

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Immunizations	P&T DATE:	5/11/2021
THERAPEUTIC CLASS:	Infectious Disease	REVIEW HISTORY:	5/20, 5/19, 2/18, 2/17,
LOB AFFECTED:	MCL	(MONTH/YEAR)	2/16, 2014, 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.

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. 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.

Table 1: Available Scheduled Vaccinations (Current as of 4/2021)

Vaccination For:	Vaccination(s)	Pharmacy Benefit	Medical Benefit	Vaccine for Children
Diphtheria, tetanus, & acellular pertussis (DTaP)	Daptacel®, Infanrix®		X	X
Haemophilus influenzae type b (Hib)	PedvaxHIB®, ActHIB®, Hiberix®	X	X	X
Hepatitis A (HepA)	Vaqta®, Havrix®	X	X	X
Hepatitis B (HepB)	Engerix B®, Recombivax HB®	X	X	X
Human papillomavirus	Gardasil®, Gardasil®9, Cervarix®	X	X	X
Inactivated poliovirus (IPV)	IPOL®		X	X
Influenza	Afluria-no preservative, Fluzone Quadrivalent no preservatives		X	X
	Fluzone®, Fluzone® Quadrivalent, Flucelvax®, Fluvirin®, FluLaval Quadrivalent, Afluria®, Flublok®	X	X	X
	Fluzone® Intradermal Quadrivalent, Fluarix®	X	X	
Measles, mumps, rubella (MMR)	M-M-R®II	X	X	X
Meningococcal	Menactra®, Menveo®	X	X	X
Meningococcal B (MenB)	Trumenba®, Bexsero®	X	X	X

Pneumococcal conjugate (PCV13)	Prennar 13™	X	X	X
Pneumococcal polysaccharide (PPSV23)	Pneumovax®23	X	X	X
Rabies	Rabavert®, Imovax®	X	X	
Rotavirus (RV)	RotaTeq®, Rotarix®		X	X
Tetanus & diphtheria (Td)	Tenivac®	X	X	X
Tetanus, diphtheria, & acellular pertussis (Tdap)	Boostrix®, Adacel®	X	X	X
Varicella (VAR)	Varivax®	X	X	X
Zoster	Shingrix®	X	X	
	Zostavax®	X	X	X
Combinations	DTaP-IPV (Kinrix®) DTaP-IP-HI (Pentacel®) HIBMENCY (MENHIBRIX®) MMR/Varicella (ProQuad®) Hepatitis B-DTaP-IPV (Pediatrix®)		X	X
	DTaP-IPV (Quadracel®)		X	
	Hepatitis A-Hepatitis B (Twinrix®)	X	X	X

Table 2: Available Non-Scheduled Vaccinations (Current as of 4/2021)

Vaccination For:	Vaccination(s)	Pharmacy Benefit	Medical Benefit	Vaccine for Children
Anthrax	Biothrax®		X	
Japanese Encephalitis	Ixiaro®		X	
Typhoid	Typhim VI®, Vivotif Berna® Capsules		X	
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. For member's under the age of 19, routine vaccinations available through the VFC program will only be 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.

Triage:

- **Documentation of patient's age**
- **Documentation of any pertinent health condition, behavioral risk factor, occupation, travel, or criteria matching the requested vaccination**

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity 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
- Notes: Twinrix is formulary.

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

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
- Notes: Twinrix is formulary.

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. (2021). 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. (2021). Recommended Adult Immunization Schedule for ages 19 years or older. Retrieved from: <https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html>
3. Freedman MS, Hunter P, Ault K, Kroger A. Advisory Committee on Immunization Practices Recommended Immunization Schedule for Adults Aged 19 Years or Older — United States, 2020 MMWR. 2020;69(5);133-5. DOI: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6905a4.htm>
4. Nelson N. Considerations for Use of HEPLISAV-B in Adults. Oral presentation at: Advisory Committee on Immunization Practices; October 2017; Atlanta, GA.
5. Centers for Disease Control and Prevention. (2021). ACIP Recommendations. Retrieved from: <https://www.cdc.gov/vaccines/acip/recommendations.html>

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
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

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