Vaccines

Policy Number: 2020D0031O
Effective Date: September 1, 2020

Table of Contents

<table>
<thead>
<tr>
<th>Coverage Rationale</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benefit Considerations</td>
<td>1</td>
</tr>
<tr>
<td>U.S. Food and Drug Administration</td>
<td>2</td>
</tr>
<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td>2</td>
</tr>
<tr>
<td>References</td>
<td>2</td>
</tr>
<tr>
<td>Policy History/Revision Information</td>
<td>2</td>
</tr>
<tr>
<td>Instructions for Use</td>
<td>2</td>
</tr>
</tbody>
</table>

Coverage Rationale

Conditions

The following conditions apply to all covered vaccines. A vaccine is considered covered after both of the following conditions are satisfied:
1. US Food and Drug Administration (FDA) approval; and
2. Explicit ACIP recommendations (e.g., should, shall, is) rather than a permissive (“may”) recommendation, published in the Morbidity & Mortality Weekly Report (MMWR) of the Centers for Disease Control and Prevention (CDC).

Coverage Clarifications

- Preventive: For a list of vaccines that are covered under the preventive care benefit, refer to the Coverage Determination Guideline titled Preventive Care Services.
- 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.
- Excluded: Vaccines 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.

See FDA approved product package inserts regarding precautions associated with each vaccine.

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for Immunizations. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist; see the LCDs/LCAs for Immunizations, Medicare Preventive Coverage for Certain Vaccines and Tetanus Immunization.

For specific coverage information of immunizations under the Medicare Part B program, refer to the Medicare Benefit Policy Manual, Chapter 15, Covered Medical and Other Health Services, Section 50.4.4.2 – Immunizations. (Accessed June 18, 2020)

References


Policy History/Revision Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/01/2020</td>
<td>Supporting Information</td>
</tr>
<tr>
<td></td>
<td>- Updated CMS section to reflect the most current information</td>
</tr>
<tr>
<td></td>
<td>- Archived previous policy version 2019D0031N</td>
</tr>
</tbody>
</table>

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 MCG™ Care Guidelines, 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.