

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

|                           |                    |                        |                                       |
|---------------------------|--------------------|------------------------|---------------------------------------|
| <b>POLICY:</b>            | Immunizations      | <b>P&amp;T DATE:</b>   | 3/21/2023                             |
| <b>THERAPEUTIC CLASS:</b> | Infectious Disease | <b>REVIEW HISTORY:</b> | 5/22, 5/21, 5/20, 5/19,               |
| <b>LOB AFFECTED:</b>      | MCL                | (MONTH/YEAR)           | 2/18, 2/17, 2/16, 2014,<br>2013, 2011 |

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.*

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

## OVERVIEW

Vaccinations help in reducing the health consequences of vaccine-preventable diseases among both adolescents and adults. The most recently recommended immunization schedules approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists are readily available on [www.cdc.gov/vaccines/schedules](http://www.cdc.gov/vaccines/schedules). Scheduled/routine vaccinations are listed in Table 1. Non-schedule/non-routine vaccinations that are available are listed in Table 2. Note that all vaccinations can be provided by the primary care provider, but only some can be provided at the pharmacy. Vaccinations marked as being available under the Vaccines for Children (VFC) program, anyone under the age of 19 can only obtain that vaccine at a VFC facility. For more information about the California VFC Program, follow this link: <http://eziz.org/vfc/>.

\*\*The **COVID-19 Vaccines** are available through Emergency Use Authorizations (EUA) via the CDC COVID-19 Vaccination Program. Providers who are enrolled in the Vaccination Program may not charge any fee for the vaccine and may not charge the vaccine recipient any out-of-pocket charge for the administration. The following are currently available COVID-19 Vaccines and their dosing schedules.

- Pfizer-BioNTech COVID-19 Vaccine (EUA issued 12/11/2020) – 2 dose series, separated by 3 weeks
- Moderna COVID-19 Vaccine (EUA issued 12/18/2020) – 2 dose series, separated by 4 weeks
- Janssen COVID-19 Vaccine (EUA issued 02/27/2021) – 1 dose

Please refer to <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines> for further information regarding the COVID-19 vaccines and EUAs.

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

**Table 1: Available Scheduled Vaccinations**

| CPT Code     | Vaccination For                                   | Vaccination(s)                | Pharmacy Benefit | Medical Benefit | Vaccine for Children |
|--------------|---|-------------------------------|------------------|-----------------|----------------------|
| 90700        | Diphtheria, tetanus, & acellular pertussis (DTaP) | Daptacel®, Infanrix®          | X                | X               | X                    |
| 90647, 90648 | Haemophilus influenzae type b (Hib)               | PedvaxHIB®, ActHIB®, Hiberix® | X                | X               | X                    |

|   |   |  |   |   |   |
|---|---|--|---|---|---|
| 90632, 90633, 90634   | Hepatitis A (HepA)                                | Vaqta®, Havrix®  | X | X | X |
| 90371, 90739, 90740, 90743, 90744, 90746, 90747, 90759                      | Hepatitis B (HepB)                                | Engerix B®, Recombivax HB®   | X | X | X |
| 90649, 90650, 90651   | Human papillomavirus                              | Gardasil®, Gardasil®9, Cervarix®   | X | X | X |
| 90713   | Inactivated poliovirus (IPV)                      | IPOL®  | X | X | X |
| 90630, 90654, 90655, 90656, 90661, 90662, 90674, 90682, 90685, 90686, 90694 | Influenza   | Afluria-no preservative, Fluzone Quadrivalent no preservatives   | X | X | X |
| 90653, 90657, 90658, 90682, 90687, 90688, 90756                             |   | Fluzone®, Fluzone® Quadrivalent, Flucelvax®, Fluvirin®, FluLaval Quadrivalent, Afluria®, Flublok®<br>Fluzone® Intradermal Quadrivalent, Fluarix® | X | X | X |
| 90660, 90672  |   | FluMist  | X | X | X |
| 90707, 90710  | Measles, mumps, rubella (MMR)                     | M-M-R®II   | X | X | X |
| 90619, 90733, 90734   | Meningococcal                                     | Menactra®, Menveo®   | X | X | X |
| 90620, 90621  | Meningococcal B (MenB)                            | Trumenba®, Bexsero®  | X | X | X |
| 90670   | Pneumococcal conjugate (PCV13)                    | Prevnar 13™  | X | X | X |
| 90671   | Pneumococcal conjugate (PCV15)                    | Vaxneuvance®   | X | X | X |
| 90677   | Pneumococcal conjugate (PCV20)                    | Prevnar 20™  | X | X | X |
| 90732   | Pneumococcal polysaccharide (PPSV23)              | Pneumovax®23   | X | X | X |
| 90375, 90376, 90675   | Rabies  | Rabavert®, Imovax®   | X | X |   |
| 90680, 90681  | Rotavirus (RV)                                    | RotaTeq®, Rotarix®   |   | X | X |
| 90714   | Tetanus & diphtheria (Td)                         | Tenivac®   | X | X | X |
| 90715   | Tetanus, diphtheria, & acellular pertussis (Tdap) | Boostrix®, Adacel®   | X | X | X |
| 90716   | Varicella (VAR)                                   | Varivax®   | X | X | X |
| 90750   | Zoster  | Shingrix®  | X | X |   |
| 90736   |   | Zostavax®  | X | X | X |
| 90644, 90698, 90697, 90723, 90748   | Combinations                                      | DTaP-IPV (Kinrix®)<br>DTaP-IP-HI (Pentacel®)<br>HIBMENCY (MENHIBRIX®)<br>MMR/Varicella (ProQuad®)<br>Hepatitis B-DTaP-IPV (Pediarix®)            | X | X | X |
| 90696   |   | DTaP-IPV (Quadracel®)  | X | X | X |

|       |  |                                    |   |   |   |
|-------|--|------------------------------------|---|---|---|
| 90636 |  | Hepatitis A-Hepatitis B (Twinrix®) | X | X | X |
|-------|--|------------------------------------|---|---|---|

**Table 2: Available Non-Scheduled Vaccinations**

| CPT Code     | Vaccination For       | Vaccination(s)                       | Pharmacy Benefit | Medical Benefit | Vaccine for Children |
|--------------|-----------------------|--------------------------------------|------------------|-----------------|----------------------|
| 90581        | Anthrax               | Biothrax®                            |                  | X               |                      |
| 90738        | Japanese Encephalitis | Ixiaro®                              |                  | X               |                      |
| 90690, 90691 | Typhoid               | Typhim VI ®, Vivotif Berna® Capsules |                  | X               |                      |
| 90717        | Yellow Fever          | YF-Vax®                              |                  | X               |                      |

**Clinical Justification:**

Due to the effective date change of ALL PLAN LETTER 16-009, adult immunizations are now available under the pharmacy benefit as well as under the medical benefit. This means that members can go to their local pharmacy or to their doctor’s office for their immunizations. For member’s under the age of 19, routine vaccinations available through the VFC program are available via the VFC program and administered at the provider’s office. Limitations are based on the APL 16-009 restrictions and recommended routine immunization schedules as published by ACIP

(<http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2016/APL16-009R.pdf>). In accordance with an updated ALL PLAN LETTER 18-004, effective 1/31/18, in instances where the Medi-Cal Provider Manual outlines immunization criteria that is less restrictive than ACIP criteria, MCPs must provide the immunization in accordance with the less restrictive Medi-Cal Provider Manual criteria. Also note that any immunizations that are available through the pharmacy benefit may require Prior Authorization or have other various restrictions. Details for immunizations through the pharmacy benefit can be found at <https://medi-calrx.dhcs.ca.gov/provider/drug-lookup>.

**EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION**

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

**Immunizations – Those not listed are available either under the medical benefit or under the VFC program for members under 19 years of age who meet the coverage criteria.**

**Influenza Vaccine (All types of influenza vaccines but only the most recent strain is on formulary)**

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
- Notes:
  - o Only the most recent strain is on formulary

**Pneumococcal - Prevnar-13 [13-valent pneumococcal conjugate vaccine (PCV-13)]; Pneumovax-23 [23-valent pneumococcal polysaccharide vaccine (PPSV23)]**

- Coverage Criteria: None
- Limits:
  - o Prevnar-13: Limited to 1 dose per lifetime.
  - o Pneumovax-23: Limited to 2 doses per lifetime.
- Required Information for Approval: N/A

**Boostrix/Adacel [Tdap (Tetanus, diphtheria, & pertussis)]; Tenivac [Td (Tetanus and diphtheria toxoids adsorbed)]**

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A

***Shingrix, Zostavax (Zoster)***

- Coverage Criteria:** Restricted to patients aged 50 years and older.
- Limits:** None
- Required Information for Approval:** N/A

***Havrix, Vaqta (Hepatitis A)***

- Coverage Criteria:** None
- Limits:** Limited to 2 doses per lifetime.
- Required Information for Approval:** N/A

***Engerix-B, Recombivax Hb, Heplisav-B (Hepatitis B)***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

***ActHiB, HIBerix (Haemophilus B Polysaccharide Conjugate-Tetanus Toxoid); PedvaxHIB (Haemophilus B Polysaccharide Conjugate-Meningococcal Toxoid)***

- Coverage Criteria:** PA required.
- Limits:** Medical necessity determination needed.
- Required Information for Approval:** Medical necessity determination based on ACIP guidelines.

***Human Papilloma Virus – [Gardasil (HPV Vaccine 9-Valent)], [Cervarix (HPV Vaccine Bivalent)]***

- Coverage Criteria:** None
- Limits:** Limited to 3 doses per lifetime.
- Required Information for Approval:** N/A

***Meningococcal Vaccine A,C,Y,W-135 – [Menveo (MenACWY-CRM – Meningococcal Oligosaccharide Diphtheria Conjugate)]; [Menactra (MenACWY-D – Meningococcal Polysaccharide Diphtheria Conjugate)]***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Notes:**
  - Menomune is preferred for meningococcal vaccine-naïve persons at age 56 and older who are at increased risk of meningococcal infection and require a single dose. Menomune was removed from market in August 2017 and subsequently removed from ACIP guidelines 2018.

***Imovax, Rabavert (Rabies)***

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

***Varivax (Varicella)***

- Coverage Criteria:** None
- Limits:** Limited to 2 doses per lifetime.
- Required Information for Approval:** N/A

***M-M-R II (Measles, Mumps, Rubella)***

- Coverage Criteria:** None
- Limits:** Limited to 2 doses per lifetime.
- Required Information for Approval:** N/A

***Bexsero, Trumenba (Meningococcal Group B)***

- Coverage Criteria:** None
- Limits:**
  - Bexsero: Limited to 2 doses per lifetime.
  - Trumenba: Limited to 3 doses per lifetime.
- Required Information for Approval:** N/A

## **REFERENCES**

1. Centers for Disease Control and Prevention. (2023). Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger. Retrieved from: <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>
2. Centers for Disease Control and Prevention. (2023). Recommended Adult Immunization Schedule for ages 19 years or older. Retrieved from: <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>
3. Centers for Disease Control and Prevention. (2023). ACIP Recommendations. Retrieved from: <https://www.cdc.gov/vaccines/acip/recommendations.html>

## **REVIEW & EDIT HISTORY**

| <b>Document Changes</b> | <b>Reference</b>   | <b>Date</b> | <b>P&amp;T Chairman</b>         |
|-------------------------|--|-------------|---------------------------------|
| Creation of Policy      | Medi-Cal_EOC_2011.pdf  | 2011        | Allen Shek PharmD BCPS          |
| Update to Policy        | 2013 Medi-Cal EOC.pdf  | 2013        | Allen Shek PharmD BCPS          |
| Update to Policy        | Medi-Cal EOC Addendum.pdf  | 2014        | Jonathan Szkotak, PharmD, BCACP |
| Update to Policy        | HPSJ Coverage Policy – Infectious Disease – Immunizations 2016-02.docx | 2/2016      | Johnathan Yeh, PharmD           |
| Update to Policy        | HPSJ Coverage Policy – Infectious Disease – Immunizations 2017-02.docx | 2/2017      | Johnathan Yeh, PharmD           |
| Update to Policy        | HPSJ Coverage Policy – Infectious Disease – Immunizations 2018-02.docx | 2/2018      | Johnathan Yeh, PharmD           |
| Update to Policy        | HPSJ Coverage Policy – Infectious Disease – Immunizations 2019-05.docx | 5/2019      | Matthew Garrett, PharmD         |
| Update to Policy        | Immunizations  | 5/2020      | Matthew Garrett, PharmD         |
| Review of Policy        | Immunizations  | 5/2021      | Matthew, Garrett, PharmD        |
| Review of Policy        | Immunizations  | 5/2022      | Matthew Garrett, PharmD         |
| Review of Policy        | Immunizations  | 3/2023      | Matthew Garrett, PharmD         |

*Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy*