Hepatitis B Surface Antibody and Surface Antigen

FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID number
L34003

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Hepatitis B Surface Antibody and Surface Antigen

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-02, Medicare Benefit Policy, Chapter 11, Sections 30.2.1-30.4
CMS Manual System, Pub. 100-03, Medicare National Coverage Determinations, Chapter 1, Part 3, Section 190.10
Primary Geographic Jurisdiction

Florida
Puerto Rico/Virgin Islands

Oversight Region

Region I

Original Determination Effective Date

10/01/2015

Original Determination Ending Date

N/A

Revision Effective Date

05/12/2017

Revision Ending Date

05/11/2017

Indications and Limitations of Coverage and/or Medical Necessity

Hepatitis B surface antigen (HBsAg) is the earliest indicator of an acute hepatitis B infection. It can be detected one to seven weeks before liver enzyme elevation or the onset of clinical symptoms. The serology of 50% of affected patients will be positive three weeks after acute onset, while at the seventeen week mark only 10% will remain positive. There is evidence of a “window” stage where the hepatitis B surface antigen has become negative and the patient has not yet developed the hepatitis B surface antibody. The chronic carrier state is indicated by the persistence of hepatitis B surface antigen over six months and longer (even years) while never seroconverting to hepatitis B surface antibody. The reference range is negative. The detection of the hepatitis B surface antigen establishes the presence of infection and implies infectivity.

Hepatitis B surface antibody (HbsAb or anti-HBs) is present in the serum of patients who have resolved a previous hepatitis B infection or have been vaccinated against hepatitis B. The disappearance of hepatitis B antigen with the appearance of hepatitis B antibody signals recovery from the hepatitis B infection, the status of noninfectivity and protection from recurrent hepatitis B infection. Hepatitis B surface antibody can be detected several weeks to several years after Hepatitis B antigen can no longer be detected. It may persist for life after the acute infection has been resolved. Since there are different serologic subtypes of the hepatitis B virus, it is possible for a patient to have an antibody for one subtype and be infected with another. Transfused individuals or hemophiliacs receiving plasma components may have false positive tests. Individuals vaccinated with HBV vaccine will have antibodies. The appearance of the hepatitis B antibody following vaccination signals successful vaccination against hepatitis B. The detection of hepatitis B surface antibody in the patient’s serum can be performed by either the radioimmunoassay (RIA) or enzyme immunoassay (EIA) method. The reference range varies with the clinical circumstance.

HEPATITIS B SURFACE ANTIBODY

The Hepatitis B surface antibody (86706) will be considered for coverage for any of the following indications:
Hepatitis B Surface Antibody and Surface Antigen AB

I. To confirm the resolution of a recent hepatitis B infection. The HBsAb is drawn one month after the diagnosis of acute hepatitis B is made. This test may be repeated monthly while seeking the disappearance of HBsAg and the appearance of HBsAb indicating immunity and recovery. If the HBsAg is still evident at the end of six months of testing, the patient is considered a persistent hepatitis B carrier. No further HBsAb would be considered reasonable and necessary.

II. After percutaneous or mucosal exposure to blood and/or serum-derived fluids when the SOURCE is HBsAg-positive and the previously vaccinated exposed person is either a known responder or the response to vaccination is unknown, in order to determine adequate antibody response. One test would be sufficient to make this determination. EXCEPTION- Vaccinated persons who have not been tested within the past 24 months should undergo testing to determine immunity.

III. After percutaneous or mucosal exposure to blood and/or serum-derived fluids when the SOURCE is not tested or unknown and the previously vaccinated exposed person’s response to the vaccination is unknown, in order to determine adequate antibody response. One test would be sufficient to make this determination.

IV. Following the administration of the Hepatitis B vaccine series in order to determine adequate antibody response. Coverage for this indication is limited to two instances.

1. To determine the antibody response of vaccination due to prophylaxis treatment following percutaneous and/or mucosal exposure, or

2. To determine the antibody response of vaccination following a vaccination furnished to a beneficiary who is at high or intermediate risk of contracting hepatitis B.

It is recommended this testing occur between one to six months following the completion of the series. If the patient was given Hepatitis B immunoglobulin (HBIG) during this time period, the testing should be delayed until four to six months after the HBIG administration. Those beneficiaries who do not respond to the initial vaccination series, can receive up to three additional doses of vaccine at one to two month intervals. Serologic testing can occur following each dose.

V. To determine the serological status of a hemodialysis, intermittent peritoneal dialysis, or continuous cycling peritoneal dialysis patient upon entry into a Medicare dialysis facility in accordance with CMS National coverage policy. Further testing is dependent upon the initial result and the vaccination status. Please refer to the following table:

<table>
<thead>
<tr>
<th>Vaccination and Serologic Status</th>
<th>Freq. of HBsAb Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td></td>
</tr>
<tr>
<td>Susceptible</td>
<td>Semiannually</td>
</tr>
<tr>
<td>HBsAg Carrier</td>
<td>None</td>
</tr>
<tr>
<td>HBsAb positive (*)</td>
<td>Annually</td>
</tr>
<tr>
<td>Vaccinated</td>
<td></td>
</tr>
<tr>
<td>HBsAb positive (*)</td>
<td>Annually</td>
</tr>
<tr>
<td>HBsAb of 9 or less SRUs by RIA</td>
<td>Semiannually</td>
</tr>
</tbody>
</table>

*At least 10 sample ratio units (SRUs) by radioimmunoassay or positive by enzyme immunoassay. Antibody titers 10 mIU/ml are recognized as conferring protection against hepatitis.

ESRD patients who are in the process of receiving the hepatitis B vaccine, but have not completed the series, should be followed as susceptible. Between one and six months following the final vaccine dose, all patients should be tested for HBsAb response to the vaccine. Once the response is confirmed as positive, there is no further need to perform semiannual HBsAb tests. If, during future annual HBsAb testing, it is determined that the SRUs drop below 10 or the result by EIA is negative, a booster dose of hepatitis B vaccine should be given. A booster dose, otherwise known as re-vaccination, requires the complete three-injection-series be repeated.

HEPATITIS B SURFACE ANTIGEN

The Hepatitis B surface antigen (87340) will be considered for coverage for any of the following indications:

I. To aid in the differential diagnosis of hepatitis when the patient presents with signs and symptoms of acute viral infection. If the initial HBsAg test is positive with the Anti-HBc-IgM being negative, both of these tests are repeated in two weeks. The results of the repeat tests aid in the differential diagnosis of acute HBV infection vs. chronic HBV carrier status. If the initial HBsAg test is positive with the Anti-HBc-IgM being positive, HBV infection is confirmed. The hepatitis B surface antigen
Hepatitis B Surface Antibody and Surface Antigen

Test can be repeated monthly until negative. If, at the end of six months, the hepatitis B surface antigen remains positive, the beneficiary is diagnosed as a chronic HBV carrier and further hepatitis B surface antigen testing would not be reasonable or necessary.

II. To evaluate patients with chronic elevations (6 months or longer) of the following serum liver enzyme levels: alanine aminotransferase (ALT) and aspartate aminotransferase (AST) to rule out the diagnosis of Hepatitis B. It is expected that only one HBsAg test will be required in this clinical situation (ICD-10 code R74.0).

III. To evaluate patients with polyarteritis nodosa to determine if the illness is associated with replicating hepatitis B. In this instance HBsAg and HBeAg would be evaluated. It is expected that only one HBsAg test will be required ICD-10 code M30.0, M30.2, M30.8, or M31.7)

IV. To determine the serological status of a hemodialysis, intermittent peritoneal dialysis, or continuous cycling peritoneal dialysis patient upon entry into a Medicare dialysis facility in accordance with CMS National coverage policy. Further testing is dependent upon the initial result as well as the vaccination status. Please refer to the following table:

<table>
<thead>
<tr>
<th>Vaccination and Serologic Status</th>
<th>Freq. of HBsAg Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td></td>
</tr>
<tr>
<td>Susceptible</td>
<td>Monthly</td>
</tr>
<tr>
<td>HbsAg Carrier</td>
<td>Annually</td>
</tr>
<tr>
<td>HbsAb positive (*)</td>
<td>None</td>
</tr>
<tr>
<td>Vaccinated</td>
<td></td>
</tr>
<tr>
<td>HbsAb positive (*)</td>
<td>None</td>
</tr>
<tr>
<td>HbsAb of 9 or less SRUs by RIA</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

* At least 10 sample ratio units (SRUs) by radioimmunoassay or positive by enzyme immunoassay. Antibody titers 10 mlU/ml are recognized as conferring protection against hepatitis B.

ESRD patients who are in the process of receiving the hepatitis B vaccine, but have not completed the series, should be followed as susceptible. Between one and six months following the final vaccine dose, all patients should be tested for HBsAb response to the vaccine. Once the response is confirmed, there is no further need to perform monthly HBsAg tests. If, during future annual HBsAb testing, it is determined that the SRUs drop below 10 or the result by EIA is negative, a booster dose of hepatitis B vaccine should be given. Monthly HBsAg can resume while awaiting the antibody response to this booster. Once the antibody titer confirms protection, no further HBsAg testing would be necessary.

**Type of Bill Code**

- Hospital – 12x, 13x, 14x
- Skilled Nursing Facility – 21x, 22x, 23x
- End Stage Renal Dialysis Facility – 72x
- Critical Access Hospital – 85x

**Revenue Codes**

- 302 Laboratory Immunology (Hepatitis B surface antibody)
- 306 Laboratory Microbiology (Hepatitis B surface antigen)

**CPT/HCPCS Codes**

- 86706 Hepatitis B surface antibody (HBsAb)
- 87340 Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple step method; hepatitis B surface antigen (HBsAg)

**Not Otherwise Classified Codes (NOC)**

N/A
Hepatitis B Surface Antibody and Surface Antigen  AB

ICD-10 Codes that Support Medical Necessity

For procedure code 86706 (Hepatitis B surface antibody)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B16.0</td>
<td>Acute hepatitis B with delta-agent with hepatic coma</td>
</tr>
<tr>
<td>B16.1</td>
<td>Acute hepatitis B with delta-agent without hepatic coma</td>
</tr>
<tr>
<td>B16.2</td>
<td>Acute hepatitis B without delta-agent with hepatic coma</td>
</tr>
<tr>
<td>B16.9</td>
<td>Acute hepatitis B without delta-agent and without hepatic coma</td>
</tr>
<tr>
<td>B18.0-B18.1</td>
<td>Chronic viral hepatitis</td>
</tr>
<tr>
<td>B19.10</td>
<td>Unspecified viral hepatitis B without hepatic coma</td>
</tr>
<tr>
<td>B19.11</td>
<td>Unspecified viral hepatitis B with hepatic coma</td>
</tr>
<tr>
<td>I12.0</td>
<td>Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease</td>
</tr>
<tr>
<td>I13.11</td>
<td>Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease</td>
</tr>
<tr>
<td>I13.2</td>
<td>Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease</td>
</tr>
<tr>
<td>N18.4</td>
<td>Chronic kidney disease, stage 4 (severe)</td>
</tr>
<tr>
<td>N18.5</td>
<td>Chronic kidney disease, stage 5</td>
</tr>
<tr>
<td>N18.6</td>
<td>End stage renal disease</td>
</tr>
<tr>
<td>Z08</td>
<td>Encounter for follow-up examination after completed treatment for malignant neoplasm</td>
</tr>
<tr>
<td>Z09</td>
<td>Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm</td>
</tr>
<tr>
<td>Z20.5-Z20.6</td>
<td>Contact with and (suspected) exposure to communicable diseases</td>
</tr>
<tr>
<td>Z20.820-Z20.828</td>
<td>Contact with and (suspected) exposure to other viral communicable diseases</td>
</tr>
<tr>
<td>Z23</td>
<td>Encounter for immunization</td>
</tr>
<tr>
<td>*Z99.2</td>
<td>Dependence on renal dialysis</td>
</tr>
</tbody>
</table>

*ICD-10-CM diagnosis code Z99.2 should not be billed as the primary diagnosis. Please submit codes I12.0, I13.11, I13.2, or N18.4-N18.6 to report the approved indication.

Note: Renal dialysis facilities (72x) should report a diagnosis code of N18.6 for submission of claims.

For procedure code 87340 (Hepatitis B surface antigen)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B16.0</td>
<td>Acute hepatitis B with delta-agent with hepatic coma</td>
</tr>
<tr>
<td>B16.1</td>
<td>Acute hepatitis B with delta-agent without hepatic coma</td>
</tr>
<tr>
<td>B16.2</td>
<td>Acute hepatitis B without delta-agent with hepatic coma</td>
</tr>
<tr>
<td>B16.9</td>
<td>Acute hepatitis B without delta-agent and without hepatic coma</td>
</tr>
<tr>
<td>B17.9</td>
<td>Acute viral hepatitis, unspecified</td>
</tr>
<tr>
<td>B18.0-B18.1</td>
<td>Chronic viral hepatitis</td>
</tr>
<tr>
<td>B19.0</td>
<td>Unspecified viral hepatitis with hepatic coma</td>
</tr>
<tr>
<td>B19.9</td>
<td>Unspecified viral hepatitis without hepatic coma</td>
</tr>
<tr>
<td>B19.10</td>
<td>Unspecified viral hepatitis B without hepatic coma</td>
</tr>
<tr>
<td>B19.11</td>
<td>Unspecified viral hepatitis B with hepatic coma</td>
</tr>
<tr>
<td>B25.1</td>
<td>Cytomegaloviral hepatitis</td>
</tr>
<tr>
<td>G93.3</td>
<td>Postviral fatigue syndrome</td>
</tr>
<tr>
<td>I12.0</td>
<td>Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease</td>
</tr>
<tr>
<td>I13.11</td>
<td>Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease</td>
</tr>
<tr>
<td>I13.2</td>
<td>Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease</td>
</tr>
<tr>
<td>K71.0-K71.9</td>
<td>Toxic liver disease</td>
</tr>
<tr>
<td>K72.00-K72.01</td>
<td>Acute and subacute hepatic failure</td>
</tr>
<tr>
<td>K75.2-K75.3</td>
<td>Other inflammatory liver diseases</td>
</tr>
<tr>
<td>K75.81-K75.9</td>
<td>Other inflammatory liver diseases</td>
</tr>
<tr>
<td>K76.2</td>
<td>Central hemorrhagic necrosis of liver</td>
</tr>
<tr>
<td>K76.4</td>
<td>Peliosis hepatitis</td>
</tr>
</tbody>
</table>
Hepatitis B Surface Antibody and Surface Antigen  AB
K77  Liver disorders in diseases classified elsewhere
M25.50-M25.579  Pain in joint
M30.0  Polyarteritis nodosa
M30.2  Juvenile polyarteritis
M30.8  Other conditions related to polyarteritis nodosa
M31.7  Microscopic polyangiitis
M60.80-M60.9  Myositis
M79.1  Myalgia
M79.646  Pain in unspecified finger(s)
M79.7  Fibromyalgia
N18.4  Chronic kidney disease, stage 4 (severe)
N18.5  Chronic kidney disease, stage 5
N18.6  End stage renal disease
P59.1-P59.29  Neonatal jaundice from other and unspecified causes
R11.0  Nausea
R16.0  Hepatomegaly, not elsewhere classified
R16.2  Hepatomegaly with splenomegaly, not elsewhere classified
R17  Unspecified jaundice
R19.5  Other fecal abnormalities
R21  Rash and other nonspecific skin eruption
R50.2  Drug induced fever
R50.81  Fever presenting with conditions classified elsewhere
R50.83  Postvaccination fever
R50.84  Febrile nonhemolytic transfusion reaction
R50.9  Fever, unspecified
R53.0-R53.1  Malaise and fatigue
R53.81  Other malaise
R53.83  Other fatigue
R63.0  Anorexia
R74.0  Nonspecific elevation of levels of transaminase and lactic acid dehydrogenase [LDH]
R82.5  Elevated urine levels of drugs, medicaments and biological substances
R82.6  Abnormal urine levels of substances chiefly nonmedicinal as to source
R82.71-R82.79  Bacteriuria - Other abnormal findings on microbiological examination of urine
R82.8  Abnormal findings on cytological and histological examination of urine
R82.90  Unspecified abnormal findings in urine
R82.91  Other chromoabnormalities of urine
R82.99  Other abnormal findings in urine
Z20.5-Z20.6  Contact with and (suspected) exposure to communicable diseases
Z20.820-Z20.828  Contact with and (suspected) exposure to other viral communicable diseases
Z99.2  Dependence on renal dialysis

*   ICD-10 Diagnosis code Z99.2 should not be billed as the primary diagnosis. Please submit codes I12.0, I13.11, I13.2, or N18.4-N18.6 to report the approved indication.

Note:  Renal dialysis facilities (72X) should report a diagnosis code of N18.6 for submission of claims.

Diagnoses that Support Medical Necessity

N/A
For someone suspected of having been recently exposed to the hepatitis B virus, the medical record documentation must contain information regarding the beneficiary’s vaccination status, and the suspected incident including an assessment of current signs and symptoms. It is expected that the initial and, if needed, subsequent hepatitis B lab test results (e.g., HBsAg, HBsAb, and/or Anti-HBc-IgM) be contained within the medical record. This information is usually found in the history and physical, office notes, test results, and/or progress notes.

Medical record documentation for ESRD beneficiaries receiving services through Medicare dialysis facilities must contain information regarding the method of dialysis, their hepatitis B vaccination status and the results of their initial admission serology testing and all subsequent hepatitis B surface antigen and antibody tests.

If the provider of service is other than the ordering/referring physician, that provider must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician’s order for the test(s). The physician must state the beneficiary’s vaccination status as well as the clinical indication/medical necessity for the study in his order for the test(s).

Utilization Guidelines

It is expected that these services would be performed as indicated in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy. When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Sources of Information and Basis for Decision

First Coast Service Options, Inc. reference LCD number(s) – L28885, L29189, L29346


Start Date of Comment Period

N/A

End Date of Comment Period

N/A
Hepatitis B Surface Antibody and Surface Antigen

Start Date of Notice Period

04/01/2014

Revision History

Revision History Number: R3

Revision Number: 3
Publication: June 2017 Connection
LCR A/B2017-023

Explanation of Revision: Based on CR 8776, the following verbiage was removed from the “CPT/HCPCS Codes” section of the LCD: “Per CR 8572, beginning in CY 2014, payment for most laboratory tests (except for molecular pathology tests) will be packaged under the OPPS, therefore the clinical laboratory tests listed below, for TOB 13X (outpatient hospital), are packaged in this setting.” The effective date of this revision is for claims processed on or after 05/12/2017, for dates of service on or after 01/01/2014.

Revision History Number: R2

Revision Number: 2
Publication: October 2016 Connection
LCR A/B2016-097

Explanation of Revision: Based on CR 9677 (Annual 2017 ICD-10-CM Update) the LCD was revised. Added ICD-10-CM diagnosis code range R82.71-R82.79 for procedure code 87340. Deleted ICD-10-CM diagnosis codes R82.7 and Z22.51 for procedure code 87340. The effective date of this revision is based on date of service.

Revision History Number: R1

Revision Number: 1
Publication: December 2015 Connection
LCR A/B2016-010

Explanation of Revision: Annual 2016 HCPCS Update. Descriptor revised for CPT code 87340. The effective date of this revision is based on date of service

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments

Coding Guidelines

Document formatted 04/28/2017 (MP/mb)