

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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Service Category

- Anesthesia
- Surgery
- Radiology Procedures
- Pathology and Laboratory Procedures
- Medicine Services and Procedures
- Evaluation and Management Services
- DME/Prosthetics or Supplies
- Part B Drugs

Service Description

This document addresses the use of Hepatitis B and Tetanus vaccines when evaluated under the Part B benefit of the plan.

The following products fall under this Medical Policy:

Tetanus-Containing Vaccines
Tdap (Adacel® and Boostrix®)
Td (Tetanus and diphtheria toxoids absorbed)
Hepatitis B Vaccines
Engerix-B® (hepatitis b vaccine- recombinant injection, suspension)
Heplisav-B® (hepatitis b vaccine- recombinant adjuvanted injection, solution)
PreHevbrio® (hepatitis b vaccine- recombinant injection, suspension)
Recombivax HB® (hepatitis b vaccine- recombinant injection, suspension)
Twinrix® (Hepatitis A & Hepatitis B (Recombinant) Vaccine] injectable suspension)

Background Information

Hepatitis B Vaccination

Hepatitis B is a liver disease that can be prevented by vaccination and is caused by the hepatitis B virus (HBV). Transmission occurs through percutaneous (skin puncture) or mucosal (contact with mucous membranes) exposure to infected blood or body fluids. Since the hepatitis B vaccine was introduced in 1982, the number of reported cases has dramatically decreased.

The most effective strategy to prevent HBV transmission is pre-exposure vaccination of at-risk individuals. Universal immunization is essential to reduce and ultimately eradicate HBV transmission. Hepatitis B vaccination has been part of routine early childhood immunizations since 1991, making it crucial to vaccinate all children before or during adolescence. Immunizing adults in high-risk groups is also recommended. Additionally, post-exposure evaluation and treatment, which include diagnostic testing and selective immunization, are crucial in preventing HBV infection across all age groups, regardless of specific risk factors.

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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These guidelines are informed by recommendations from the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP). These organizations, in collaboration with federal agencies, have established a unified childhood immunization schedule, as well as immunization recommendations for adults.

The latest ACIP recommendations advise hepatitis B vaccination for adults aged 19–59 years and those aged 60 and older who have risk factors for hepatitis B. Adults aged 60 and older without known risk factors may also receive the vaccine. Infants and individuals under 19 years of age are already recommended to receive the hepatitis B vaccine.

Tetanus Vaccination

Since 2005, the Advisory Committee on Immunization Practices (ACIP) has recommended a single dose of the tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap) vaccine for adolescents and adults. Following the initial Tdap dose, booster shots of the tetanus and diphtheria (Td) vaccine are advised every 10 years or as needed for wound care.

In October 2019, ACIP revised its guidelines to permit the use of either Tdap or Td in situations where previously only Td was recommended. These situations include the routine 10-year Td booster, tetanus prophylaxis for wound management in individuals who have already received Tdap, and for multiple doses in the catch-up immunization schedule for individuals aged 7 years and older with incomplete or unknown vaccination history.

Approved Indications

Tetanus Vaccines	
Tdap (Adacel® and Boostrix®)	For single-dose active booster immunization against tetanus, diphtheria, and pertussis
Td (Tetanus and diphtheria toxoids absorbed)	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
PreHevbrio (hepatitis b vaccine- recombinant injection, suspension)	For prevention of infection caused by all known subtypes of hepatitis B virus. PreHevbrio is approved for use in adults 18 years of age and older

Medical Policy

Healthcare Services Department

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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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
Twinrix (Hepatitis A & Hepatitis B (Recombinant) Vaccine] injectable suspension)	Indicated for active immunization against disease caused by hepatitis A virus and infection by all known subtypes of hepatitis B virus. TWINRIX is approved for use in persons 18 years of age or older

Other Uses

None

Applicable Codes

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.

CPT Codes	Description
90715	Tetanus, diphtheria toxoids and acellular pertussis vaccine (Tdap), older than 7
90714	Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, older than 7

CPT Codes	Description
90756	Engerix-B
90739	Heplisav-B
90759	PreHevbrio
90746	Recombivax HB
90636	Twinrix

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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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 based on risk (medium or high) for hepatitis B. The risk for hepatitis B increases if one or more of the following criteria are met:
 - A. 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. Persons diagnosed with diabetes mellitus.
 - OR**
 - B. The patient is at medium risk of acquiring hepatitis B, defined as being a healthcare worker who frequently comes into contact with blood or blood-derived body fluids during routine work;
 - AND**
 - C. 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. To be candidate for a booster dose after an injury or burn, at least 5 years have elapsed since the last administration; **OR**

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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- iii. It is unknown whether the patient completed the tetanus primary series.

B. Criteria For Continuation of Therapy

- i. Administration of Hepatitis B and Tetanus Vaccines is not considered as maintenance treatment.
- ii. MMM considers retreatment with tetanus vaccine medically necessary when used for tetanus prophylaxis for wound management if at least 5 years have elapsed since the last administration. For hepatitis B vaccine, revaccination is considered medically necessary only in specific circumstances related to high risk healthcare workers, as detailed by the CDC Guidelines ([Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices](#)). Information regarding the patient current immunization status should be submitted for evaluation.

C. Authorization Duration

- i. Initial Approval Duration: To complete recommended vaccination series.
- ii. Reauthorization Approval Duration: None.

D. Conditions Not Covered

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 a patients previously vaccinated patient who is not candidate for revaccination according to the CDC ([Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices](#)).
- ii. Routine tetanus vaccination services (not related to a an injury or direct exposure to a disease or condition) are not covered by Medicare Part B.

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.

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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Drug	Recommended Dosing Schedule
Engerix-B	<ul style="list-style-type: none"> Persons from birth through 19 years of age: A series of 3 doses (0.5 mL each) on a 0-, 1-, 6-month schedule. Persons 20 years of age and older: A series of 3 doses (1 mL each) on a 0-, 1-6-month schedule.
Heplisav-B	Two doses (0.5 mL each) one month apart.
PreHevbrio	A series of three doses (1.0 mL each) on a 0-, 1- and 6-month schedule.
Recombivax HB	<ul style="list-style-type: none"> Adolescents 11 through 15 years of age: A series of either 3 doses (0.5 mL each) given on a 0-, 1-, and 6-month schedule or a series of 2 doses (1.0 mL) on a 0- and 4- to 6-month schedule). Persons 20 years of age and older: A series of 3 doses (1.0 mL each) given on a 0-, 1-, and 6-month schedule
Recombivax HB Dialysis Formulation	<ul style="list-style-type: none"> Adults on predialysis or dialysis: A series of 3 doses (1.0 mL each) given on a 0-, 1-, and 6-month schedule.
Twinrix	<ul style="list-style-type: none"> Standard Dosing: A series of 3 doses (1-mL each) given on a 0-, 1-, and 6-month schedule. Accelerated Dosing: A series of 4 doses (1-mL each) given on Days 0, 7, and 21 to 30 followed by a booster dose at Month 1.
Diphtheria and Tetanus Toxoids (Td)	<ul style="list-style-type: none"> If 5 years or more have elapsed since the last dose administration, a booster dose may be administered for tetanus prophylaxis for wound management.
Adacel and Boostrix (Tdap)	<ul style="list-style-type: none"> If 5 years or more have elapsed since the last dose administration, a booster dose may be administered for tetanus prophylaxis for wound management.
Exceptions	
None	

Reference Information

- Connors EE, Panagiotakopoulos L, Hofmeister MG, et al. Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023. MMWR Recomm Rep 2023;72(No. RR-1):1–25. DOI: <http://dx.doi.org/10.15585/mmwr.rr7201a1>
- CDC. Clinical Guidance for Wound Management to Prevent Tetanus. <https://www.cdc.gov/tetanus/hcp/clinical-guidance/index.html>

Medical Policy

Healthcare Services Department

Policy Name Hepatitis B and Tetanus-Containing Vaccines	Policy Number MP-RX-FP-156-24	Scope <input checked="" type="checkbox"/> MMM MA <input type="checkbox"/> MMM Multihealth
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- 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
- First Coast Service Options, Inc. Avoid claim processing delays when billing tetanus vaccinations. https://medicare.fcso.com/Billing_news/0422983.asp

Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	New Medical Policy Creation	8/8/2024	8/15/2024

Revised: 06/30/2024