



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, 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.

**MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE**

**ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:**

IMMUNIZATIONS (cont.)

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:

- Diphtheria
- Haemophilus influenza B (HIB)
- Hepatitis A
- Hepatitis B
- Herpes zoster (shingles)
- Human papillomavirus (HPV)
- Influenza virus (seasonal)
- Measles
- Meningococcal (MCV4 or MenACWY [Menactra®, Menveo®], MPSV4 [Menomune®])
- Meningococcal B (MenB) [Trumenba®, Bexsero®]
- Mumps
- Pertussis
- Pneumococcal
- Polio
- Rotavirus¹
- Rubella
- Tetanus
- Varicella (chickenpox)

Information on routine immunizations may be obtained at:

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

**MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE**

**ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:**

IMMUNIZATIONS (cont.)

Description: (cont.)

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:

- Cholera
- Hepatitis A
- Hepatitis B
- Japanese encephalitis
- Meningococcal (MCV4 or MenACWY [Menactra, Menveo], MPSV4 [Menomune])
- 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:

<http://wwwnc.cdc.gov/travel/yellowbook/2016/table-of-contents.htm>

Non-Routine Immunizations:

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

- Adenovirus²
- Anthrax (BioThrax®)
- Plague
- Smallpox (ACAM2000®)³
- Tuberculosis (Bacillus Calmette-Guerin[BCG])

Non-routine immunizations also include pandemic influenza immunizations. An influenza pandemic occurs when a new influenza 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 influenza immunizations include:

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

MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Criteria:

Routine Immunizations:

COVERAGE FOR IMMUNIZATIONS IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO THE MEMBER'S SPECIFIC BENEFIT PLAN BOOK FOR BENEFIT COVERAGE.

➤ If benefits for immunizations are available, the following routine immunizations are considered ***medically necessary***:

1. Diphtheria
2. Haemophilus influenza B
3. Hepatitis A
4. Hepatitis B
5. Herpes zoster (Shingrix®, Zostavax®) for age 50 years and older
6. Human papillomavirus (Gardasil™)
 - Series of 3 injections for individuals age 9 – 26 years **or**
 - 2nd or 3rd dose to complete series for individual age 27 who began series at age 26
7. Human papillomavirus (Gardasil® 9)
 - Series of 3 injections for individuals age 9 – 45 years **or**
 - 2nd or 3rd dose to complete series for individual age 46 who began series at age 45
8. Human papillomavirus (Cervarix™)
 - Series of 3 injections for female age 9 – 25 years **or**
 - 2nd or 3rd dose to complete series for female age 26 who began series at age 25
9. Influenza virus (seasonal)
10. Measles
11. Meningococcal (MCV4 or MenACWY [Menactra, Menveo], MPSV4 [Menomune])
12. Meningococcal B (Trumenba or Bexsero for age 10 - 25 years)
13. Mumps
14. Pertussis
15. Pneumococcal (Pneumovax® 23, Prevnar®, Prevnar 13®)
16. Polio (injectable or oral)
17. Rotavirus (RotaTeq® or Rotarix®) for age 1 and younger
18. Rubella
19. Tetanus
20. Varicella

IMMUNIZATIONS (cont.)

Criteria: (cont.)

Routine Immunizations: (cont.)

- If benefits for immunizations are available, the following routine combination immunizations are considered **medically necessary**:
 1. Diphtheria and tetanus
 2. Diphtheria, tetanus and acellular pertussis (Infanrix®, Daptacel®)
 3. Diphtheria, tetanus, acellular pertussis and haemophilus influenza type B
 4. Diphtheria, tetanus, acellular pertussis, haemophilus influenza B and polio (Pentacel®) for age 4 years and younger
 5. Diphtheria, tetanus, acellular pertussis and polio (Kinrix™, Quadracel™) for age 4 – 6 years
 6. Diphtheria, tetanus, acellular pertussis, hepatitis B and polio (Pediatrix™) Haemophilus influenza type B and tetanus
 7. Hepatitis A and hepatitis B
 8. Hepatitis B and haemophilus influenza type B
 9. Measles, mumps and rubella
 10. Measles, mumps, rubella and varicella
 11. Meningococcal conjugate vaccine, serogroups C & Y and Haemophilus influenza b vaccine, tetanus toxoid conjugate (Hib-MenCY or MenHibrix)
 12. Tetanus and diphtheria
 13. Tetanus, reduced diphtheria and acellular pertussis (Adacel®, Boostrix®)

- 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** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

These immunizations include, *but are not limited to*:

 - DTaP-IPV-Hib-HepB vaccine, intramuscular
 - Vaccines removed, withdrawn or suspended from marketing

- If benefits for immunizations are available, routine immunizations for all other indications not previously listed will be reviewed for medical necessity by the medical director(s) and/or clinical advisor(s).

MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Criteria: (cont.)

Foreign Travel Immunizations:

- If benefits for immunizations are available, the following foreign travel immunizations are considered **medically necessary**:
 1. Cholera
 - Vaxchora™ for individuals 18 to 64 years of age
 2. Hepatitis A
 3. Hepatitis B
 4. Japanese encephalitis
 - Ixiaro® for 2 months of age and older
 5. Meningococcal (MCV4 or MenACWY [Menactra, Menveo], MPSV4 [Menomune])
 6. Polio (injectable or oral)
 7. Rabies
 8. Typhoid and paratyphoid fever
 9. Yellow fever
- 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** based upon:
 1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

IMMUNIZATIONS (cont.)

Criteria: (cont.)

Non-Routine Immunizations:

- If benefits for immunizations are available, the following non-routine immunizations are considered **medically necessary**:
 1. Anthrax vaccine (Biothrax) for individuals 18 to 65 years of age with documentation of **ANY** of the following:
 - Pre-exposure prophylaxis of disease in persons whose occupation or other activities place them at high risk of exposure
 - Post-exposure prophylaxis of disease following suspected or confirmed Bacillus anthracis exposure, when administered in conjunction with recommended antibacterial drugs
 2. Tuberculosis
- Non-routine immunizations provided by the government at no charge to the member are considered a **benefit plan exclusion** and **not eligible for coverage**. These immunizations include, *but are not limited to*:
 1. Smallpox vaccine
 2. Vaccines for military personnel, i.e., adenovirus, anthrax
- 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** based upon lack of final approval from the FDA.

These immunizations include, *but are not limited to*:

 1. Dengue vaccine
 2. Lyme Disease vaccine (withdrawn from market)
 3. Plague vaccine



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Criteria: (cont.)

Pandemic Immunizations:

The following criterion applies 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 immunizations include, *but are not limited to*:

- H1N1 (swine influenza)
 - H5N1 (avian influenza)
- Pandemic immunization administration costs are considered **eligible for coverage** under the preventive services benefit.
- ¹ Infants with Severe Combined Immunodeficiency Disease (SCID) should not receive rotavirus vaccines. Postmarketing reports of gastroenteritis, including severe diarrhea and prolonged shedding of vaccine virus, have been reported in infants who were administered live, oral rotavirus vaccines and later identified as having SCID.
 - ² Available for military personnel only.
 - ³ For non-commercial distribution only. Non-commercial distribution means the vaccine is not available to the general public and therefore not available through physician offices. The vaccine is being produced under contract by the United States federal government for inclusion within the country's national stockpile.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Resources:

Literature reviewed 11/28/17. We do not include marketing materials, poster boards and non-published literature in our review.

1. Coding News - June 8, 2009. Received 06/08/2009.
2. American Academy of Pediatrics. HPV Vaccine Recommendations. 02/27/2012.
3. Aventis Pasteur, K H. New Preservative-Free Tetanus Diphtheria Vaccine Letter. 01/2005 2005.
4. Blue Cross Blue Shield of Arizona. Benefit Plan Booklet.
5. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. 03/27/2015;64:300-304.
6. Centers for Disease Control Advisory committee on Immunization Practices. Vaccines to Prevent Poliomyelitis Vaccines for Children Program. 06/26/2008, received 07/14/2008 2008;Resolution No. 6/08-4.
7. Centers for Disease Control and Prevention. Vaccinations: What You Need to Know About Vaccinations and Travel: A Checklist <http://wwwn.cdc.gov/travel/contentVaccinations.aspx>. Accessed 09/22/2008.
8. Centers for Disease Control and Prevention. Recommended Immunization Schedules for Persons Ages 0 Through 18 Years--United States, 2009. *Morbidity and Mortality Weekly Report Erratum; Volume 57; Numbers 51; 52*. 01/09/2009;57(53)(1419).
9. Centers for Disease Control and Prevention. Lyme Disease Vaccination. Modified 02/01/2008.
10. Centers for Disease Control and Prevention. Chapter 2: Travel Related Vaccines - Preventable Diseases. *Travel Health: Online Yellow Book*. Accessed 06/17/16, 08/26/15, 10/23/14, 08/07/09.
11. Centers for Disease Control and Prevention. Appendix C: Travel Vaccine Summary Table. Accessed 06/17/16, 08/26/15, 10/23/14, 11/12/13, 11/21/12, 11/14/11.
12. Centers for Disease Control and Prevention. Notice to Readers: Recommendation from the Advisory Committee on Immunization Practices (ACIP) for Use of Quadrivalent Meningococcal Conjugate Vaccine (MCV4) in Children Aged 2 - 10 Years at Increased Risk for Invasive Meningococcal Disease. *MMWR Weekly*. 12/07/2007 2007;56(48):1265-1266.
13. Centers for Disease Control and Prevention. Notice to Readers: Revised Recommendations of the Advisory Committee on Immunization Practices to Vaccinate All Persons Aged 11 - 18 Years with Meningococcal Conjugate Vaccine. *MMWR Weekly*. 08/10/2007 2007;56(31):794-795.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Resources: (cont.)

14. Centers for Disease Control and Prevention. Recommended Immunization Schedules for Persons Ages 0 Through 18 Years--United States. *Morbidity and Mortality Weekly Report*. 01/02/2009 2009;57(51; Q-1-Q-4).
15. Centers for Disease Control and Prevention. Prevention of Rotavirus Gastroenteritis Among Infants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP); Prepared by Cortese; M; Parashar; U. *Morbidity and Mortality Weekly Report*. 02/06/2009 2009;58(RR02).
16. Centers for Disease Control and Prevention Department of Health and Human Services National Immunization Program. Rotavirus Vaccine What You Need to Know. 04/12/2006, accessed 07/31/2006 2006.
17. Centers for Disease Control and Prevention Division of Vector Borne Infectious Diseases. Lyme Disease Prevention and Control. 11/18/2003, accessed 06/10/2004 2003.
18. Centers for Disease Control and Prevention Division of Vector-Borne Infectious Diseases. Learn About Lyme Disease. Modified 12/29/2007.
19. Centers for Disease Control and Prevention Press Release. CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination. June 29, 2006.
20. Centers for Disease Control and Prevention: Respiratory and Enteric Viruses Branch. Adenoviruses. 01/21/2005, Accessed 10/25/2006 2005.
21. Department of Health and Human Services Centers for Disease Control and Prevention. Live, Intranasal Influenza Vaccine: What You Need to Know 2004-2005. 05/24/2004 2004.
22. Department of Health and Human Services Centers for Disease Control and Prevention. Inactivated Influenza Vaccine: What You Need to Know 2004-2005. 05/24/2004 2004.
23. Department of Health and Human Services Centers for Disease Control and Prevention. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report (MMWR) Early Release*. 07/13/2005 2005;54.
24. Department of Health and Human Services Centers for Disease Control and Prevention Advisory Committee on Immunizations Practices (ACIP). Recommended Immunization Schedule for Persons Aged 0-18 Years - United States. Accessed 11/21/17, 06/17/16, 08/26/2015, 07/30/2007.
25. Department of Health and Human Services Centers for Disease Control and Prevention Advisory Committee on Immunizations Practices (ACIP). Recommended Adult Immunization Schedule. Accessed 11/28/17, 06/21/17, 06/17/16, 08/26/2015, 04/13/2015, 10/23/2014, 07/30/2007.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Resources: (cont.)

26. Deshmukh AA, Cantor SB, Fenwick E, et al. Adjuvant HPV vaccination for anal cancer prevention in HIV-positive men who have sex with men: The time is now. *Vaccine*. Sep 12 2017;35(38):5102-5109.
27. Earnhart CG, Marconi RT. An octavalent lyme disease vaccine induces antibodies that recognize all incorporated OspC type-specific sequences. *Hum Vaccin*. 2007 Nov-Dec 2007;3(6):281-289.
28. Emery, G. Effects of Chickenpox Vaccine Fade Over Time. *Reuters*. 03/15/2007 2007.
29. FDA. Questions and Answers on FluMist. Updated 07/16/07.
30. FDA. H5N1 Influenza Virus Vaccine Q & A. 04/17/2007 2007.
31. FDA. FDA Expands Age Range for Use of Bacterial Meningitis Vaccine. *FDA News*. 10/18/2007 2007.
32. FDA. Center for Biologics Evaluation and Research - Licensed Product Approval Information. 02/06/2009 2009.
33. GlaxoSmithKline. Products Overview: Vaccines. 03/02/2003 2003.
34. Immunization Action Coalition. Standing Orders for Administering Rotavirus Vaccine to Infants. 05/26/2009.
35. Immunization Action Coalition. CDC posts provisional recommendations for use of shingles (herpes zoster) vaccine on the ACIP web section. *IAC Express 2006*. 11/27/2006 2006(632).
36. Immunization Action Coalition. AAP releases policy statement recommending routine immunization of infants with pentavalent rotavirus vaccine. *IAC Express 2006*. 11/13/2006 2006(629).
37. Immunization Coalitions Assistance Center. Shingles Vaccine for People Over 60 wins FDA Approval. Accessed 08/01/2006.
38. MedImmune, Warner, L. FluMist ® Package Insert and Letter to K. Kelley, PharmD. 08/2005 Package Insert, 08/12/2005 Letter 2005.
39. Palefsky JM, Giuliano AR, Goldstone S, et al. HPV vaccine against anal HPV infection and anal intraepithelial neoplasia. *The New England journal of medicine*. Oct 27 2011;365(17):1576-1585.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Resources: (cont.)

40. Wheeler CM, Skinner SR, Del Rosario-Raymundo MR, et al. Efficacy, safety, and immunogenicity of the human papillomavirus 16/18 AS04-adjuvanted vaccine in women older than 25 years: 7-year follow-up of the phase 3, double-blind, randomised controlled VIVIANE study. *Lancet Infect Dis.* Jun 28 2016.

FDA Product Approval Information for BioThrax:

- FDA-approved indication: For the active immunization for the prevention of disease caused by *Bacillus anthracis* in individuals between 18 and 65 years of age:
 - Pre-exposure prophylaxis of disease in persons whose occupation or other activities place them at high risk of exposure
 - Post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs

The efficacy of BioThrax for post-exposure prophylaxis is based solely on studies in animal models of inhalational anthrax.

FDA Product Approval Information for Cervarix:

- FDA-approved indication: For vaccination in females 9 to 25 years of age for prevention of the following diseases caused by oncogenic Human Papillomavirus (HPV) types 16 and 18:
 - Cervical cancer
 - Cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma *in situ*
 - Cervical intraepithelial neoplasia (CIN) grade 1

FDA Product Approval Information for Flud:

- FDA-approved indication: For active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine in individuals 65 years of age and older.

FDA Product Approval Information for Flublok:

- FDA-approved indication: For active immunization against disease caused by influenza virus subtypes A and Type B contained in the vaccine in individuals 18 years of age and older.

IMMUNIZATIONS (cont.)

Resources: (cont.)

FDA Product Approval Information for FluMist:

- FDA-approved indication: For active immunization of individuals, 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

FDA Product Approval Information for Gardasil 9:

- FDA-approved indication: For vaccination in girls and women 9 through 45 years of age for prevention of the following diseases:
 - Cervical, vulvar, vaginal, and anal cancer caused by Human Papillomavirus (HPV) types 16, 18, 31, 33, 45, 52, and 58
 - Genital warts (condyloma acuminata) caused by HPV types 6 & 11
 - The following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58:
 - Cervical intraepithelial neoplasia (CIN) grade 2/3 & cervical adenocarcinoma *in situ* (AIS)
 - Cervical intraepithelial neoplasia (CIN) grade 1
 - Vulvar intraepithelial neoplasia (VIN) grade 2 & 3
 - Vaginal intraepithelial neoplasia (VaIN) grade 2 & 3
 - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

For vaccination in boys and men 9 through 45 years of age for prevention of the following diseases:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
- Genital warts (condyloma acuminata) caused by HPV types 6 & 11
- The following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58:
 - Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.

FDA Product Approval Information for Ixiaro:

- FDA-approved indication: For the prevention of disease caused by Japanese encephalitis virus in persons 2 months of age and older.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Resources: (cont.)

FDA Product Approval Information for Kinrix:

- FDA-approved indication: Active immunization against diphtheria, tetanus, pertussis and poliomyelitis as the fifth dose in the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine series and the fourth dose in the inactivated poliovirus vaccine (IPV) series in children 4 through 6 years of age whose previous DTaP vaccine doses have been with INFANRIX® and/or PEDIARIX® for the first three doses and INFANRIX® for the fourth dose.

FDA Product Approval Information for Pentacel:

- FDA-approved indication: Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease caused by Haemophilus influenzae type B when administered to infants and children 6 weeks through 4 years of age (prior to fifth birthday).

FDA Product Approval Information for Rotarix:

- FDA-approved indication: Indicated for the prevention of rotavirus gastroenteritis caused by G1 and non-G1 types (G3, G4, and G9) when administered as a 2-dose series in infants 6 weeks to 24 weeks of age. The first dose should be administered to infants beginning at 6 weeks of age. There should be an interval of at least 4 weeks between the first and second dose. The 2-dose series should be completed by 24 weeks of age.

FDA Product Approval Information for RotaTaq:

- FDA-approved indication: For the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, G4 and G9 when administered as a 3-dose series to infants between the ages of 6 to 32 weeks. The first dose should be administered between 6 and 12 weeks of age. The third dose should not be given after 32 weeks of age.

FDA Product Approval Information for Shingrix:

- FDA-approved indication: Prevention of herpes zoster (shingles) in adults aged 50 years and older.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

Resources: (cont.)

FDA Product Approval Information for Trumenba and Bexsero:

- FDA-approved indication: Active immunization to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. Trumenba and Bexsero are approved for use in individuals 10 through 25 years of age.

FDA Product Approval Information for Vaxchora:

- FDA-approved indication: For active immunization against disease caused by *Vibrio cholera* serogroup O1 in individuals 18-64 years of age traveling to cholera-infected areas.

FDA Product Approval Information for Zostavax:

- FDA-approved indication: For the prevention of herpes zoster (shingles) in individuals 50 years of age and older.



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 07/07/16
LAST REVIEW DATE: 10/16/18
LAST CRITERIA REVISION DATE: 11/20/18
ARCHIVE DATE:

IMMUNIZATIONS (cont.)

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'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 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 تساعد 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.

