CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 198	**Date: June 29, 2017**
	Change Request 9859

Transmittal 197, Pub. 100-03, and Transmittal 3793, Pub. 100-04 dated June 9, 2017, are being rescinded and replaced by Transmittals 198 and Transmittal 198, dated June 29, 2017 to correct the verbiage in split release dates to state the following: October 2, 2017 analysis and design. January 2, 2018 Testing and implementation. All other information remains the same.

SUBJECT: Screening for Hepatitis B Virus (HBV) Infection

I. SUMMARY OF CHANGES: CMS has determined that effective September 28, 2016, screening for HBV infection will be covered 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 (CLIA) regulations.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: September 28, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 2, 2017 - analysis and design; January 2, 2018 - testing and implementation

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	Table of Contents
N	1/210.6/Screening for Hepatitis B Virus (HBV) Infection

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is

not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-03	Transmittal: 198	Date: June 29, 2017	Change Request: 9859

Transmittal 197, Pub. 100-03, and Transmittal 3793, Pub. 100-04 dated June 9, 2017, are being rescinded and replaced by Transmittals 198 and Transmittal 198, dated June 29, 2017, to correct the verbiage in split release dates to state the following: October 2, 2017 analysis and design. January 2, 2018 Testing and implementation. All other information remains the same.

SUBJECT: Screening for Hepatitis B Virus (HBV) Infection

EFFECTIVE DATE: September 28, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 2, 2017 - analysis and design; January 2, 2018 - testing and implementation

I. GENERAL INFORMATION

A. Background: Pursuant to §1861(ddd) of the Social Security Act, the Centers for Medicare & Medicaid Services (CMS) may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria:

(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.

CMS reviewed the USPSTF recommendations and supporting evidence for screening for hepatitis B Virus (HBV) infection and determined that the criteria listed above were met. Therefore, effective November 8, 2011, CMS covered screening for HBV infection only for pregnant women at the first prenatal visit when the diagnosis of pregnancy is known and then rescreening at time of delivery for those with new or continuing risk factors. Screening for HBV infection was not covered for any other populations.

B. Policy: The USPSTF updated its recommendations regarding HBV screening. Therefore, CMS has determined that the evidence is adequate to conclude that screening for HBV infection, consistent with the grade A and 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.

Effective September 28, 2016, CMS will cover screening for HBV infection 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 (CLIA) 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.

A screening test is covered for asymptomatic, non-pregnant adolescents and adults at high risk for HBV infection. "High risk" is defined as persons born in countries and regions with a high prevalence of HBV infection (i.e., ≥ 2%), US-born persons not vaccinated as infants whose parents were born in regions with a very high prevalence of HBV infection (i.e., ≥ 8%), HIV-positive persons, men who have sex with men, injection drug users, household contacts or sexual partners of persons with HBV infection. In addition, CMS has determined that repeated screening would be appropriate annually only for beneficiaries with continued high risk (men who have sex with men, injection drug users, household contacts or sexual partners of

persons with HBV infection) who do not receive hepatitis B vaccination.

A screening test at the first prenatal visit is covered for pregnant women and then rescreening at time of delivery for those with new or continuing risk factors. In addition, CMS has determined that screening during the first prenatal visit would be appropriate for each pregnancy, regardless of previous hepatitis B vaccination or previous negative hepatitis B surface antigen (HBsAg) test results.

The determination of "high risk for HBV" 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.

Note: There are no changes to the policy in CR 7610 for the requirements related to HBV screening for pregnant women. Beginning the effective date of this policy, contractors will file their HBV claims according to the instructions here in NCD 210.6

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9859 - 03.1	Effective September 28, 2016, CMS will cover Hepatitis B screening in non-pregnant, high risk individuals 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 (CLIA) regulations. NOTE: Refer to Pub. 100-03, Medicare NCD Manual, Chapter 1, Section 210.6 for coverage policy, and Pub. 100-04, Claims Processing Manual, Chapter 18, Section 170 for claims processing instructions.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9859 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Wendy Knarr, 410-786-0843 or Wendy.Knarr@cms.hhs.gov (Practitioner Claims) , Leah Cromwell, 410-786-2243 or Leah.Cromwell@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage) , William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional Claims) , Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Practitioner Claims)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual Chapter 1, Part 4(Sections 200-310.1)

Table of Contents
(Rev. 198, Issued: 06-29-17)

210.6 -Screening for Hepatitis B Virus (HBV) Infection
(Rev. 198, Issued: 06-29-17, Effective: 09-28-16, Implementation: 10- 02- 17, October 2, 2017 - analysis and design; January 2, 2018 - testing and implementation)

A. General

Hepatitis B Virus (HBV) is transmitted by exposure to blood or blood-containing body fluids such as serum, semen or saliva. HBV infection attacks the liver and leads to inflammation. An infected person may initially develop symptoms such as nausea, anorexia, fatigue, fever and abdominal pain, or may be asymptomatic. An acute HBV infection may become a chronic infection and progress to serious and potentially life-threatening complications including cirrhosis, liver failure, hepatocellular carcinoma and death.

Pursuant to §1861(ddd) of the Social Security Act, the Secretary may add coverage of "additional preventive services" if certain statutory requirements are met.

B. Nationally Covered Indications

Effective for services performed on or after September 28, 2016, CMS has determined that the evidence is sufficient to cover screening for HBV infection 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 (CLIA) 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 asymptomatic, nonpregnant adolescents and adults at high risk for HBV infection. "High risk" is defined as persons born in countries and regions with a high prevalence of HBV infection (i.e., ≥ 2%), US-born persons not vaccinated as infants whose parents were born in regions with a very high prevalence of HBV infection (i.e., ≥ 8%), HIV-positive persons, men who have sex with men, injection drug users, household contacts or sexual partners of persons with HBV infection. In addition, CMS has determined that repeated screening would be appropriate annually only for beneficiaries with continued high risk (i.e., men who have sex with men, injection drug users, household contacts or sexual partners of persons with HBV infection) who do not receive hepatitis B vaccination.*

2. *A screening test at the first prenatal visit is covered for pregnant women and then rescreening at time of delivery for those with new or continuing risk factors. In addition, CMS has determined that screening during the first prenatal visit would be appropriate for each*

pregnancy, regardless of previous hepatitis B vaccination or previous negative HBsAg test results.

The determination of "high risk for HBV" 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.

For the purposes of this decision memorandum, a primary care setting is defined by the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

For the purposes of this decision memorandum, a "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Social Security Act (§1833(u)(6), §1833(x) (2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after September 28, 2016:

- Medicare beneficiaries who are symptomatic, or who have already been diagnosed with HBV infection, or who are nonpregnant and have already received a hepatitis B vaccination are non-covered.

D. Other

Medicare coinsurance and the Part B deductible are waived for this "additional preventive service."

(NCD updated September 2016)