The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

March 14, 2023

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard; Baltimore, MD 21244

Submitted electronically: NCDRequest@cms.hhs.gov

Re: Request for formal reconsideration of NCD 210.13

Dear Ms. Jenson:

The American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 obstetrician-gynecologists and partners in women's health, provides indispensable decision support guidance and resources for the clinical delivery of women's health care that are grounded in scientific evidence and developed through a rigorous and inclusive process. ACOG has been collaborating with the Centers for Disease Control and Prevention (CDC) to ensure that stakeholders are aware of updated guidance that recommends screening for Hepatitis C for all pregnant people in each pregnancy.[1,2] Consistent with these efforts, we are submitting a formal request for reconsideration of the National Coverage Determination 210:13: *Screening for Hepatitis C Virus (HCV) in Adults*, which has not been updated (outside of coding updates) since 2014.

CDC data indicate that over two million adults in the United States are infected with HCV infection and the incidence is rising annually.[3] One study estimates that approximately 14% of all people with HCV in the United States are Medicare beneficiaries.[4] Another study indicates 0.38% of live births were delivered by women with HCV.[5] This is relevant to CMS, as 42% of all births are financed by Medicaid, and approximately 22,000 pregnancies are covered by Medicare (including dual-eligible).[6,7]

There are significant health disparities in HCV outcomes. In 2019, HCV contributed to more than 14,200 deaths with death rates occurring at significantly higher rates among Black individuals (five per 100,000) and Hispanic individuals (four per 100,000) as compared to White individuals (three per 100,000).[8]

The US Preventive Services Task Force updated their recommendations for HCV screening in 2020, indicating that adults ages 18 through 79 should be screened.[9] They also recommend that pregnant persons should be screened and further report that HCV prevalence has doubled in women aged 15 to 44 years from 2006 to 2014.[10] These recommendations, along with the recommendations from the CDC and ACOG, are not reflected in NCD 210.13. Please note below our recommended edits to a subsection of NCD 210.13 text:

Therefore, CMS will cover screening for HCV with the appropriate U.S. Food and Drug Administration (FDA)-approved/cleared laboratory tests, used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Act regulations, when ordered by the beneficiary's primary care physician ~~or~~ practitioner, or obstetric provider ~~within the context of a primary care setting,~~ and performed by an eligible Medicare provider for these services, for beneficiaries who meet either of the following conditions:

A screening test is covered for adults at high risk for HCV infection. "High risk" is defined as persons with a current or past history of illicit injection drug use; and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high risk persons is covered annually only for persons who have had continued illicit injection drug use since the prior negative screening test.

A single screening test is covered for all asymptomatic adults aged 18 years through 79 years ~~who do not meet the high risk definition above, but who were born from 1945 through 1965~~.

The determination of "high risk for HCV" is identified by the primary care physician or practitioner who assesses the patient's history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

A screening test is covered for of all pregnant women, regardless of age, during each pregnancy, regardless of risk for HCV.

ACOG formally requests a reconsideration of NCD 210.13 and recommends CMS update the NCD as requested, to be consistent with current guidelines. To further discuss this request, please feel free to contact me and my colleague, Erin Alston, at ealston@acog.org.

Sincerely,

Lisa Satterfield, MS, MPH, CAE, CPH
Senior Director, Health Economics & Practice Management

cc: Katonak, Rachel (CMS/CCSQ), Rachel.Katonak@cms.hhs.gov

[1] Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB. CDC Recommendations for Hepatitis C Screening Among Adults — United States, 2020. MMWR Recomm Rep 2020;69(No. RR-2):1–17. DOI: http://dx.doi.org/10.15585/mmwr.rr6902a1external.

[2] American College of Obstetricians and Gynecologists. Practice Advisory: Routine Hepatitis C Virus Screening in Pregnant Individuals. Reaffirmed October 2022. Available at: https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2021/05/routine-hepatitis-c-virus-screening-in-pregnant-individuals.

[3] Thompson WW, Symum H, Sandul A, et al. *Vital Signs:* Hepatitis C Treatment Among Insured Adults — United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:1011-1017.

[4] Wittenborn J, Brady J, Dougherty M, Rein D. Potential epidemiologic, economic, and budgetary impacts of current rates of hepatitis C treatment in medicare and non-medicare populations. Hepatol Commun. 2017 Mar 30;1(2):99-109.

[5] Schillie SF, Canary L, Koneru K, Nelson NP, Tanico W, Kaufman HW, et al. Hepatitis C virus in women of childbearing age, pregnant women, and children. Am J Prev Med 2018;55:633-41.

[6] Martin JA, Hamilton BE, Osterman MJK. Births in the United States, 2019. NCHS Data Brief, no 387. Hyattsville, MD: National Center for Health Statistics. 2020. Available at: https://www.cdc.gov/nchs/data/databriefs/db387-H.pdf.

[7] Department of Health and Human Services (HHS). Characteristics of Medicare Fee-for-Service Beneficiaries with Evidence of Pregnancy and Delivery in any setting, in Physician services data, 2016. Available at: https://aspe.hhs.gov/sites/default/files/private/pdf/255906/MNAdditionalInformationAnalysesDataTables.pdf.

[8] Thompson WW, Symum H, Sandul A, et al. *Vital Signs:* Hepatitis C Treatment Among Insured Adults — United States, 2019–2020. MMWR Morb Mortal Wkly Rep 2022;71:1011-1017.

[9] US Preventive Services Task Force. Screening for Hepatitis C Virus Infection in Adolescents and Adults: US Preventive Services Task Force Recommendation Statement. JAMA. 2020;323(10):970–975. doi:10.1001/jama.2020.1123.

[10] Ibid.