February 23, 2021

National Coverage Determinations (NCD)
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Windsor Mill, MD 21244

RE: Formal Request for Reconsideration
National Coverage Determination (NCD) for Screening for Hepatitis C Virus (HCV) in Adults (210.13)

Dear CMS NCD Reviewers:

Quest Diagnostics requests reconsideration for NCD 210.13, Screening for Hepatitis C Virus (HCV) in Adults in the category of "additional preventive services." The current NCD was implemented on January 5, 2015, effective for services on or after June 2, 2014. The NCD specifically states:

The evidence is adequate to conclude that screening for HCV, consistent with the grade B recommendations by the USPSTF, is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B, as described below. 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 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:

1. *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.*
2. *A single screening test is covered for adults 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.

As noted in the NCD, a single screening test is covered for adults who do not meet the high risk definition who were born from 1945 through 1965. Currently these individuals would be between 56 and 76 years old. The United States Preventive Services Task Force (USPSTF) issued this recommendation in 2013 with evidence grade B.

The USPSTF commissioned a review to update the evidence on screening for HCV infection in both adolescents and adults. The results of the review, published in March, 2020,[1] updated the Task Force's recommendations related to screening of patients who do not meet the high risk definition, again with an evidence grade of B. Specifically, "This recommendation expands the population that should be screened. The USPSTF now recommends that all adults aged 18 to 79 years be screened. Previously, it recommended screening adults born between 1945 and 1965 and others at high risk." Therefore, based

on the evidence review and findings of the Task Force, in 2021 adults born between 1942 and 2003 are recommended for a one time screening given the balance between the benefits and risks. The driver for the expanded recommendation was evolution of effective HCV treatment, specifically direct acting antiviral therapy, with very few risks.

Under §1861(ddd) of the Social Security Act, CMS has the authority to add coverage of additional preventive services if certain statutory requirements are met. The regulations (42 CFR §410.64) provide:

(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under 42 CFR §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following: (1) reasonable and necessary for the prevention or early detection of illness or disability,(2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

Based on the above provision: 1) the USPSTF cited clear evidence that HCV testing is reasonable and necessary to prevent long term consequences of HCV in adults ages 18 to 79; 2) the USPSTF graded their recommendation as "B"; and 3) while CMS has already determined the appropriateness of HCV screening for patients enrolled in Medicare Part B, the new 2020 recommendation expands the age range to include other beneficiaries not previously covered by the 2013 NCD.

We request that CMS review the current version of NCD 210.13 and consider revision to align coverage age (indication 2, one time screening benefit) of the NCD with newly published 2020 USPSTF and specialty society guidance.

Sincerely,

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Senior Medical Director, Medical Affairs

1. 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