
POLICY DETERMINATION



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 1/1/22**
(See policy history boxes for previous effective dates)

Title: 90759 - Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2) 10 mcg dosage, 3 dose schedule, for intramuscular use

Brief Description of Service:

On November 30, 2020, VBI Vaccines Inc. (the Applicant) submitted a biologics license application (BLA) for licensure of a recombinant hepatitis B vaccine. The proper name of the vaccine is Hepatitis B Vaccine (Recombinant). The Applicant originally proposed 3-antigen, Hepatitis B Vaccine (Recombinant) as the proper name. It was considered by the review team that this could be interpreted to imply a tri-valent vaccine, which would be misleading as this vaccine does not provide protection against more viral variants than any of the currently licensed hepatitis B vaccines. PREHEVBRIO is a recombinant hepatitis B vaccine produced in Chinese hamster ovary (CHO) cells that have been genetically modified to produce the hepatitis B virus (HBV) envelope proteins: the small (S), middle (pre-S2), and large (pre-S1) hepatitis B surface antigens (HBsAg). Currently U.S.-licensed yeast-derived hepatitis B vaccines contain the small S protein alone.

The U.S. Food and Drug Administration approved this vaccine (known as PREHEVBRIO) on November 30, 2021 for adults 18 years of age and older.

The CPT code 90759 for this vaccine is effective 1/1/22.

On April 1, 2022, Morbidity and Mortality Weekly Report (MMWR) published: HepB vaccination is recommended for adults aged 19–59 years and adults aged ≥60 years with risk factors for hepatitis B. Adults aged ≥60 years without known risk factors for hepatitis B may also receive HepB vaccines. Infants and all other persons aged <19 years are already recommended to receive HepB vaccines.

PreHevbrio (ACIP-recommended in 2022)

HepB vaccine*/Age group, yrs	Dose (µg)	Volume (mL)	Schedule
≥18¶	10	1	3 doses at 0, 1, and 6 mos

¶ The safety and effectiveness of Heplisav-B and PreHevbrio have not been established in adults on hemodialysis. Data are not available to assess the effects of Heplisav-B and PreHevbrio on breastfed infants or on maternal milk production and excretion. Data on Heplisav-B (<https://www.fda.gov/media/108745/download>) and PreHevbrio are currently insufficient to inform vaccine-associated risks in pregnancy. Thus, providers should vaccinate pregnant persons needing HepB vaccination with Engerix-B, Recombivax HB, or Twinrix.

Recommendation:

The Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2) (PREHEVBRIO) vaccine is established. It has been approved by the U.S. Food & Drug Administration and recommended by ACIP.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

90759

Other codes (investigational, not medically necessary, etc.):

References:

1. U.S. Food & Drug Administration; Vaccines Licensed for Use in the United States, February 18, 2022. <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states> (1/31/22)
2. VBI submits application for Prehevbrio for adults 18 years of age and older. November 30, 2020. <https://www.fda.gov/media/154807/download>
3. U.S. Food & Drug Administration. Approval letter Prehevbrio. November 30, 2021 <https://www.fda.gov/media/154560/download>
4. Weng MK, Doshani M, Khan MA, et al. Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:477–483. DOI: <http://dx.doi.org/10.15585/mmwr.mm7113a1external>. Accessed 4/5/22.

Joint Blue Cross/BCN Medical Policy History

Policy Effective Date	Blue Cross Signature Date	BCN Signature Date	Comments
1/1/22	4/19/22		Joint policy established. This procedure code is established: based on FDA approval, ACIP recommendations, and accepted by CDC & published in MMWR 4/1/22. Procedure code 90759 effective date is 1/1/22. This PDF is retired.

Next Review Date: This is an established procedure; it is no longer subject to routine review