

Preventive Vaccines (Immunizations)

Policy Number: 2024D0031S
Effective Date: December 1, 2024

[Instructions for Use](#)

Table of Contents	Page
Coverage Rationale	1
Benefit Considerations	1
U.S. Food and Drug Administration	2
References	2
Policy History/Revision Information	2
Instructions for Use	2

Related Commercial Policy
<ul style="list-style-type: none"> Preventive Care Services

Coverage Rationale

[See Benefit Considerations](#)

Coverage Conditions

A vaccine (immunization) is considered covered after **all** of the following conditions are satisfied:

- The US Food and Drug Administration (FDA) has approved the vaccine (immunization); **and**
- The vaccine (immunization) is subject to explicit ACIP recommendations (e.g., should, shall, is), and not permissive (“may”) recommendations, for routine use as published in the Morbidity & Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC); **and**
- The vaccine (immunization) is listed on the applicable immunization schedule of ACIP; **and**
- The vaccine (immunization) is not otherwise excluded by the plan as explained in the member specific benefit plan document

Coverage Clarifications

- **Preventive:** For a list of vaccines that are covered under the preventive care benefit, refer to the Medical Policy titled [Preventive Care Services](#). In the case of a public health emergency (as defined by the Centers for Disease Control or state or local public health departments), UnitedHealthcare may choose to apply preventive benefits to a new vaccine if the vaccine has FDA approval, even if an ACIP recommendation has not been announced.
- **Therapeutic:** Certain vaccines are used as a medical treatment. For example, therapeutic treatment of an animal bite using the rabies vaccine. These vaccines are under the plan’s treatment benefits, not under preventive care benefits. These vaccines are not subject to the coverage criteria in this section.
- **Excluded:** Vaccines that that fall under one of the exclusions in the member specific benefit plan document. For example, most plans exclude travel-specific vaccines.

Benefit Considerations

UnitedHealthcare covers certain services under the Preventive Care Services benefit. Effective for plan years on or after September 23, 2010, the federal Patient Protection and Affordable Care Act (PPACA) requires non-grandfathered plans to cover certain preventive services identified by PPACA. For non-grandfathered plans, and for grandfathered plans wishing to offer such coverage, UnitedHealthcare will cover preventive services as mandated by PPACA, with no cost sharing when provided by a network provider for those vaccines with a definitive approval from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), and Health Resources and Services Administration (HRSA) Guidelines including the American Academy of Pediatrics Bright Futures periodicity guidelines.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Refer to the FDA approved product package inserts regarding precautions associated with each vaccine.

References

1. ACIP Vaccine Recommendations and Guidelines: https://www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html?CDC_AAref_Val=https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html . Accessed September 12, 2024.
2. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf. Accessed September 12, 2024.
3. U.S. Food and Drug Administration (FDA), Complete List of Vaccines Licensed for Immunization and Distribution in the US: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833>. Accessed September 12, 2024.
4. Vaccines and Immunizations resource page. Centers for Disease Control and Prevention Web site. <https://www.cdc.gov/vaccines/index.html> . Accessed September 12, 2024.

Policy History/Revision Information

Date	Summary of Changes
12/01/2024	<p>Title Change</p> <ul style="list-style-type: none">• Previously titled <i>Vaccines</i> <p>Coverage Rationale</p> <p>Coverage Conditions</p> <ul style="list-style-type: none">• Revised language to indicate a vaccine (immunization) is considered covered after all of the following conditions are satisfied:<ul style="list-style-type: none">○ The U.S. FDA has approved the vaccine (immunization)○ The vaccine (immunization) is subject to explicit ACIP recommendations (e.g., “should”, “shall”, “is”), and not permissive (“may”) recommendations, for routine use as published in the Morbidity & Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC)○ The vaccine (immunization) is listed on the applicable immunization schedule of ACIP○ The vaccine (immunization) is not otherwise excluded by the plan as explained in the member specific benefit plan document <p>Coverage Clarifications</p> <ul style="list-style-type: none">• Added language to indicate:<ul style="list-style-type: none">○ In the case of a public health emergency (as defined by the Centers for Disease Control or state or local public health departments), UnitedHealthcare may choose to apply preventive benefits to a new vaccine if the vaccine has FDA approval, even if an ACIP recommendation has not been announced○ Therapeutic vaccines are not subject to the coverage criteria in this policy <p>Supporting Information</p> <ul style="list-style-type: none">• Updated <i>References</i> section to reflect the most current information• Archived previous policy version 2023D0031R

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.