June 26, 2025

Nicole Brennan, MPH, DrPH

Executive Director

Partnership for Quality Measurement

submitted via https://p4qm.org/2025-MSR-Cycle-Proposed-Measure-Comments

Re: 2025 Measure Set Review Cycle - (00058-01-C-MIPS) Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users; (00319-01-C-MIPS) Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis; and (00385-01-C-MIPS) Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy.

Dear Dr. Brennan,

We would like to thank Battelle and the Partnership for Quality Measurement for its ongoing engagement with stakeholders towards an informed and thoughtful quality measure review process.

The American Gastroenterological Association (AGA) represents and supports approximately 16,000 providers and requests the following measures: (00058-01-C-MIPS) Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (QID 387); (00319-01-C-MIPS) Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (QID 401); and (00385-01-C-MIPS) Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (QID 275) remain in the Quality Payment Program (QPP) as these measures continue to promote high value care for gastroenterologists and other specialties. These are a few measures that specifically address patient safety among high-risk populations.

(00058-01-C-MIPS) Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (QID 387)

The goal of QID 387 is to improve HCV screening rates among patients who are at high risk of contracting HCV as compared to the general population. Unlike the general population that is recommended for *one-time* screening as outlined in QID 400 - One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation, QID 387 ensures that patients who have ongoing IV drug use have *annual* HCV screening due to their ongoing exposure to contracting this virus. Of the estimated 3.5 million people living in the United States with HCV, only 49-75% have been tested for HCV and are aware of their status[1]. Reported cases of HCV have

[1] Yehia BR, Schranz AJ, Umscheid CA, Lo Re V 3rd. The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. PLoS One. 2014 Jul 2;9(7):e101554. doi: 10.1371/journal.pone.0101554. PMID: 24988388; PMCID: PMC4079454.

increased (approximately 20% per year) between 2010 - 2016 which is partially due to improved case detection and more likely due to rising rates of injection drug use[2,3,4]. Additionally, only one third have been referred for HCV care and only 5.6% receive recommended treatment. HCV is highly prevalent among patients with IV drug use and individuals with early-stage HCV often have no symptoms. In a recent analysis of data from a national health survey, 67.9% of persons ever infected with HCV reported an exposure risk (e.g., injection drug use, having sexual contact with suspected/confirmed HCV+ patient), 2 weeks to 6 months prior to symptom onset, and the remaining 32.1% reported no known exposure risk.[5,6] Current testing strategies have had limited success, as evidenced by the substantial number of HCV-infected persons who remain unaware of their HCV status and this measure intends to improve this success rate. Hepatitis C, if left untreated, leads to poor outcomes including the development of chronic liver disease (cirrhosis), liver cancer (hepatocellular carcinoma), and deaths, along with high rates of transmission to others that could have been otherwise preventable.

(00319-01-C-MIPS) Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (QID 401)

The goal of QID 401 is to prevent liver cancer related mortality among HCV patients through regular HCC screening intervals. HCC is a primary tumor of the liver and constitutes more than 90% of liver tumors. HCC occurs in approximately 85% of patients diagnosed with cirrhosis[7] and HCC is now the fifth most common cause of cancer worldwide.[8] A recent study found that being up to date with screening for at least 50% of time during the 4 years preceding HCC diagnosis was associated with improved overall survival (log-rank test of equality over strata P = 0.002). In multivariate analysis, each 10% increase in follow-up time consistent with up to date with screening was associated with a 3.2% decrease in the hazard of death (hazard ratio, 0.97; 95% CI, 0.95-0.99). And each 10% of time spent up to date with screening was associated with a

---

[2] Park D, Oh S, Cano M, Salas-Wright CP, Vaughn MG. Trends and distinct profiles of persons who inject drugs in the United States, 2015-2019. Prev Med. 2022 Nov;164:107289. doi: 10.1016/j.ypmed.2022.107289. Epub 2022 Oct 6. PMID: 36209817.
[3] Marks LR, Nolan NS, Liang SY, Durkin MJ, Weimer MB. Infectious Complications of Injection Drug Use. Med Clin North Am. 2022 Jan;106(1):187-200. doi: 10.1016/j.mcna.2021.08.006. PMID: 34823730.
[4] Hall EW, Rosenberg ES, Jones CM, Asher A, Valverde E, Bradley H. Estimated number of injection-involved drug overdose deaths, United States, 2000 - 2018. Drug Alcohol Depend. 2022 May 1;234:109428. doi: 10.1016/j.drugalcdep.2022.109428. Epub 2022 Mar 26. PMID: 35364419.
[5] Tsang CA, Tonzel J, Symum H, et al. State-Specific Hepatitis C Virus Clearance Cascades — United States, 2013–2022. MMWR Morb Mortal Wkly Rep 2024;73:495–500. DOI: http://dx.doi.org/10.15585/mmwr.mm7321a4
[6] Liu CH, Kao JH. Acute hepatitis C virus infection: clinical update and remaining challenges. Clin Mol Hepatol. 2023 Jul;29(3):623-642. doi: 10.3350/cmh.2022.0349. Epub 2023 Feb 20. PMID: 36800699; PMCID: PMC10366792.
[7] oannou GN, Splan MF, Weiss NS, McDonald GB, Beretta L, Lee SP. Incidence and predictors of hepatocellular carcinoma in patients with cirrhosis. Clin Gastroenterol Hepatol. 2007 Aug;5(8):938-45, 945.e1-4.
[8] Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray F. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer. 2015 Mar 01;136(5):E359-86.

10.1% increased likelihood of diagnosis with early-stage HCC (95% CI, 6.3%-14.0%) and a 6.8% increased likelihood of curative treatment (95% CI, 2.8%-11.0%).[9,10] This measure ensures that patients with HCV related cirrhosis are screened for HCC at regular intervals to reduce liver cancer mortality among this high risk population. Importantly, this measure is directly reflective of the guidelines by the American Association for the Study of Liver Diseases (AASLD), which emphasizes the evidence and best-practice behind this critical measure[11].

(00385-01-C-MIPS) Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (QID 275)

The goal of QID 275 is to reduce patient safety risks before initiating biologic anti-TNF therapy for patients with IBD and is the only measure specific to IBD patients available in the QPP. It is essential to screen the patient for HBV, as research has documented reactivation of HBV after initiation of anti-TNF therapy. Tumor necrosis factor (TNF) alpha antagonists are potent immunosuppressive drugs that are first-line treatments for many autoimmune diseases, including IBD. Because TNF-alpha plays an important role in the host defense against many infections, patients treated with anti-TNFs are at higher risk for severe infections and reactivation of chronic infections, including HBV. A recent study involving a cohort of 8,887 patients found a HBV reactivation rate of 39% underscoring the importance of screening for HBV *before* initiating anti-TNF therapy.[12] This measure ensures that patients do not have unintended consequences of activated HBV after starting ant-TNF therapy and reactivation of HBV in the setting of immunosuppression in IBD can lead to acute liver failure and increased mortality rate

Core Quality Measures Collaborative (CQMC) Gastroenterology & HIV/HCV Measures Sets

QID 387, QID 401 and QID 275 are included in the updated 2025 Core Quality Measures Collaborative (CQMC) Gastroenterology (GI) Measures Set, QID 401 is included in the

---

[9] Mezzacappa C, Kim NJ, Vutien P, Kaplan DE, Ioannou GN, Taddei TH. Screening for Hepatocellular Carcinoma and Survival in Patients With Cirrhosis After Hepatitis C Virus Cure. JAMA Netw Open. 2024 Jul 1;7(7):e2420963. doi: 10.1001/jamanetworkopen.2024.20963. PMID: 38985470; PMCID: PMC11238019.
[10] Asafo-Agyei KO, Samant H. Hepatocellular Carcinoma. [Updated 2023 Jun 12]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559177/
[11] Singal, Amit G.1; Llovet, Josep M.2,3,4; Yarchoan, Mark5; Mehta, Neil6; Heimbach, Julie K.7; Dawson, Laura A.8; Jou, Janice H.9; Kulik, Laura M.10; Agopian, Vatche G.11; Marrero, Jorge A.12; Mendiratta-Lala, Mishal13; Brown, Daniel B.14; Rilling, William S.15; Goyal, Lipika16; Wei, Alice C.17; Taddei, Tamar H.18,19. AASLD Practice Guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma. Hepatology 78(6):p 1922-1965, December 2023. | DOI: 10.1097/HEP.0000000000000466
[12] Incidence of Hepatitis B Virus Reactivation and Hepatotoxicity in Patients Receiving Long-term Treatment With Tumor Necrosis Factor Antagonists Pauly, Mary Patricia et al. Clinical Gastroenterology and Hepatology, Volume 16, Issue 12, 1964 - 1973.e1

HIV/HCV measure set and QID 387 has been recommended to be included in this measure set. The measures included in these measure sets involved input and direction from the Partnership for Quality Measurement (PQM) and Centers for Medicare & Medicaid Services (CMS). All three measures were voted by the collaborative to continue in the GI Measures Set for 2025[13,14].

The CQMC was initially created in 2015 as a "broad-based coalition of healthcare leaders working to facilitate cross-payer measure alignment through the development of core sets of measures to assess the quality of healthcare in the United States" with the aims of:

- Identifying high-value, high-impact, evidence-based measures that promote better patient outcomes, and provide useful information for improvement, decision-making and payment.
- Aligning measures across public and private payers to achieve congruence in the measures being used for quality improvement, transparency, and payment purposes.
- Reducing the burden of measurement by eliminating low-value metrics, redundancies, and inconsistencies in measure specifications and quality measure reporting requirements across payers. (https://p4qm.org/CQMC)

The CQMC has described maintenance process considerations to include measures that no longer have an opportunity for improvement, no longer align with clinical guidelines, or have implementation challenges. None of these scenarios apply to these measures.

Since the initial development of the GI Measures Set, QID 401 and QID 275 was determined by multiple stakeholders, including CMS, commercial payers, and other experts, to be of high value and important to drive improvement in priority areas. QID 401 has been in the HIV/HCV measure set since initial development and in 2025, QID 387 was voted to be added to the GI measure set following a full collaborative vote in early 2025. Removal of these measures does not align with expert consensus and multi-stakeholder input.

MVP ID: M1422: Gastroenterology Care MIPS Value Pathway (MVP)

QID 401 and QID 275 are included in the 2025 Gastroenterology Care MIPS Value Pathway (MVP ID: M1422)[15]. Due to the limited number of gastroenterology specific quality measures available in the QPP, any reduction in measures will significantly impact our specialty's ability to participate in MIPS in both traditional MIPS and MVP reporting mechanisms.

AGA strongly encourages Battelle and the Partnership for Quality Measurement to exclude (00058-01-C-MIPS) Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users; (00319-01-C-MIPS) Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis; and (00385-01-C-MIPS) Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis

[13] https://p4qm.org/sites/default/files/2025-05/CQMC-Gastroenterology-Core-Set-2024-508.pdf
[14] https://p4qm.org/sites/default/files/2025-03/CQMC-HIV-Hepatitis-C-Core-Set-v5.0.pdf
[15] https://qpp.cms.gov/mips/explore-mips-value-pathways/2025/M1422

Factor) Therapy from the 2025 Measure Set Review Cycle as they continue to be meaningful and feasible measures that have been vetted by multiple stakeholders for inclusion in a variety of national reporting programs, are designed specifically for clinicians providing treatment for digestive and liver related conditions and are three of 7 gastroenterology-specific measures available in MIPS outside of a Qualified Clinical Data Registry (QCDR). Removal of these measures would significantly impact gastroenterologists' ability to meaningfully participate in the MIPS program.

We appreciate the opportunity to provide comments on the 2025 MSR Cycle. If you have any questions about our feedback or if we may provide any additional information, please contact Kathleen Teixeira, at AGA (kteixeira@gastro.org).

Sincerely,

Lawrence Kim, MD, AGAF

President, American Gastroenterological Association