10.7326/0003-4819-158-2-201301150-00576.

• Coppola N, De PS, Pisaturo M, et al. Sustained virological response to antiviral treatment in chronic hepatitis C patients may be predictable by HCV-RNA clearance in peripheral blood mononuclear cells. J Clin Virol. 2013;58(4):748-750.

• Feld JJ, Moreno C, Trinh R, et al. Sustained virologic response of 100% in HCV genotype 1b patients with cirrhosis receiving ombitasvir/paritaprevir/r and dasabuvir for 12weeks. J Hepatol. 2016;64(2):301-7.

• Mira JA, Rivero-Juárez A, López-Cortes LF, et al. Benefits from sustained virologic response to pegylated interferon plus ribavirin in HIV/hepatitis C virus-coinfected patients with compensated cirrhosis. Clin Infect Dis. 2013;56(11):1646-1653.

• Morgan TR, Ghany MG, Kim HY, et al. Outcome of sustained virological responders with histologically advanced chronic hepatitis C. Hepatology. 2010;52(3):833-844.

• Morisco F, Granata R, Stroffolini T, et al. Sustained virological response: a milestone in the treatment of chronic hepatitis C. World J Gastroenterol. 2013;19(18):2793-2798.

• Neary MP, Cort S, Bayliss MS, Ware JE, Jr. Sustained virologic response is associated with improved health-related quality of life in relapsed chronic hepatitis C patients. Semin Liver Dis. 1999;19(Suppl 1):77-85.

• Picciotto FP, Tritto G, Lanza AG, et al. Sustained virological response to antiviral therapy reduces mortality in HCV reinfection after liver transplantation. J Hepatol. 2007;46(3):459-465.

• Singal AG, Volk ML, Jensen D, Di Bisceglie AM, Schoenfeld PS. A sustained viral response is associated with reduced liver-related morbidity and mortality in patients with hepatitis C virus. Clin Gastroenterol Hepatol. 2010;8(3):280-8, 288.

• van der Meer AJ, Veldt BJ, Feld JJ, et al. Association between sustained virological response and all-cause mortality among patients with chronic hepatitis C and advanced hepatic fibrosis. JAMA. 2012;308(24):2584-2593.

• Veldt BJ, Heathcote EJ, Wedemeyer H, et al. Sustained virologic response and clinical outcomes in patients with chronic hepatitis C and advanced fibrosis. Ann Intern Med. 2007;147(10):677-684.

• Zeuzem S, Berg T, Gane E, et al. Simeprevir increases rate of sustained virologic response among treatment-experienced patients with HCV genotype-1 infection: a phase IIb trial. Gastroenterology 2014c;146:430-441 e436.

1. **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

Performance scores

Clinician-level performance scores – 2021

Sample size: 13

Mean: 48%

SD: 22%

Min: 20%

Max:88%

10th percentile: 21%

50th percentile: 47%

90th percentile: 76%

Reliability

Moderate reliability – 0.4 – 0.7

High reliability - >0.7

Intraclass correlation (random split-half) clinician-Level – 2021

Clinician sample size: 13

Clinician mean: 0.81

Interpretation: There is high reliability at the clinician level for 2021 with mean correlation greater than 0.7.

Intraclass correlation (random split-half) clinician group-level – 2021 and 2022

2021

Clinician Group sample size: 3

Clinician Group mean: 0.88

Interpretation: There is high reliability at the clinician group-level for 2021 with mean correlation greater than 0.7.

2022

Clinician Group sample size: 4

Clinician Group mean: 0.55

Interpretation: There is moderate reliability at the clinician group-level for 2022 with mean correlation between 0.4 and 0.7.

* + Face Validity Testing Results, Clinician Sites

All clinicians/experts (7) agreed that measures scores would distinguish between good and poor care and identify care quality gaps.

* + Empiric Validity Testing Results at the accountable entity level

## Validity

2021 Clinician-level hypothesis-based validity results

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Group** | **Denominator count** | **Numerator count** | **Mean** | **Min** | **Max** | **Cohen** |
| Sex: Male | 204 | 119 | 0.55 | 0.22 | 0.90 | 0.72 |
| Sex: Female | 121 | 51 | 0.40 | 0.14 | 0.86 | 0.72 |
| Insurance status: Insured | 315 | 170 | 0.50 | 0.21 | 0.88 | 3.15 |
| Insurance status: Not insured | 11 | 0 | 0.00 | 0.00 | 0.00 | 3.15 |
| Comorbidities: Yes | 35 | 18 | 0.54 | 0.00 | 1.00 | 0.22 |
| Comorbidities: No | 291 | 152 | 0.48 | 0.18 | 0.92 | 0.22 |

2021+2022 Patient-level hypothesis-based validity results

| **Group** | **Denominator count** | **Numerator count** | **Mean** | **Min** | **Max** | **Cohen** |
| --- | --- | --- | --- | --- | --- | --- |
| Sex: Male | 340 | 171 | 0.52 | 0.00 | 1.00 | 0.04 |
| Sex: Female | 200 | 92 | 0.50 | 0.00 | 1.00 | 0.04 |
| Insurance status: Insured | 523 | 260 | 0.53 | 0.00 | 1.00 | 0.84 |
| Insurance status: Not insured | 17 | 2 | 0.13 | 0.00 | 1.00 | 0.84 |
| Comorbidities: Yes | 71 | 41 | 0.69 | 0.00 | 1.00 | 0.40 |
| Comorbidities: No | 470 | 222 | 0.49 | 0.00 | 1.00 | 0.40 |

* + Data Element/Patient Encounter Level Testing

N/A

* + Exclusion Frequency

N/A

* + What were the minimum sample sizes used for reliability results?

At least 11 patients

* + Other Information
* Is it risk adjusted? If so, how?

This measure is not recommended for risk adjustment.

* What benchmarking information is available?

There are no benchmarks for this measure.

* Collection Type: Specify the data collection type.

Most data elements Electronic Health Records or will be available in electronic health records when HCPCS codes are assigned.

* Specify measure stage of development.

Fully Developed and tested.

* For Patient Reported Outcome Performance Measures:
  + The survey or tool has been tested and doesn’t require modifications based on results?

Not Applicable

* + Patient/encounter level testing for each critical data element doesn’t require changes to the tool base on the results?

Not Applicable

1. **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 has not been submitted to a CBE for endorsement.

1. **Summary**

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

Chronic Conditions

* Relevance to MIPS or other CMS programs.

This measure aligns with the treatment continuum for HCV testing, treatment and eradication.

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

This measure is intended to be used in the Quality Payment Program (QPP)

* Public reporting (if applicable).

N/A

* Preferable relevant peer-reviewed journal for publication.

Gastroenterology

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

There are no cost measures associated with HCV treatment.