



An Independent Licensee of the Blue Cross Blue Shield Association

**EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE**

**ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.



An Independent Licensee of the Blue Cross Blue Shield Association

**EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE**

**ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Description:

Vaccines to induce immunity.

Routine Immunizations:

According to the Centers for Disease Control and Prevention (CDC), the following routine immunizations or combination of immunizations are recommended:

- Dengue
- Diphtheria
- Haemophilus influenza B (HIB)
- Hepatitis A
- Hepatitis B
- Herpes zoster (shingles)
- Human papillomavirus (HPV)
- Influenza virus (seasonal)
- Measles
- Meningococcal serogroups A, C, W, Y
- Meningococcal serogroup B
- Mpox
- Mumps
- Pertussis
- Pneumococcal
- Polio
- Respiratory syncytial virus
- Rotavirus¹
- Rubella
- SarsCoV2
- Tetanus
- Varicella (chickenpox)
- Zoster

Information on routine immunizations may be obtained at:

<http://www.cdc.gov/vaccines/schedules/index.html>



An Independent Licensee of the Blue Cross Blue Shield Association

**EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE**

**ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Foreign Travel Immunizations:

Foreign travel immunizations are necessary for protection from diseases that are still common in many parts of the world. According to the CDC, the following are foreign travel immunizations:

- Hepatitis A
- Hepatitis B
- Japanese encephalitis
- Meningococcal (MenACWY-D and MENACWY-CRM)
- Polio
- Rabies
- Typhoid and paratyphoid fever
- Yellow fever

In addition to the foreign travel immunizations listed above, the CDC also recommends that routine immunizations be up-to-date before travel. See "Routine Immunizations".

Information on foreign travel immunizations may be obtained at:

<https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/vaccination-and-immunoprophylaxis-general-principles>

Non-Routine Immunizations:

Non-routine immunizations include all other vaccines not previously identified as "routine immunizations" or "foreign travel immunizations". Non-routine immunizations include:

- Adenovirus
- Anthrax
- Plague
- Smallpox
- Tuberculosis (Bacillus Calmette-Guerin[BCG])

Non-routine immunizations also include pandemic immunizations. A pandemic occurs when a new virus emerges for which there is little or no immunity in the human population, begins to cause serious illness, and then spreads easily person-to-person worldwide. Pandemic immunizations include:

- Avian influenza, avian flu or "bird flu" (H5N1)
- Swine influenza or swine flu (H1N1)



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE

ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Criteria:

Refer to FDA website for current guidelines and dosage.

Routine Immunizations:

- Routine immunizations are considered **medically necessary** and **eligible for coverage** when **ALL** of the following are met:
 1. Individual's provider recommends immunization
 2. Immunization is given with U.S. Food and Drug Administration (FDA) approved vaccine
 3. Immunization is appropriate for individual's age and gender as recommended by **ONE** of the following:
 - Advisory Committee on Immunization Practices (ACIP) routine immunization recommendations at cdc.gov/vaccines/hcp/acip-recs/index.html
 - Health Resources and Services Administration (HRSA) guidelines for pediatric and adolescent preventive care and screening at [mchb.hrsa.gov/maternal-child-health-topics/child\[1\]health/bright-futures.html](https://mchb.hrsa.gov/maternal-child-health-topics/child[1]health/bright-futures.html)
 - HRSA guidelines for women's healthcare services at hrsa.gov/womens-guidelines/index.html
 - U.S. Preventive Services Task Force (USPSTF) A or B rated services at [uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b\[1\]recommendations](https://uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b[1]recommendations)
- Routine immunizations without FDA approval, administered outside of the FDA-approved age range or administered outside of the FDA-approved indications are considered **experimental or investigational** when any one or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE

ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Foreign Travel Immunizations:

- If benefits for immunizations are available, foreign travel immunizations are considered **medically necessary** and **eligible for coverage**.
- **If benefits for immunization services are not available**, foreign travel immunizations are considered a **benefit plan exclusion** and **not eligible for coverage**.
- Foreign travel immunizations without FDA approval, administered outside of the FDA-approved age range or administered outside of the FDA-approved indications, are considered **experimental or investigational** when any one or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

Non-Routine/Post-Exposure Immunizations:

- If benefits for immunizations are available, post-exposure immunizations are considered **medically necessary** and **eligible for coverage**.
- Non-routine immunizations provided by the government at no charge to the member are considered a **benefit plan exclusion** and **not eligible for coverage**.
- **If benefit for immunization services is not available**, post-exposure/non-routine immunizations are considered a **benefit plan exclusion** and **not eligible for coverage**.
- Non-routine immunizations without FDA approval, administered outside of the FDA-approved age ranges or administered outside of the FDA-approved indications, are considered **experimental or investigational** when any one or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE

ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Pandemic/Emergency Use Immunizations:

The following criteria apply to BCBSAZ local lines of business only. For all other lines of business, refer to *“Included Services” Pricing Guideline*.

- Pandemic immunizations provided by the government at no charge to the member are considered included in the administration and **not eligible for separate reimbursement**, as well as a **benefit plan exclusion**.
- Pandemic immunization administration costs are considered **eligible for coverage** under the preventive services benefit.

Resources:

Literature reviewed 06/18/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 06/18/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. About Plague. Centers for Disease Control and Prevention. Updated May 15, 2024. Accessed June 5, 2024. <https://www.cdc.gov/plague/index.html>
2. Adult Immunization Schedule by Age: Recommendations for Ages 19 Years or Older. Centers for Disease Control and Prevention. Updated February 29, 2024. Accessed June 6, 2024. <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>
3. Blue Cross Blue Shield of Arizona. Benefit Plan Booklet.
4. Child and Adolescent Immunization Schedule by Age: Recommendations for Ages 18 Years or Younger. Centers for Disease Control and Prevention. Updated November 16, 2023. Accessed June 6, 2024. <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>
5. Lyme disease vaccine. Centers for Disease Control and Prevention. Updated May 15, 2024. Accessed June 6, 2024. <https://www.cdc.gov/lyme/prev/vaccine.html>
6. Mpox Vaccination Basics. Centers for Disease Control and Prevention. Updated March 22, 2023. Accessed June 6, 2024. https://www.cdc.gov/poxvirus/mpox/vaccines/index.html?s_cid=qr2022
7. TB Elimination BCG Vaccine. Centers for Disease Control and Prevention. Updated October 2011. Accessed June 5, 2024. <https://www.cdc.gov/tb/publications/factsheets/prevention/BCG.pdf>
8. U.S. Food and Drug Administration. Premarket Approval (PMA) Database. Accessed June 5, 2024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE

ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

9. U.S. Food and Drug Administration. 510(k) Premarket Notification Database. Accessed June 5, 2024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>
10. Vaccination & Immunoprophylaxis— General Principles: Viral CDC Yellow Book 2024. Centers for Disease Control and Prevention. Updated May 1, 2023. Accessed June 6, 2024. <https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/vaccination-and-immunoprophylaxis-general-principles>
11. Vaccine Information Statement Anthrax Vaccine. Centers for Disease Control and Prevention. Updated January 8, 2020. Accessed June 6, 2024. <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/anthrax.pdf>
12. Vaccine Information Statement Dengue Vaccine. Centers for Disease Control and Prevention. Updated December 17, 2021. Accessed June 6, 2024. <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/dengue.pdf>
13. Vaccine Information Statement Rabies Vaccine. Centers for Disease Control and Prevention. Updated June 2, 2022. Accessed June 6, 2024. <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/rabies.pdf>
14. Vaccines Licensed for Use in the United States. U.S. Food and Drug Administration. Updated May 31, 2024. Accessed June 6, 2024. <https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states>

Coding:

CPT: 0001A, 0002A, 0011A, 0012A, 90460, 90461, 90471, 90472, 90473, 90474, 90476, 90477, 90581, 90585, 90586, 90587, 90620, 90621, 90625, 90630, 90632, 90633, 90634, 90636, 90644, 90647, 90648, 90649, 90650, 90651, 90653, 90654, 90655, 90656, 90657, 90658, 90660, 90661, 90662, 90664, 90666, 90667, 90668, 90670, 90672, 90673, 90674, 90675, 90676, 90680, 90681, 90682, 90685, 90686, 90687, 90688, 90689, 90690, 90691, 90696, 90697, 90698, 90700, 90702, 90707, 90710, 90713, 90714, 90715, 90716, 90717, 90723, 90732, 90733, 90734, 90736, 90738, 90739, 90740, 90743, 90744, 90746, 90747, 90748, 90749, 90750, 90756, 91300, 91301, 91303, 91305, 91306, 91307, 91308, 91309

HCPCS: G0008, G0009, G0010, J3530, Q2034, Q2035, Q2036, Q2037, Q2038, Q2039



An Independent Licensee of the Blue Cross Blue Shield Association

**EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE**

**ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	06/18/24	Review with revisions
Medical Directors (Dr. Raja, Dr. Sutanto)	06/06/24	Review with revisions
Legal Department	06/06/24	Review with no revisions
Medical Policy Panel (ad hoc)	07/20/23	Review with revisions
Legal Division	06/29/23	Review with no revisions
Medical Directors (Dr. Raja)	06/21/23	Review with revisions
Pediatric Subspecialty Advisory Sub-Committee	02/16/23	Review with revisions

Policy Revisions:

06/18/24	Added	“Dengue”, “Mpox”, “Respiratory syncytial virus” and “Zoster” to Routine Immunizations in the Description section.
06/18/24	Removed	“Cholera” from Foreign Travel Immunizations in the Description section; “Monkeypox” from Non-Routine Immunizations in the Description section; “3” from the Description section.
06/18/24	Revised	“ http://wwwnc.cdc.gov/travel/yellowbook/2016/table-of-contents.htm ” to “ https://wwwnc.cdc.gov/travel/yellowbook/2024/preparing/vaccination-and-immunoprophylaxis-general-principles ” under Foreign Travel Immunizations in the Description section.
06/18/24	Updated	Resources section.



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: ADMINISTRATIVE PROCEDURE

ORIGINAL EFFECTIVE DATE: 07/20/23
LAST REVIEW DATE: 06/18/24
CURRENT EFFECTIVE DATE: 06/18/24
LAST CRITERIA REVISION DATE: 07/20/23
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

IMMUNIZATIONS

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'ánii hólo díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínigóó. Ata' halne'ígíí kojí' bich'í'í hodíílinih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعدته أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

