

Utilization Management and Clinical Medical Policy

Policy Name: Hepatitis B and Tetanus-Containing Vaccines	Policy Number: MP-RX-FP-156-24	Scope: <input checked="" type="checkbox"/> MMM MA <input checked="" type="checkbox"/> MMM MultiHealth	Origination Date: 8/15/2024 Last Review Date: 5/6/2026	Effective Date: 5/6/2026 Frequently Revision: Annual
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Service Category:

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| <input type="checkbox"/> Anesthesia | <input type="checkbox"/> Medicine Services and Procedures |
| <input type="checkbox"/> Surgery | <input type="checkbox"/> Evaluation and Management Services |
| <input type="checkbox"/> Radiology Procedures | <input type="checkbox"/> DME/Prosthetics or Supplies |
| <input type="checkbox"/> Pathology and Laboratory Procedures | <input checked="" type="checkbox"/> Other: Part B Drugs |

Service Description:

This document addresses the use of Hepatitis B vaccines and tetanus-containing vaccines when evaluated under the Medicare Part B benefit of the plan. Medicare Part B covers hepatitis B vaccine as a preventive service for beneficiaries who have not previously received a completed hepatitis B vaccination series, whose previous hepatitis B vaccination history is unknown, or who are at high or intermediate risk of contracting hepatitis B. Medicare Part B covers tetanus-containing vaccines only when they are directly related to the treatment of an injury or direct exposure to a disease or condition; routine tetanus booster vaccination is not a Part B benefit.

The following products fall under this Medical Policy:

Tetanus-Containing Vaccines
Tdap (Adacel® and Boostrix®)
Td (TENIVAC® and TDVAX®)
Hepatitis B Vaccines
Engerix-B® (hepatitis b vaccine- recombinant injection, suspension)
Heplisav-B® (hepatitis b vaccine- recombinant adjuvanted injection, solution)
Recombivax HB® (hepatitis b vaccine- recombinant injection, suspension)

Background Information:

Hepatitis B Vaccination

Hepatitis B is a vaccine-preventable liver infection caused by hepatitis B virus (HBV). Transmission occurs through percutaneous or mucosal exposure to infectious blood or body fluids. Current CDC recommendations advise HepB vaccination for all infants, all unvaccinated children and adolescents younger than 19 years, all adults 19 through 59 years of age, and adults 60 years of age and older with risk factors for HBV infection; adults 60 years of age and older without known risk factors may also receive HepB vaccination, and any adult 60 years of age and older who requests vaccination should receive a HepB vaccine series. Available U.S. HepB vaccines currently used in adults include 2-dose and 3-dose products, with specific higher-dose regimens for dialysis and certain immunocompromised populations. In Medicare, Part B coverage for hepatitis B vaccine was expanded effective January 1, 2025, to include beneficiaries who have not previously received a completed hepatitis B vaccination series or whose previous vaccination history is unknown, in addition to beneficiaries at high or intermediate risk.

People with a documented, complete HepB vaccine series generally do not need revaccination, except in special populations such as patients on hemodialysis or certain healthcare personnel for whom post-vaccination serologic testing and revaccination may be indicated under current CDC guidance.

PreHevbrio® (hepatitis B vaccine [recombinant]) is no longer included as an active product under this Medical Policy because the manufacturer, VBI Vaccines Inc., voluntarily withdrew the product from the U.S. market due to

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bankruptcy and termination of operations. The market withdrawal was not related to safety or effectiveness concerns; however, any remaining product should not be used or distributed. Individuals who began a hepatitis B vaccine series with PreHevbrio may complete the series with another age-appropriate hepatitis B vaccine in accordance with current CDC recommendations.

Twinrix® is also not included as an active product under this Medical Policy because it is a combination vaccine indicated for immunization against both hepatitis A virus and hepatitis B virus in adults 18 years of age and older, whereas this policy is limited to vaccines evaluated under the Medicare Part B benefit for hepatitis B and tetanus-containing vaccines. Medicare Part B specifically covers hepatitis B shots as a preventive vaccine benefit, while vaccines not covered under Part B are generally covered under Part D; therefore, for purposes of this Part B policy, Twinrix should be evaluated outside this document.

Tetanus Vaccination

CDC recommends tetanus-containing vaccines across the lifespan. For adults, 1 dose of Tdap is recommended, followed by Td or Tdap booster doses every 10 years. Either Td or Tdap may also be used for tetanus prophylaxis in wound management. For wound management, tetanus vaccination is recommended for all wounds in persons with unknown vaccination history, no prior tetanus vaccination, or an incomplete primary tetanus series. In persons who have completed a primary tetanus series, tetanus vaccination is recommended for clean and minor wounds if the last tetanus-containing vaccine was administered 10 or more years earlier, and for dirty or major wounds if the last tetanus-containing vaccine was administered 5 or more years earlier. No tetanus vaccination is needed, regardless of wound type, if the patient completed the primary series and received the last tetanus-containing vaccine less than 5 years earlier. Under Medicare Part B, tetanus vaccination is covered only when directly related to the treatment of an injury or direct exposure to a disease or condition; routine preventive tetanus vaccination is not covered under Part B.

Approved Indications

Tetanus Vaccines	
Tdap (Adacel®)	For active booster immunization against tetanus, diphtheria, and pertussis in persons 10 through 64 years of age; and for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age.
Tdap (Boostrix®)	For active booster immunization against tetanus, diphtheria, and pertussis in individuals 10 years of age and older; and for immunization during the third trimester of pregnancy to prevent pertussis in infants younger than 2 months of age.
Td (TENIVAC® and TDVAX®)	For active immunization for the prevention of tetanus and diphtheria in patients 7 years or older.
Hepatitis B Vaccines	
Engerix-B (hepatitis b vaccine- recombinant injection, suspension)	Indicated for immunization against infection caused by all known subtypes of hepatitis B virus
Heplisav-B (hepatitis b vaccine- recombinant adjuvanted injection, solution)	For prevention of infection caused by all known subtypes of hepatitis B virus. Heplisav-B is approved for use in adults 18 years of age and older

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Recombivax HB (hepatitis b vaccine- recombinant injection, suspension)	Indicated for prevention of infection caused by all known subtypes of hepatitis B virus. Recombivax HB is approved for use in individuals of all ages. Recombivax HB Dialysis Formulation is approved for use in predialysis and dialysis patients 18 years of age and older
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Other Uses

- A. None

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

A. Criteria For Initial Approval

Hepatitis B Vaccines

- i. Medicare Part B covers the Hepatitis B preventive shots when **one or more** of the following criteria are met:
 - A. The patient has not previously received a completed hepatitis B vaccination series; **OR**
 - B. The patient’s previous hepatitis B vaccination history is unknown; **OR**
 - C. The patient has at least one of the following characteristics, which places them at high risk of contracting hepatitis B:
 - 1. ESRD patients; **OR**
 - 2. Hemophiliacs who receive Factor VIII or IX concentrates; **OR**
 - 3. Clients of institutions for the mentally retarded; **OR**
 - 4. Persons who live in the same household as a Hepatitis B Virus (HBV) carrier; **OR**
 - 5. Homosexual men; **OR**
 - 6. Illicit injectable drug abusers; **OR**
 - 7. Pacific Islanders (that is, Medicare beneficiaries who reside on Pacific islands under U.S. jurisdiction, other than residents of Hawaii); **OR**
 - 8. Persons diagnosed with diabetes mellitus.

OR

- D. The patient is at medium risk of acquiring hepatitis B, including one of the following:
 - 1. Staff in institutions for individuals with intellectual disabilities and classroom employees who work with individuals with intellectual disabilities; **OR**
 - 2. Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work, including workers outside of a hospital setting who have frequent contact with blood or other infectious secretions; **OR**

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3. Heterosexually active persons with multiple sexual partners, defined as beneficiaries who have had at least two documented episodes of sexually transmitted diseases within the preceding 5 years; **AND**
- E. For patients qualifying under D.1-D.3, the patient does not have laboratory evidence positive for antibodies to hepatitis B (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy).

Tetanus Vaccines (Td or Tdap)

- i. Medicare Part B only covers tetanus vaccination when it is related to the treatment of an injury or direct exposure to a disease or condition; **AND**
- ii. The patient requires tetanus prophylaxis for wound management because one of the following criteria is met:
 - A. It is unknown whether the patient completed the tetanus primary series; **OR**
 - B. The patient has never received tetanus vaccination; **OR**
 - C. The patient has an incomplete tetanus primary series; **OR**
 - D. The patient completed the tetanus primary series, has a clean and minor wound, and 10 years or more have elapsed since the last tetanus-containing vaccine; **OR**
 - E. The patient completed the tetanus primary series, has a dirty or major wound, and 5 years or more have elapsed since the last tetanus-containing vaccine.

B. Criteria For Continuation of Therapy

- i. Administration of Hepatitis B and Tetanus Vaccines is not considered as maintenance treatment.
- ii. MMM considers additional hepatitis B vaccination medically necessary only when needed to complete a covered hepatitis B vaccine series or when revaccination is recommended for specific populations under current CDC guidance, including certain patients on hemodialysis or certain healthcare personnel after appropriate post-vaccination serologic evaluation. Information regarding the patient's current immunization status and the indication for revaccination should be submitted for evaluation.
- iii. MMM considers additional tetanus-containing vaccine under Part B medically necessary only for a new qualifying injury or exposure episode meeting the Criteria for Initial Approval. Subsequent routine doses to complete or continue a tetanus series when not directly related to treatment of an injury or direct exposure to a disease or condition are not covered under Part B.

C. Authorization Duration

- i. Initial Approval Duration:
 - A. Hepatitis B vaccines: To complete the recommended covered vaccination series.
 - B. Tetanus-containing vaccines: One dose per qualifying injury or exposure episode.
- ii. Reauthorization Approval Duration: None.

D. Conditions Not Covered

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Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

- i. Revaccination with Hepatitis B in an individual with documentation of a completed hepatitis B vaccine series when revaccination is not recommended for a special population under current CDC guidance. ([Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices](#)).
- ii. Routine tetanus vaccination services, including decennial Td or Tdap booster vaccination, that are not related to treatment of an injury or direct exposure to a disease or condition, are not covered by Medicare Part B.
- iii. Routine Tdap vaccination during pregnancy is not covered under Medicare Part B vaccine benefit.
- iv. Completion of a tetanus primary series or catch-up tetanus vaccination when not directly related to treatment of an injury or direct exposure to a disease or condition is not covered under Medicare Part B.
- v. Use of PreHevbrio[®] is not covered under this policy because the product has been voluntarily withdrawn from the U.S. market.

Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

- i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Enerix-B	<ul style="list-style-type: none"> • Persons 20 years of age and older: A series of 3 doses (1 mL each) on a 0-, 1-, and 6-month schedule. • Adults on hemodialysis: A series of 4 doses (2 mL each) on a 0-, 1-, 2-, and 6-month schedule.

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Heplisav-B	<ul style="list-style-type: none"> Adults 18 years of age and older: A series of 2 doses (0.5 mL each) given 1 month apart. Safety and effectiveness have not been established in adults on hemodialysis.
Recombivax HB	<ul style="list-style-type: none"> Persons 20 years of age and older: A series of 3 doses (1 mL each) on a 0-, 1-, and 6-month schedule. Recombivax HB Dialysis Formulation: Adults on predialysis or dialysis: A series of 3 doses (1 mL each) on a 0-, 1-, and 6-month schedule.
Td (TENIVAC or TDVAX)	<ul style="list-style-type: none"> A single 0.5 mL intramuscular dose when indicated for tetanus prophylaxis in wound management under Medicare Part B. In persons with a complete primary tetanus series, vaccinate for clean and minor wounds if the last tetanus-containing vaccine was administered 10 or more years earlier, and for dirty or major wounds if the last tetanus-containing vaccine was administered 5 or more years earlier. In persons with unknown vaccination history, no prior tetanus vaccination, or an incomplete primary series, administer 1 dose as part of wound management; completion of additional routine catch-up doses outside the qualifying injury/exposure episode is not covered under Part B.
Adacel and Boostrix (Tdap)	<ul style="list-style-type: none"> A single 0.5 mL intramuscular dose when indicated for tetanus prophylaxis in wound management under Medicare Part B. In persons with a complete primary tetanus series, vaccinate for clean and minor wounds if the last tetanus-containing vaccine was administered 10 or more years earlier, and for dirty or major wounds if the last tetanus-containing vaccine was administered 5 or more years earlier.
Exceptions	
None	

Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Codes:

Codes	Description
G0010	Administration of hepatitis B vaccine

CPT Codes:

Codes	Description
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90715	Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), older than 7, intramuscular use
90714	Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, older than 7, intramuscular use
90739	Hepatitis B vaccine, adult dosage (2 dose schedule), for intramuscular use
90740	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (3 dose schedule), for intramuscular use
90743	Hepatitis B vaccine, adolescent (2 dose schedule), for intramuscular use
90744	Hepatitis B vaccine, pediatric/adolescent dosage (3 dose schedule), for intramuscular use
90746	Hepatitis B vaccine, adult dosage, for intramuscular use
90747	Hepatitis B vaccine, dialysis or immunosuppressed patient dosage (4 dose schedule), for intramuscular use

Reference Information:

- Centers for Disease Control and Prevention. (2023). *Screening and testing for hepatitis B virus infection: CDC recommendations—United States, 2023. MMWR Recommendations and Reports, 72(1), 1–25.* Retrieved March 31, 2026.
- Centers for Disease Control and Prevention. (2025, June 10). *Clinical guidance for wound management to prevent tetanus.* Retrieved March 31, 2026.
- Centers for Disease Control and Prevention. (2025, June 10). *Tetanus vaccine recommendations.* Retrieved March 31, 2026.
- Centers for Disease Control and Prevention. (2025, September 18). *Hepatitis B vaccine administration.* Retrieved March 31, 2026.
- Centers for Disease Control and Prevention. (2025, October 7). *Adult immunization schedule notes: Recommendations for ages 19 years or older, United States, 2025.* Retrieved March 31, 2026.
- Centers for Medicare & Medicaid Services. (2026). *Medicare Benefit Policy Manual (Pub. 100-02, Chapter 15).* Retrieved March 31, 2026.
- Centers for Medicare & Medicaid Services. (2026, February 5). *Billing and Coding: Medicare Preventive Coverage for Certain Vaccines (A54767).* Retrieved March 31, 2026.
- Centers for Medicare & Medicaid Services. (2025, July 25). *MLN Matters MM14031 Revised: Updates to colorectal cancer screening & hepatitis B vaccine policies.* Retrieved March 31, 2026.
- Centers for Medicare & Medicaid Services. (2025). *MLN908764 – Medicare Part D vaccines.* Retrieved March 31, 2026.
- Centers for Medicare & Medicaid Services. (2026). *Hepatitis B shots coverage.* Retrieved March 31, 2026.
- Food and Drug Administration. (2026, March 9). *Vaccines licensed for use in the United States.* Retrieved March 31, 2026.
- Food and Drug Administration. (2024, November 29). *PREHEVBRIO.* Retrieved March 31, 2026.
- Food and Drug Administration. (2026, February 4). *CBER-regulated products: Permanent discontinuations.* Retrieved March 31, 2026.
- GlaxoSmithKline. (n.d.). *ENGRIX-B [Prescribing information].* Retrieved March 31, 2026.
- Dynavax Technologies Corporation. (n.d.). *HEPLISAV-B [Prescribing information].* Retrieved March 31, 2026.
- Merck Sharp & Dohme LLC. (n.d.). *RECOMBIVAX HB [Prescribing information].* Retrieved March 31, 2026.

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17. GlaxoSmithKline. (n.d.). *BOOSTRIX [Prescribing information]*. Retrieved March 31, 2026.
18. Sanofi Pasteur Limited. (n.d.). *Adacel [Prescribing information]*. Retrieved March 31, 2026.
19. Sanofi Pasteur Limited. (n.d.). *TENIVAC [Prescribing information]*. Retrieved March 31, 2026.
20. MassBiologics. (n.d.). *TDVAX [Prescribing information]*. Retrieved March 31, 2026.
21. GlaxoSmithKline. (n.d.). *TWINRIX [Prescribing information]*. Retrieved March 31, 2026.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Updated the policy to align with current Medicare Part B, CDC/ACIP, and FDA information by revising the hepatitis B coverage criteria to reflect current Part B eligibility, updating tetanus coverage criteria to current wound-management intervals and injury/exposure-based Part B coverage, correcting and expanding the vaccine code section, refining continuation and non-covered use language, updating product indications and dosing schedules, and removing Twinrix from active coverage under this policy because it is a combination hepatitis A/hepatitis B vaccine rather than a hepatitis B-only Part B vaccine, while removing PreHevbrio from active coverage content because it was voluntarily withdrawn from the U.S. market due to the manufacturer’s bankruptcy/termination of operations, not for safety or effectiveness reasons. Coding review: added 90740, 90743, 90744, 90747, and G0010 and removed 90636, 90756, and 90759 Updated references list. Administrative update to incorporate new policy template.	5/1/2026	5/6/2026
Annual Review	Minimal changes; Word formatting. No coding changes.	6/9/2025	6/19/2025
Policy Inception	New Medical Policy Creation	8/8/2024	8/15/2024