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Department of Origin: Integrated Healthcare Services	**Effective Date:** 03/06/24
Approved by: Chief Medical Officer	**Date Approved:** 02/29/24
Clinical Policy Document: Preventive Coverage for Routine Immunizations	**Replaces Effective Clinical Policy Dated:** 03/03/23
Reference #: MP/P020	**Page:** 1 of 3

The Patient Protection and Affordable Care Act of 2010 (the "ACA") requires that "non-grandfathered" insured and self-insured group health plans and individual insurance policies provide full coverage, with no cost-sharing for the member, for certain preventive care services that members receive from *participating providers*. The ACA defines preventive services to include for covered adults and children, as applicable, certain annual or periodic exam, screening, counseling and immunization services, and, for women with reproductive capacity, certain contraceptive methods and related counseling.

These preventive services are described in the United States Preventive Services Task Force (USPSTF) A and B recommendations, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC), the Health Resources and Services Administration (HRSA) Guidelines including the Health and Human Services (HHS) Health Plan Coverage Guidelines for Women's Preventive Services and the American Academy of Pediatrics (AAP) Bright Futures periodicity guidelines.

For insured individual, small and large groups, additional preventive services are covered in accordance with applicable state statues. This coverage also applies to self-insured group plans that are sponsored by governmental entities and political subdivisions.

PURPOSE:
The intent of this clinical policy is to provide guidelines for coverage of affirmative routine immunizations at the at the preventive, no cost-sharing level of benefit.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Immunizations are a covered benefit with no cost-sharing if they are considered community standard based on the recommendations released by the Centers for Disease Control (CDC) and for which the Advisory Council on Immunization Practices (ACIP) has issued an affirmative recommendation for routine use and when they are delivered by an in-network provider. In the event of an emergency situation, eg, a pandemic or a disaster, the plan will follow the vaccine recommendations and guidelines of the ACIP.

For access to the most current immunization schedules, see the following
https://www.cdc.gov/vaccines/schedules/index.html

A new immunization that is pending ACIP recommendations, but is a combination of previously approved individual components, is eligible for coverage under the preventive care benefit.

Immunizations that are required for travel (eg, typhoid, yellow fever, cholera, plague, and Japanese encephalitis virus), are available for coverage, but not at the preventive level.

An immunization is not covered if it does not meet requirements for FDA labeling (including age and/or gender limitations) and if it does not have definitive ACIP recommendations published in the CDC's Morbidity and Mortality Weekly Report (MMWR).

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COVERAGE:

- The services are 100% or fully covered by the plan, when they are received from participating providers. The plan's benefit level will be lower (less than 100%) when these services are received from non-participating providers. Refer to the applicable COC or SPD for the applicable non-participating provider benefit level.
- These services are covered services under the plan, and the plan will pay for them only when, at the time of service, the member is eligible for and properly enrolled in coverage, and the member and/or employer have timely paid for your coverage.
- New ACIP recommendations that are issued or updated, are required to be covered without cost-sharing starting with the plan year (in the individual market, policy year) that begins on or after the date that is one year after the date the recommendation is issued.
- The services listed are generally covered as preventive health care services when they are provided during an annual or other periodic preventive physical or wellness exam. Unless otherwise specifically stated, the services listed are preventive when: (i) they are performed by a primary care practitioner or in a primary care setting (exceptions may apply), (ii) for the purpose of preventing diseases or conditions in asymptomatic persons (those with no symptoms), and (iii) are properly coded by the practitioner.
- If the service is a screening (whether involving completion of a written assessment, a lab test, or a procedure that uses diagnostic equipment), the member must be asymptomatic, meaning that they do not have symptoms of a condition or disease and either have not previously received a screening or have previously received the applicable screening according to the applicable time frame with "normal" results.
- If a preventive service results in follow up treatment for an identified condition or illness, such follow up treatment is not a preventive health care service. Services that are not preventive may be covered as medical care or treatment services under another non-preventive provision of the plan, and subject to the applicable member cost-sharing.
- Many drugs, medications, vitamins and supplements, both prescribed and over-the-counter are not preventive health care services. When prescribed, they may be covered under a separate non-preventive benefit provision of the plan, and subject to the applicable member cost-sharing.
- Coverage and benefits for preventive health care services, and the frequency, method, treatment or setting for them is subject to any limits and exclusions set forth in the applicable certificate of coverage or contract, plan document or SPD, and to the plan's usual policies, processes and requirements.

BACKGROUND:

This coverage position is based on recommendations of the Advisory Committee On Immunization Practices (Advisory Committee - ACIP) that have been adopted by the Director of the Centers for Disease Control and Prevention and are considered to be for routine use.

Generally, immunizations are among the safest and most effective medicines. The overwhelming majority of medical experts in the United States and abroad believe that the benefits of complete immunization far outweigh the risks. The health experts in many countries are in full accord with the concept that everyone who is healthy should be immunized as recommended.

ACIP, a United States federal advisory committee, provides guidance to the Secretary and the Assistant Secretary for Health and Human Services (HHS), and the Director of CDC, regarding vaccines and

related agents for control of vaccine-preventable diseases within the United States. As a result of the Omnibus Budget Reconciliation Act of 1993, ACIP assumed the role of developing a list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program, along with schedules regarding correct dosages, dosing intervals and contraindications applicable to pediatric vaccines. VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and usage.

Following an ACIP vaccination recommendation (vote), a full recommendation (ACIP statement) will be posted as a provisional recommendation on the ACIP website within three weeks. Provisional recommendations are under review by the HHS and the CDC. Provisional recommendations will become official when published in CDC's Morbidity and Mortality Weekly Report (MMWR). Publication occurs within 6 to 8 months of an ACIP vote. Provisional recommendation provides interim information for healthcare personnel on ACIP recommendations most recently voted upon that have yet to be officially approved by HHS and the CDC.

Full recommendations developed by ACIP may be either affirmative or permissive recommendations. Affirmative recommendations are characterized as routine, catch-up and risk based. Routine vaccinations are most commonly implemented for a specific age group; catch-up vaccinations are usually for defined periods of time and cohorts; and risk-based recommendations are typically those for a high-risk population. A permissive recommendation is issued to reflect situations where vaccination may be effective, but ACIP is not recommending routine use.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. U.S. Department of Labor: July 19, 2010 IRS Interim Rules. Retrieved from https://www.irs.gov/irb/2010-29_IRB. Accessed 02-28-24.
4. U.S. Department of Labor: Employee Benefits Security Administration: Affordable Care Act. Retrieved from https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers Accessed 02-28-24.
5. U.S. Department of Labor: Employee Benefits Security Administration. Affordable Care Act Implementation Frequently Asked Questions. Retrieved from https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12 Accessed 02-28-24.
6. Centers for Disease Control and Prevention/ Immunization Schedules. Retrieved from https://www.cdc.gov/vaccines/schedules/index.html. Accessed 02-28-24.

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Created Date: 02/04/20 (previously part of MP/I003)
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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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