Medical Policy

Subject: Immunizations

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Description/Scope

This document addresses the use of childhood and adult immunizations as recommended by the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention (CDC). Immunization is a technique used to induce immune resistance to a specific disease in humans by exposing the individual to an antigen in order to raise antibodies to that antigen. This process increases an individual's reaction to an antigen and therefore improves the ability to resist or overcome infection. Current immunization schedules and recommendations can be found at the following websites:

- American Academy of Family Physicians: https://www.aafp.org/family-physician/patient-care/prevention-wellness/immunizations-vaccines.html
- American Academy of Pediatrics: https://www.aap.org/en/patient-care/immunizations/
- Advisory Committee on Immunization Practices: https://www.cdc.gov/vaccines/schedules

Position Statement

Medically Necessary:

For Childhood Immunizations:
The most recent recommendations of the American Academy of Family Physicians (AAFP), or the American Academy of Pediatrics (AAP), or the affirmative recommendations of the Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention (CDC) for childhood immunizations are considered **medically necessary.**

For Adult Immunizations:
The most recent recommendations of the American Academy of Family Physicians (AAFP) or affirmative recommendations of the Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention (CDC) for adult immunizations are considered **medically necessary.**

Not Medically Necessary:

Childhood and adult immunizations are considered **not medically necessary** for all other indications not listed above.

Note:
Permissive recommendations of the Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention (CDC) for childhood and adult immunizations are reviewed on an individual basis to determine medical necessity and will be listed in the position statement of this document when determined to be not medically necessary.

Rationale

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. Global health experts 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 and the Director of the 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.

Recommendations developed by ACIP may be either affirmative, permissive or shared clinical decision-making 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. Shared clinical decision-making recommendations represent a paradigm shift; recommendations are not targeted to a specific population (for example, age or risk), but are based upon an informed conversation between the individual and their provider. The key distinction between shared clinical decision-making and the previous categories is outlined on the CDC website noting:

> The key distinction between routine, catch-up, and risk-based recommendations and shared clinical decision-making recommendations is the default decision to vaccinate. For routine, catch-up, and risk-based recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default- the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process.

Background/Overview

Immunization is the process of inducing or providing immunity artificially by administering an immunobiologic. Immunization can be active or passive. Active immunization is the production of antibody or other immune responses through the administration of a vaccine or toxoid. Passive immunization means the provision of temporary immunity by the administration of preformed antibodies. Recommendations for vaccinating infants, children, and adults are based on characteristics of immunobiologics, scientific knowledge about the principles of active and passive immunization and the epidemiology of diseases, and judgments by public health officials and specialists in clinical and preventive medicine. Immunization programs help build defenses against disease and should be started early and carried out on a regular and routine basis.

Childhood immunizations consist of a series of intramuscular injections, subcutaneous injections, or oral dosing of inactivated bacteria, toxoids, live attenuated viruses, or inactive viral antigens against several diseases: diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, haemophilus influenzae type b, human papilloma virus (HPV), hepatitis A, hepatitis B, influenza, varicella, pneumococcus and rotavirus. Many of the immunizations are given as combined vaccines during routine well-child checks in the first 2 years of life. Immunizations against diseases for which risk factors are related to adolescent issues are recommended at ages prior to when exposure most frequently occurs. These include meningitis, hepatitis B, and HPV.

Most adult immunizations are administered in primary series (in previously unimmunized persons), booster doses, and periodic doses. Agents include toxoids (diphtheria and tetanus), live virus vaccines (measles, mumps, and rubella), influenza, inactive viral particles (hepatitis B), highly purified virus-like particles (HPV), and inactivated bacterial polysaccharide vaccine (pneumococcal).

Vaccines using a non-viral vector or messenger RNA (mRNA) delivered via a nucleic acid-based agent is the most recent technology publicly available. The mRNA technique delivers a transcript which encodes one or more immunogens into the host cell, subsequent translation generates immunogenic proteins. The advantage of using mRNA vaccines is the ability to develop and produce large quantities of vaccine in a shorter period of time.

Recommended immunization schedules are grouped by types of vaccine and the recipient's age. Certain vaccinations are present on both childhood and adult schedules, while others may be limited to a specific schedule. ACIP provides the following recommendations:

- Age specific: https://www.cdc.gov/vaccines/schedules.
- Vaccine-specific: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html.

For criteria related to specific immunizations, such as palivizumab, refer to applicable guidelines used by the plan.

Definitions

Antibody: A type of protein produced by the immune system in response to foreign substances that may be a threat to the body such as chemicals, virus particles, spores, or bacterial toxins. These foreign substances are called antigens. Each type of antibody is unique and defends the body against one specific type of antigen.

Antigen: Any substance that, when introduced into the body, evokes an immune response and stimulates the production of antibodies.

Attenuated vaccine: A vaccine using a weakened virus to stimulate an immune response. The virus can be weakened using chemical or physical processes.

Coding

Coding edits for medical necessity review are not implemented for this administrative policy. Where a more specific policy or guideline exists, that document will take precedence and may include specific coding edits and/or instructions. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

References

Peer Reviewed Publications:

1. Kowalzik F, Schreiner D, Jensen C, et al. mRNA-Based Vaccines. Vaccines (Basel). 2021; 9(4):390.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Family Physicians. Immunization schedules. Available at: https://www.aafp.org/family-physician/patient-care/prevention-wellness/immunizations-vaccines/immunization-schedules.html. Accessed on March 25, 2024.
2. American Academy of Pediatrics. Immunization schedules. 2024. Available at: https://publications.aap.org/redbook/pages/Immunization-Schedules?autologincheck=redirected. Accessed on March 25, 2024.
3. Centers for Disease Control and Prevention. ACIP Shared Clinical Decision-Making Recommendations. Available at: https://www.cdc.gov/vaccines/acip/acip-scdm-faqs.html#scdm. Accessed on March 25, 2024.
4. Centers for Disease Control and Prevention. Heplisav-B® (HepB-CpG) Vaccine. Available at: https://www.cdc.gov/vaccines/schedules/vacc-updates/heplisav-b.html. Accessed on March 25, 2024.
5. Centers for Disease Control and Prevention. Prevention and control of seasonal influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023–24 Influenza Season. Available at: https://www.cdc.gov/mmwr/volumes/72/rr/rr7202a1.htm. Accessed on March 25, 2024.
6. Centers for Disease Control and Prevention. Recommended adult immunization schedule for ages 19 years or older: United States, 2024. Available at: http://www.cdc.gov/vaccines/schedules/hcp/adult.html. Accessed on March 25, 2024.
7. Centers for Disease Control and Prevention. Recommended child and adolescent immunization schedule for ages 18 years or younger, United States, 2024. Available at: http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html. Accessed on March 25, 2024.
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9. Department of Health and Human Services. Affordable Care Act. Coverage of Preventive Health Services.
    - 26 CFR 54.9815-2713(a)(1)(ii). Available at: https://www.govinfo.gov/content/pkg/CFR-2020-title26-vol19/pdf/CFR-2020-title26-vol19-sec54-9815-2713A.pdf. Accessed on March 25, 2024.
    - 29 CFR 2590.715-2713(a)(1)(ii). Available at: https://www.govinfo.gov/content/pkg/CFR-2020-title29-vol9/pdf/CFR-2020-title29-vol9-sec2590-715-2713.pdf. Accessed on March 25, 2024.
    - 45 CFR 147.130(a)(1)(ii). Available at: https://www.govinfo.gov/content/pkg/CFR-2019-title45-vol2/pdf/CFR-2019-title45-vol2-sec147-130.pdf. Accessed on March 25, 2024.
10. United States Food & Drug Administration (FDA). Vaccines Licensed for Use in the United States. Current as of December 1, 2022. Available at: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states. Accessed on March 25, 2024.

Websites for Additional Information

1. American Academy of Pediatrics (AAP). Healthy Children. Immunization. Available at: https://www.healthychildren.org/english/safety-prevention/immunizations/Pages/default.aspx. Accessed on March 25, 2024.
2. Centers for Disease Control and Prevention. Glossary. Available at: https://www.cdc.gov/vaccines/terms/glossary.html#:~:text=Attenuated%20vaccine%3A%20Listen%20%5BMP3%5D,severe%20effects%20of%20the%20disease. Accessed on March 25, 2024.
3. Centers for Disease Control and Prevention. Recommendations and guidelines: Advisory Committee on Immunization Practices (ACIP). Available at: http://www.cdc.gov/vaccines/acip/index.html. Accessed on March 25, 2024.

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Document History

Status	Date	Action
Reviewed	05/09/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Background and References sections.
Reviewed	05/11/2023	MPTAC review. Updated Rationale and References sections.
Reviewed	05/12/2022	MPTAC review. Updated References section.
Reviewed	05/13/2021	MPTAC review. Updated Rationale, Definitions and References sections.
Reviewed	05/14/2020	MPTAC review. Updated Rationale, References and Index sections.
Reviewed	06/06/2019	MPTAC review. Updated Description/Scope, References and Websites sections.
Revised	07/26/2018	MPTAC review. Removed NMN statement regarding the use of the live attenuated influenza vaccine. Updated Rationale, Background, References, and Websites sections. Updated Coding section to remove code 90672, no longer applicable.
	05/10/2018	Added new vaccine to Index section. Background section updated.
	02/28/2018	Added new vaccine to Index section. The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	08/03/2017	MPTAC review. Rationale and References sections updated.
Revised	08/04/2016	MPTAC review. Added new NMN statement regarding the use of the live attenuated influenza vaccine. Updated Coding, Rationale, Background/Overview and Reference sections.
Reviewed	02/04/2016	MPTAC review. Rationale, Background/Overview and Reference sections updated.
Reviewed	02/05/2015	MPTAC review. Description, Background, Reference and Index sections updated.
Reviewed	02/14/2014	MPTAC review. Rationale and Reference sections updated.
Reviewed	02/14/2013	MPTAC review. Reference section updated.
Revised	02/16/2012	MPTAC review. Added a not medically necessary statement. Description, Coding and Reference sections updated.
Reviewed	11/17/2011	MPTAC review. Rationale, Background, Description, Reference and Index sections updated. Immunization references moved from ADMIN.00002 to this document if not already present.
Reviewed	02/17/2011	MPTAC review. Rationale, Background and References updated.
Reviewed	02/25/2010	MPTAC review. Rationale and references updated.
Revised	11/19/2009	MPTAC review. Position statements updated to include affirmative ACIP recommendations and clarified by changing American Academy of Family Practice to American Academy of Family Physicians. Note regarding permissive recommendations added to position statement section. Description, rationale, background, and references updated.
	02/19/2009	Updated references to reflect 2009 CDC releases.
Reviewed	11/20/2008	MPTAC review. Rationale section added. Background/Overview, references, and index updated.
Reviewed	11/29/2007	MPTAC review. References updated.
New	12/07/2006	MPTAC initial document development.

Pre-Merger Organizations	Last Review Date	Document Number	Title
WellPoint Health Networks, Inc.	Archived 05/31/2002	8.01.11	Immunizations

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical

Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.