

Policy:	Immunizations	P&T DATE:	3/19/2024
THERAPEUTIC CLASS:	Infectious Disease	REVIEW HISTORY:	3/23, 5/22, 5/21, 5/20, 5/19,
LOB AFFECTED:	MCL	(MONTH/YEAR)	2/18, 2/17, 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/MVHP Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-<u>calrx.dhcs.ca.gov/home/</u> 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 (APP), 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/.

According to the 10/6/2023 CDC update, the US government is no longer purchasing COVID-19 vaccines; therefore, the CDC COVID-19 Vaccination Program has ended. Updated 2023-2024 COVID-19 vaccines are now available for private purchase in the commercial marketplace.4 The following are currently available COVID-19 Vaccines.

- Cormirnaty COVID-19 Vaccine, mRNA
- Moderna COVID-19 Vaccine
- Novavax COVID-19 Vaccine, Adjuvanted
- Pfizer-BioNTech COVID-19 Vaccine
- Spikevax COVID-19 Vaccine, mRNA

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.

***Note: The CDC's Bridge Access Program provides free COVID-19 vaccines to adults without health insurance and adults whose insurance does not cover all COVID-19 vaccine costs. This program will end by December 31, 2024.5

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	Х	X
90647, 90648	Haemophilus influenzae type b (Hib)	PedvaxHIB®, ActHIB®, Hiberix®	Х	Х	Х
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		Afluria-no preservative, Fluzone Quadrivalent no preservatives	X	X	X
90653, 90657, 90658, 90682, 90687, 90688, 90756	Influenza	Fluzone®, Fluzone® Quadrivalent, Flucelvax®, Fluvirin®, FluLaval Quadrivalent, Afluria®, Flublok® 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	Х
90620, 90621	Meningococcal B (MenB)	Trumenba®, Bexsero®	X	X	X
90623	Meningococcal and Meningococcal B	Penbraya	x	x	X
90670	Pneumococcal conjugate (PCV13)	Prevnar 13 TM	X	X	X
90671	Pneumococcal conjugate (PCV15)	Vaxneuvance®	X	X	X
90677	Pneumococcal conjugate (PCV20)	Prevnar 20™	X	Х	Х
90732	Pneumococcal polysaccharide (PPSV23)	Pneumovax®23	X	Х	Х
90375, 90376, 90675	Rabies	Rabavert ®, Imovax ®	X	X	
90680, 90681	Rotavirus (RV)	RotaTeq®, Rotarix®		X	X
90714	Tetanus & diptheria (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	Zostei	Zostavax®	X	X	X
90585	Tuberculosis	BCG Vaccine	X	X	
91304, 91318, 91319, 91320, 91321, 91322	COVID-19	Novavax Covid-19 Vaccine, Adjuvanted Pfizer-BioNTech COVID-19 Vaccine 2023-2024 COMIRNATY (COVID-19 Vaccine, mRNA) 2023-2024 Moderna COVID-19 Vaccine 2023-2024 SPIKEVAX 2023-2024	х	х	X
90611	Mpox	Jynneos	X	X	X
90678 90679	RSV	Abrysvo Arexvy	X	x	X
90644, 90698, 90697, 90723, 90748	Combinations	DTaP-IPV (Kinrix®) DTaP-IP-HI (Pentacel®) HIBMENCY (MENHIBRIX®) MMR/Varicella (ProQuad®) Hepatitis B-DTaP-IPV (Pediarix®)	Х	X	X
90696		DTaP-IPV (Quadracel®)	X	X	X
90636		Hepatitis A-Hepatitis B (Twinrix®)	X	X	X

Table 2: Available Non-Scheduled Vaccinations

1 40 10 2 1 11 4 11 4 11 4 11 4 11 4 11					
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	

Table 3: Immunizations

CPT Code	Prophylaxis for	Immunization(s)	Pharmacy Benefit	Medical Benefit	Vaccine for Children
90396	Varicella	Varizig®	X	X	X
90380	DCM	Beyfortus®	v	v	X
90378	RSV	Synagis®	X	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 members 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/MVHP Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ/MVHP will make the determination based on Medical Necessity criteria as described in HPSJ/MVHP Medical Review Guidelines (UM06).

	nunizations – Those not listed are available either under the medical benefit or under the VFC gram for members under 19 years of age who meet the coverage criteria.
	nenza 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
adsa □ □	strix/Adacel [Tdap (Tetanus, diphtheria, & pertussis)]; Tenivac [Td (Tetanus and diphtheria toxoids orbed) Coverage Criteria: None Limits: None Required Information for Approval: N/A
	Igrix, Zostavax (Zoster) Coverage Criteria: Restricted to patients aged 50 years and older. Limits: None Required Information for Approval: N/A
	rix, Vaqta (Hepatitis A) Coverage Criteria: None Limits: Limited to 2 doses per lifetime. Required Information for Approval: N/A
	erix-B, Recombivax Hb, Heplisav-B (Hepatitis B) Coverage Criteria: None Limits: None Required Information for Approval: N/A
Poly □ □	diB, HIBerix (Haemophilus B Polysaccharide Conjugate-Tetanus Toxoid); PedvaxHIB (Haemophilus B esaccharide Conjugate-Meningococcal Toxoid) Coverage Criteria: None Limits: None Required Information for Approval: N/A
	nan 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
	ingococcal Vaccine A,C,Y,W-135 – [Menveo (MenACWY-CRM – Meningococcal Oligosaccharide Diptheria iugate)]; [Menactra (MenACWY-D – Meningococcal Polysaccharide Diphtheria Conjugate)] Coverage Criteria: None Limits: None Required Information for Approval: N/A

	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.
	vax, Rabavert (Rabies) Coverage Criteria: None Limits: None Required Information for Approval: N/A
	ivax (Varicella) Coverage Criteria: None Limits: Limited to 2 doses per lifetime. Required Information for Approval: N/A
	I-R II (Measles, Mumps, Rubella) Coverage Criteria: None Limits: Limited to 2 doses per lifetime. Required Information for Approval: N/A
	Coverage Criteria: None Limits: O Bexsero: Limited to 2 doses per lifetime. Trumenba: Limited to 3 doses per lifetime. Required Information for Approval: N/A
	braya (Meningococcal Groups A, B, C, W, and Y) Coverage Criteria: None Limits: None Required Information for Approval: N/A
	coverage Criteria: PA required. Limits: Medical necessity determination needed. Required Information for Approval: Medical necessity determination based on ACIP guidelines.
	Vaccine Coverage Criteria: PA required. Limits: Medical necessity determination needed. Required Information for Approval: Medical necessity determination based on ACIP guidelines.
19 V	avax Covid-19 Vaccine, Adjuvanted, Pfizer-BioNTech COVID-19 Vaccine 2023-2024, COMIRNATY (COVID-Vaccine, mRNA) 2023-2024, Moderna COVID-19 Vaccine 2023-2024, SPIKEVAX 2023-2024 Coverage Criteria: None Limits: None Required Information for Approval: N/A
	vsvo, Arexvy (RSV) Coverage Criteria: None Limits: None Required Information for Approval: N/A

REFERENCES

- 1. Centers for Disease Control and Prevention. (2024). 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. (2024). 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. (2024). ACIP Recommendations. Retrieved from: https://www.cdc.gov/vaccines/acip/recommendations.html
- 4. Centers for Disease Control and Prevention. (202). CDC COVID-19 Vaccination Program Provider Requirements and Support. Retrieved from: https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html
- 5. Centers for Disease Control and Prevention. (2023). CDC's Bridge Access Program. Retrieved from: https://www.cdc.gov/vaccines/programs/bridge/index.html
- 6. Abrysvo [package insert]. New York, NY: Pfizer, Inc.; 2023.
- 7. Arexvy [package insert]. Durham, NC: GlaxoSmithKline Biologicals; 2023.

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	Review of Policy Immunizations		Matthew, Garrett, PharmD	
Review of Policy	eview of Policy Immunizations 5/2022 Ma		Matthew Garrett, PharmD	
Review of Policy	Immunizations	3/2023	Matthew Garrett, PharmD	
Review of Policy	Immunizations	3/2024	Matthew Garrett, PharmD	

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