DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Implementation Date: January 2, 2018

Screening for Hepatitis B Virus (HBV) Infection

Note: This article was revised on August 8, 2017, to reflect an updated Change Request (CR) 9859. In the article, the CR release date, transmittal numbers, and the Web address of the CR are revised. Also, a clarification was made on page 3 to denote that HBV is not separately payable for ESRD TOB 72X unless reported with modifier AY. Another bullet point was added on page 3 to show that contractor pricing applies to G0499 with dates of service September 28, 2016 through December 31, 2017. All other information is unchanged.

Provider Types Affected

This MLN Matters® Article is intended for physicians and other providers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

CR 9859 provides that the Centers for Medicare & Medicaid Services (CMS) has determined that, effective September 28, 2016, Medicare will cover screening for Hepatitis B Virus (HBV) infection when performed 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. **Medicare coinsurance and the Part B deductible are waived for this additional preventive service.** You should ensure that your billing staffs are aware of this coverage change.

Background

Pursuant to Section 1861(ddd) of the Social Security Act (the Act), 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

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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.

The USPSTF has updated its recommendations for HBV screening, and CMS has reviewed these recommendations and supporting evidence; and has determined that the evidence is adequate to conclude that screening for HBV infection is reasonable and necessary for individuals entitled to benefits under Part A or enrolled under Part B, as described below.

Effective for services performed on or after September 28, 2016, Medicare will cover screening for HBV infection, 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, within the context of a primary care setting 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, for beneficiaries who meet either of the following conditions:

1. 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 (that is, ≥ 2%), US-born persons not vaccinated as infants whose parents were born in regions with a very high prevalence of HBV infection (≥ 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 for beneficiaries with continued high risk persons. Testing is covered annually only for persons who have continued high risk (men who have sex with men, injection drug users, household contacts or sexual partners of persons with HBV infection) who have not received 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 hepatitis B surface antigen (HBsAg) test results.

For the purposes of CR9859:

- 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.

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,

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clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

Key Points of CR9859

Applicable Healthcare Common Procedure Coding System (HCPCS) Code

Effective for claims with dates of service on or after September 28, 2016, the claims processing instructions for payment of screening for hepatitis B virus will apply to the following HCPCS and CPT codes:

- HBV screening for asymptomatic, non-pregnant adolescents and adults at high risk - code G0499
- HBV screening for pregnant women - CPT codes 86704, 86706, 87340, and 87341

Types of Bills (TOB) for Institutional Claims

Effective for claims with dates of service on or after September 28, 2016, you should use the following TOBs when submitting claims with G0499, 87340, 87341, 86704, or 86706 for HBV screening:

- Outpatient hospitals - TOB 13X (payment based on Outpatient Prospective Payment System)
- Non-patient laboratory specimen - TOB 14X (payment based on laboratory fee schedule)
- Critical Access Hospitals (CAHs) - TOB 85X, (payment based on reasonable cost when the revenue code is not 096X, 097X, and 098X)
- End Stage Renal Disease (ESRD) - TOB 72X (payment based on ESRD Prospective Payment System when submitting code G0499 with diagnosis code N18.6. HBV is not separately payable for ESRD TOB 72X unless reported with modifier AY.)
- Contractor pricing applies to G0499 with dates of service September 28, 2016 through December 31, 2017.

Professional Billing Requirements

For claims with dates of service on or after September 28, 2016, CMS will allow coverage for HBV screening only when services are submitted by the following provider specialties found on the provider's enrollment record:

- 01 - General Practice
- 08 - Family Practice
- 11 - Internal Medicine
- 16 - Obstetrics/Gynecology
- 37 - Pediatric Medicine
- 38 - Geriatric Medicine
- 42 - Certified Nurse Midwife
- 50 - Nurse Practitioner
- 89 - Certified Clinical Nurse Specialist
- 97 - Physician Assistant

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Claims submitted by providers other than the specialty types noted above will be denied.

Additionally, for claims with dates of service on or after September 28, 2016, CMS will allow coverage for HBV screening only when submitted with one of the following Place of Service (POS) codes:

- 11 - Physician's Office
- 19 - Off Campus Outpatient Hospital
- 22 - On Campus Outpatient Hospital
- 49 - Independent Clinic
- 71 - State or Local Public Health Clinic
- 81 - Independent Laboratory

Claims submitted without one of the POS codes noted above will be denied.

Diagnosis Code Reporting Requirements

For claims with dates of service on or after September 28, 2016, CMS will allow coverage for G0499 for HBV screening only when services are reported with both of the following diagnosis codes denoting high risk:

- Z11.59 - Encounter for screening for other viral disease
- Z72.89 - Other Problems related to life style.

For claims with dates of service on or after September 28, 2016, CMS will allow coverage for G0499 for subsequent visits, only when services are reported with the following diagnosis codes:

- Z11.59 and one of the high risk codes below
  - F11.10-F11.99
  - F13.10-F13.99
  - F14.10-F14.99
  - F15.10-F15.99
  - Z20.2
  - Z20.5
  - Z72.52
  - Z72.53

For claims with dates of service on or after September 28, 2016, CMS will allow coverage for HBV screening (CPT codes 86704, 86706, 87340 and 87341) in pregnant women only when services are reported with one of the following diagnosis codes:

- Z11.59 - Encounter for screening for other viral diseases, **and one of the following**
- Z34.00 - Encounter for supervision of normal first pregnancy, unspecified trimester
- Z34.80 - Encounter for supervision of other normal pregnancy, unspecified trimester
- Z34.90 - Encounter for supervision of normal pregnancy, unspecified, unspecified trimester
- O09.90 - Supervision of high risk pregnancy, unspecified, unspecified trimester

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For claims with dates of service on or after September 28, 2016, CMS will allow coverage for HBV screening (CPT codes 86704, 86706, 87340, and 87341) in pregnant women at high risk only when services are reported with one of the following diagnosis codes:

- Z11.59 - Encounter for screening for other viral diseases; and
- Z72.89 - Other problems related to lifestyle, and also one of the following:

Code	Description
Z34.00	Encounter for supervision of normal first pregnancy, unspecified trimester
Z34.01	Encounter for supervision of normal first pregnancy, first trimester
Z34.02	Encounter for supervision of normal first pregnancy, second trimester
Z34.03	Encounter for supervision of normal first pregnancy, third trimester
Z34.80	Encounter for supervision of other normal pregnancy, unspecified trimester
Z34.81	Encounter for supervision of other normal pregnancy, first trimester
Z34.82	Encounter for supervision of other normal pregnancy, second trimester
Z34.83	Encounter for supervision of other normal pregnancy, third trimester
Z34.90	Encounter for supervision of normal pregnancy, unspecified, unspecified trimester
Z34.91	Encounter for supervision of normal pregnancy, unspecified, first trimester
Z34.92	Encounter for supervision of normal pregnancy, unspecified, second trimester
Z34.93	Encounter for supervision of normal pregnancy, unspecified, third trimester
O09.90	Supervision of high risk pregnancy, unspecified, unspecified trimester
O09.91	Supervision of high risk pregnancy, unspecified, first trimester
O09.92	Supervision of high risk pregnancy, unspecified, second trimester
O09.93	Supervision of high risk pregnancy, unspecified, third trimester

Claim/Service Denial

When denying payment for HBV screening use, your MAC will use the appropriate Claim Adjustment Reason Codes (CARCs), Remittance Advice Remark Codes (RARCs), or group codes.

When denying services submitted on a TOB other than 13X, 14X, or 85X, they will use:

- CARC 170 - Payment is denied when performed/billed by this type of provider. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present
- RARC N95 - This provider type/provider specialty may not bill this service
- Group Code CO (Contractual Obligation) - Assigning financial liability to the provider

When denying services when HCPCS G0499 is paid in history for claims with dates of service on and after September 28, 2016, or if the beneficiary's claim history shows claim lines containing

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CPT codes 86704, 86706, 87340, and 87341 submitted in the previous 11 full months they will use the following messages:

- CARC 119 - "Benefit maximum for this time period or occurrence has been reached."
- RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD."
- Group Code PR (Patient Responsibility) - Assigning financial responsibility to the beneficiary (if a claim is received with occurrence code 32 with or without GA modifier or a claim –line is received with a GA modifier indicating a signed ABN is on file).).
- Group Code CO (Contractual Obligation) - Assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

When denying services for G0499, when ICD-10 diagnosis code Z72.89 and Z11.59 are not present on the claim, MACs will use:

- CARC 167 - "This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
- RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code CO

Denying services for HBV screening, HCPCS G0499, when ICD-10 diagnosis code Z34.00, Z34.01, Z34.02, Z34.03, Z34.80, Z34.81, Z34.82, Z34.83, Z34.90, Z34.91, Z34.92, Z34.93, O09.90, O09.91, O09.92, or O09.93 is present on the claim:

- CARC 167 – "This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."
- RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code: CO (Contractual Obligation)

When denying services for G0499 for subsequent visits, when ICD-10 diagnosis code Z11.59 and one of the following high risk diagnosis codes: F11.10- F11.19, F13.10 - F13.99, F14.10 - F14.99, F15.10 - F15.99, Z20.2, Z20.5, Z72.52, or Z72.53 are not present on the claim, MACs will use:

- CARC 167 - "This (these) diagnosis(es) is (are) not covered. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present."

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- RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code CO

When denying claim lines for G0499 without the appropriate POS code, MACs will use:

- CARC 171 - Payment is denied when performed by this type of provider on this type of facility. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N428 - Not covered when performed in certain settings.
- Group Code CO

When denying claim lines for G0499 that are not submitted from the appropriate provider specialties, MACs will use:

- CARC 184 - The prescribing/ordering provider is not eligible to prescribe/order the service billed. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **http://www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD."
- Group Code PR (Patient Responsibility) - Assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file).
- Group Code CO (Contractual Obligation) - Assigning financial liability to the provider (if a claim line-item is received with a GZ modifier indicating no signed ABN is on file).

When denying services where previous HBV screening, HCPCS 86704, 86706, 87340, or 87341, is paid during the same pregnancy period or more than two screenings are paid to women that are at high risk, they will use:

- CARC 119 - "Benefit maximum for this time period or occurrence has been reached."
- RARC N362 - "The number of days or units of service exceeds our acceptable maximum."
- RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD."
- Group Code PR (Patient Responsibility) - Assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file).
- Group Code CO (Contractual Obligation) - Assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

When denying claim lines for HBV screening, HCPCS G0499 for a subsequent HBV screening test for non-pregnant, high risk beneficiary when a claim line for an initial HBV screening has not yet been posted in history, use the following messages:

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- CARC B15 - This service/procedure requires that a qualifying service/procedure be received and covered. The qualifying other service/procedure has not been received/adjudicated. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code - CO (Contractual Obligation).

When denying services for HBV screening, HCPCS 86704, 86706, 87340, and 87341 that are billed without the appropriate diagnosis code MACs will use:

- CARC 50 - These are non-covered services because this is not deemed a "medical necessity" by the payer. Note: Refer to the 835 Healthcare Policy identification Segment (loop 2110 Service Payment information REF), if present.
- RARC N386 - "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at **www.cms.gov/mcd/search.asp**. If you do not have web access, you may contact the contractor to request a copy of the NCD."
- Group Code PR (Patient Responsibility) - Assigning financial responsibility to the beneficiary (if a claim is received with a GA modifier indicating a signed ABN is on file).
- Group Code CO (Contractual Obligation) - Assigning financial liability to the provider (if a claim is received with a GZ modifier indicating no signed ABN is on file).

Additional Notes

- HCPCS code G0499 will appear in the January 1, 2018, Clinical Laboratory Fee Schedule (CLFS), in the January 1, 2017, Integrated Outpatient Code Editor (IOCE), and in the January 1, 2017, Medicare Physician Fee Schedule (MPFS) with indicator 'X'. HCPCS code G0499 will be effective retroactive to September 28, 2016, in the IOCE.
- Your MAC will not search for claims containing HCPCS G0499 with dates of service on or after September 28, 2016, but may adjust claims that you bring to their attention.
- You should be aware that the 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.)
- MACs will apply contractor pricing to claim lines with G0499 with dates of service September 28, 2016, through December 31, 2017.
- Deductible and coinsurance do not apply to G0499.

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Additional Information

The official instruction, CR9859, was issued to your MAC via two transmittals. The first updates the "Medicare Claims Processing Manual" and it is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3831CP.pdf**. The second transmittal updates the NCD Manual and it is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R198NCD.pdf**.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/**.

Document History

Date	Description
August 8, 2017	This article was revised to reflect an updated CR9859. In the article, the CR release date, transmittal numbers, and the Web address of the CR are revised. A clarification was made on page 3 to denote that HBV is not separately payable for ESRD TOB 72X unless reported with modifier AY. Another bullet point was added on page 3 to show that contractor pricing applies to G0499 with dates of service September 28, 2016 through December 31, 2017. All other information is unchanged.
June 30, 2017	This article was revised to reflect an updated CR9859. In the article, the CR release date, transmittal numbers, and the Web address of the CR are revised. All other information is unchanged.
June 9, 2017	The article was revised to reflect an updated CR that changed the implementation date from January 1, 2018, to January 2, 2018.
May 4, 2017	Initial article released.

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