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# Immunizations

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This section covers the billing procedures for the administration of vaccine/toxoids, and immune globulin, serum, or recombinant prophylaxis services.

## **Important Notice and TAR Requirement**

All of the listed vaccines and respective CPT® codes may be billed if recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC), for approved indications, dosages and usages. An approved *Treatment Authorization Request* (TAR) is required for off-label use to justify medical necessity. It must meet current standards of practice, current medical literature or treatment guidelines, in accordance with statutory requirements (California Code of Regulations [CCR] Title 22, Section 51313(c) (4)). Billing codes and utilization management criteria are listed with each code. Experimental services are not a benefit (CCR, Title 22, Section 51303 (g)). Investigational services are covered in accordance with statutory requirements (CCR, Title 22, Section 51303 (h)). Authorization is required for dosages exceeding the maximum recommended dosages as approved by the FDA.

## **Reimbursement Methodology**

Vaccines are reimbursed at the Medicare rate of reimbursement when established and published by the Centers for Medicare & Medicaid Services (CMS) or the pharmacy rate of reimbursement when the Medicare rate is not available. The Medicare rate is currently defined as average sales price (ASP) plus 6 percent. The pharmacy rate is currently defined as the lower of (1) the National Average Drug Acquisition Cost (NADAC) or, when the NADAC is not available, the wholesaler acquisition cost (WAC) plus 0 percent; (2) the federal upper limit (FUL); or (3) the maximum allowable ingredient cost (MAIC). For more information on the pharmacy rate of reimbursement, providers should refer to [Medi-Cal Rx](#).

## **Billing Guidelines**

According to national coding guidelines, providers should report immunization services by listing the applicable immunization administration CPT code(s) in addition to the vaccine/toxoid CPT code(s). Reimbursement is determined by the cost of the immunization, plus the physician's administration fee. Only one administration fee will be reimbursed per immunization regardless of the quantity reflected on the claim line.

«Descriptions provided for procedure codes are only provided to assist with context. Providers are expected to utilize and refer to the official code books when billing for specific procedure codes.»

Special billing procedures apply to vaccines administered to persons under 19 years of age, who are eligible for the Vaccines For Children (VFC) Program. Since the VFC program supplies vaccine/toxoid product(s) at no cost to the provider, Medi-Cal will only reimburse a provider for the cost of administering a VFC-supplied dose. To bill Medi-Cal for the VFC dose administration fee, VFC providers shall report the vaccine/toxoid product code(s) with a modifier code of “SL”, which identifies the service as a “state-supplied vaccine”. Each CPT vaccine product code billed with a “SL” modifier is reimbursed separately for a VFC dose administration fee. Please refer to VFC section of the manual for additional details.

Vaccines/toxoids for a high-risk population must be reported with a modifier “SK”. Providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19), or on an attachment to the claim, the reason why the patient is considered high-risk.

All vaccines recommended by ACIP are a Medi-Cal benefit including for the purpose of employment, school, immigration or sports. In addition, if a beneficiary meets an ACIP-recommended indication, such as, age or a risk factor, Medi-Cal covers the indicated vaccine.

Immunizations are also covered under The Presumptive Eligibility for Pregnant Women (PE4PW) program which allows Qualified Providers to grant immediate, temporary Medi-Cal coverage for ambulatory prenatal care and prescription drugs for conditions related to pregnancy to low-income, pregnant recipients, pending their formal Medi-Cal application. PE4PW is designed for California residents who believe they are pregnant and who do not have Medi-Cal coverage for prenatal care. For additional details, please visit the *Presumptive Eligibility for Pregnant Women* section of the manual.

## **Vaccine Immunization Administration Codes**

The following CPT codes are reimbursable for immunization administration of any vaccine that is not accompanied by face-to-face physician or qualified health care professional counseling to the patient/family or for administration of vaccines to patients over 18 years of age:

- 90471 Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
- 90472 each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)
- 90473 Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)
- 90474 each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure)

The following CPT codes are reimbursable for immunization services when the physician or qualified health care professional provides face-to-face counseling of the patient/family during the administration of a vaccine.

- 90460 Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered
- 90461 each additional vaccine or toxoid component administered (list separately in addition to code for primary procedure)

### **Free Vaccines For Children (VFC) Program**

Because the VFC program provides vaccine/toxoid product(s) at no cost to a VFC provider, Medi-Cal will only reimburse a VFC provider for the cost of administering a VFC dose and not for the dose itself. According to national CPT code guidelines, immunization services are usually reported by using both the vaccine/toxoid code(s) and the vaccine immunization administration code(s). To report a VFC immunization service to Medi-Cal, providers should list each administered vaccine/toxoid product code with a modifier code of “SL”, which identifies the dose as a “state-supplied vaccine”. A separate VFC administration fee will be reimbursed for each vaccine/toxoid product code that is listed with a “SL” modifier on the claim.

Medi-Cal does not reimburse for the cost of a vaccine product that is available through the VFC program but purchased from a non-VFC source and administered to a VFC-eligible person except when justified. A provider’s non-enrollment in the VFC program is not a justified exception. Valid exceptions include documented cases of a VFC vaccine supply shortage due to a disease epidemic, vaccine manufacturing or delivery problems, or instances when the beneficiary does not meet special circumstances required by the VFC program for the vaccine billed. Providers must indicate a justified exception requiring the administration of a non-VFC dose in the *Remarks* field (Box 80)/ *Additional Claim Information* (Box 19) of the claim.

Providers should not report immunization services with an Evaluation and Management (E/M) service code (for example, office, outpatient, or preventive medicine visit, etc.) unless the provider has also completed a significant and separately identifiable E/M service at the same time. The separate E/M service must be thoroughly documented in the beneficiary’s medical record, and the claim is subject to audit and recoupment of reimbursement.

## **Free Vaccines from Source Other than VFC Program**

Providers bill CPT code 90471 (immunization administration; one vaccine) to Medi-Cal to be reimbursed for the administration of vaccines that are free to the provider through a source other than the VFC program, including doses purchased by public health departments. When billing code 90471, providers must indicate the vaccine administered and its source in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim. Code 90471 may not be billed in conjunction with other vaccine immunization codes (90284 thru 90749 and X5300 thru X7699) administered by the same provider, for the same recipient and date of service.

## **BCG Vaccine**

BCG Vaccine U.S.P. is an attenuated, live culture preparation of the Bacillus of Calmette and Guerin (BCG) strain of *Mycobacterium bovis* for percutaneous use.

### **Indications**

All ACIP-recommended indications

### **«Dosages and Dosing Schedules»**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

All ages

### **Billing**

CPT code 90585 (Bacillus Calmette-Guerin vaccine (BCG) for tuberculosis, live, for percutaneous use)

### **Required Modifier**

SK (member of a high-risk population)

## **Cholera**

Cholera vaccine is live, attenuated bacterial vaccine suspension containing the *Vibrio cholerae* strain CVD 103-HgR for oral administration (PO).

**Indications**

All ACIP-recommended indications

**Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

«2 to 64 years of age»

**Billing**

CPT code 90625 (Cholera vaccine, live, adult dosage, 1 dose schedule, for oral use)

**Required Modifier**

SK (member of a high-risk population)

**«Dengue Tetravalent Vaccine, Live**

Dengue Tetravalent Vaccine, Live is a suspension for subcutaneous (SC) Injection

**Indications**

All ACIP-recommended indications

**Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

9 through 16 years of age

**Billing**

CPT code 90587 (dengue vaccine, quadrivalent, live, 3 dose schedule, for subcutaneous use)».

### «Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

SK (member of a high-risk population)

Additional requirements:

For required documentation, refer to the *Vaccines for Children (VFC)* section.»

## **Diphtheria and Tetanus (DT)**

Diphtheria and Tetanus Toxoids Adsorbed (DT) is a suspension of (DT) diphtheria and tetanus toxoids adsorbed on aluminum phosphate for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 weeks through 6 years of age (prior to 7th birthday)

### **Billing**

CPT code 90702 (Diphtheria and tetanus toxoids adsorbed (DT) when administered to individuals younger than 7 years, for intramuscular use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program. Medi-Cal does reimburse for the DT vaccine (CPT code 90702) when administered to recipients younger than 7 years of age. Providers must not use modifier SL when billing this code for recipients who qualify for the VFC program since providers are able to bill for the vaccine and the administration fee. For claim preparation information, see “Required Documentation” in the *Vaccines For Children (VFC) Program* section of this manual.

## **Diphtheria, Tetanus, and Acellular Pertussis (DTaP)**

Diphtheria and Tetanus Toxoids and acellular Pertussis Vaccine Adsorbed (DTaP) is a suspension of pertussis antigens and diphtheria and tetanus toxoids adsorbed on aluminum phosphate for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 weeks through 6 years of age (prior to 7th birthday)

### **Billing**

CPT code 90700 (Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), when administered to individuals younger than 7 years, for intramuscular use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Diphtheria, Tetanus, and Acellular Pertussis - Hepatitis B-Poliovirus (DTaP-HepB-IPV)**

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Hepatitis B (Recombinant) and Inactivated Poliovirus Vaccine (DTaP- HepB-IPV) is a suspension for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

6 weeks through 6 years of age (prior to 7th birthday)

**Billing**

CPT code 90723 (Diphtheria, tetanus toxoids, and acellular pertussis vaccine, hepatitis B, and inactivated poliovirus vaccine (DTaP-HepB-IPV), for intramuscular use)

**Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

**Diphtheria, Tetanus, and Acellular Pertussis - Poliovirus (DTaP-IPV)**

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine (DTaP-IPV) is a suspension for Intramuscular (IM) administration.

**Indications**

All ACIP-recommended indications

**Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

Age 4 through 6 years of age (prior to 7th birthday)

**Billing**

CPT code 90696 (Diphtheria, tetanus toxoids, acellular pertussis vaccine and inactivated poliovirus vaccine (DTaP-IPV), when administered to children 4 through 6 years of age, for intramuscular use)

**Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Diphtheria, Tetanus, and Acellular Pertussis – Poliovirus – Haemophilus B Conjugate (DTaP-IPV/Hib)**

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus Vaccine, and Haemophilus B Conjugate (Tetanus Toxoid Conjugate) vaccine (DTaP-IPV/Hib) is a suspension for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 weeks through 4 years of age (prior to the 5th birthday)

### **Billing**

CPT code 90698 (Diphtheria, tetanus toxoids, and acellular pertussis vaccine, *Haemophilus influenzae* type b, and inactivated poliovirus vaccine (DTaP-IPV/Hib), for intramuscular use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Diphtheria, Tetanus and Acellular Pertussis- Poliovirus- Haemophilus B Conjugate-Hepatitis B (DTaP-IPV-Hib-HepB)**

Diphtheria, tetanus toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenzae type B PRP-OMP conjugate vaccine and hepatitis B vaccine (DTaP-IPV-Hib-HepB), is a suspension for intramuscular use.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

## **Age Limits**

6 weeks through 4 years of age (prior to the 5th birthday).

## **Billing**

CPT code 90697 (diphtheria, tetanus toxoids, acellular pertussis vaccine, inactivated poliovirus vaccine, Haemophilus influenzae type b PRP-OMP conjugate vaccine, and hepatitis B vaccine [DTaP-IPV-Hib-HepB], for intramuscular use)

## **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by Vaccines for Children (VFC) program.

## **Hepatitis A (HepA)**

Hepatitis A Vaccine (HepA) is a suspension for intramuscular (IM) administration

## **Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

## **Age Limits**

12 months and older

## **Billing**

CPT code 90632 (Hepatitis A vaccine (HepA), adult dosage, for intramuscular use)

CPT code 90633 (Hepatitis A vaccine (HepA), pediatric/adolescent dosage-2 dose schedule, for intramuscular use)

## **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Ebola Zaire Vaccine**

Ebola Zaire Vaccine, Live, is a suspension for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules.

### **Age Limits**

18 years of age and older.

### **Billing**

CPT code 90758 (Zaire ebolavirus vaccine, live, for intramuscular use).

### **Required Modifier**

SK (member of a high-risk population)

## **Hepatitis A-Hepatitis B (HepA-HepB)**

Hepatitis A & Hepatitis B (Recombinant) Vaccine (HepA-HepB) is a suspension for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

18 years and older

## Billing

CPT code 90636 (hepatitis A and hepatitis B vaccine (HepA-HepB), adult dosage, for intramuscular use)

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## Hepatitis B (HepB)

Hepatitis B Vaccine (Recombinant) (HepB) is a suspension for intramuscular (IM) administration.

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Billing

«Hepatitis B Billing Codes Table

<b>CPT Code</b>	<b>Description</b>	<b>Age Limits</b>
90739	Hepatitis B vaccine (HepB), adult dosage, 2 dose schedule, for intramuscular use	18 years of age and older
90740	Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 3 dose schedule, for intramuscular use	18 years of age and older
90743	Hepatitis B vaccine (HepB), adolescent, 2 dose schedule, for intramuscular use	11 through 15 years of age
90744	Hepatitis B vaccine (HepB), pediatric/adolescent dosage, 3 dose schedule, for intramuscular use	Birth through 19 years of age
90746	Hepatitis B vaccine (HepB), adult dosage, 3 dose schedule, for intramuscular use	20 years of age and older
90747	Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 4 dose schedule, for intramuscular use	20 years of age and older
90759	Hepatitis B vaccine (HepB), 3-antigen (S, Pre-S1, Pre-S2), 10 mcg dosage, 3 dose schedule, for intramuscular use	18 years of age and older»

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

«**Note:** The use of modifier SL applies to CPT codes 90740, 90743 and 90744. Refer to the [Modifiers Used with Procedure Codes](#) section within the appropriate manual for more information.»

## **Haemophilus b Conjugate (Hib [PRP-OMP])**

Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) (Hib [PRP-OMP]) is a suspension for intramuscular (IM) administration.

### Indications

All ACIP-recommended indications

### Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

### Age Limits

6 weeks and older

### Billing

CPT code 90647 (Haemophilus influenza type b vaccine [Hib] PRP-OMP conjugate, 3 dose schedule, for intramuscular use)

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Haemophilus b Conjugate (Hib [PRP-T])**

Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) (Hib [PRP-T]) is a suspension for intramuscular (IM) administration.

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

6 weeks and older

## Billing

CPT code 90648 (Haemophilus influenza type b vaccine [Hib] PRP-T conjugate, 4 dose schedule, for intramuscular use)

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Human Papillomavirus 9-valent Vaccine, Recombinant (9vHPV)**

Human papillomavirus 9-valent (types 6, 11, 16, 18, 31, 33, 45, 52, 58) vaccine, recombinant, is a suspension for intramuscular (IM) administration

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

9 to 45 years of age

## Billing

CPT code 90651 (Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent [9vHPV], 2 or 3 dose schedule, for intramuscular use)

## «Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.»

## Influenza Vaccine

See the *Vaccines For Children (VFC)* program and the *Presumptive Eligibility for Pregnant Women (PE4PW)* sections in this manual.

## Influenza Inactivated (IIV3) or (IIV4)

Influenza inactivated vaccine is a suspension of inactivated influenza viruses for intramuscular (IM) administration.

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

6 months of age and older

## Billing

CPT code 90655 (influenza virus vaccine, trivalent [IIV3], split virus, preservative free, 0.25 ml dosage for intramuscular use)

CPT code 90656 (influenza virus vaccine, trivalent [IIV3], split virus, preservative free, 0.5 mL dosage, for intramuscular use)

CPT code 90657 (influenza virus vaccine, trivalent [IIV3], split virus, 0.25 ml dosage for intramuscular use)

CPT code 90658 (influenza virus vaccine, trivalent [IIV3], split virus, 0.5 mL dosage, for intramuscular use)

CPT code 90685 (influenza virus vaccine, quadrivalent [IIV4], split virus, preservative free, 0.25 mL dosage, for intramuscular use)

CPT code 90686 (influenza virus vaccine, quadrivalent [IIV4], split virus, preservative free, 0.5 mL dosage, for intramuscular use)

CPT code 90687 (influenza virus vaccine, quadrivalent [IIV4], split virus, 0.25 mL dosage, for intramuscular use)

CPT code 90688 (influenza virus vaccine, quadrivalent [IIV4], split virus, 0.5 mL dosage, for intramuscular use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

### **Influenza Inactivated (IIV3) or (IIV4)**

Influenza vaccine is a suspension of inactivated influenza viruses for Intradermal Injection

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

18 years of age and older

### **Billing**

CPT code 90654 (influenza virus vaccine, trivalent [IIV3], split virus preservative free for intradermal use)

CPT code 90630 (influenza virus vaccine, quadrivalent [IIV4], split virus, preservative free, for intradermal use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

### **Influenza Adjuvanted (aIIV3) or (aIIV4)**

Influenza vaccine, adjuvanted (aIIV3) is a suspension of inactivated influenza viruses for intramuscular (IM) injection.

**Indications**

All ACIP-recommended indications

**Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

65 years of age and older

**Billing**

CPT code 90653 (influenza vaccine, inactivated [IIV], subunit, adjuvanted, for intramuscular use)

CPT code 90694 (influenza virus vaccine, quadrivalent [aIIV4], inactivated, adjuvanted, preservative free, 0.5 mL dosage, for intramuscular use)

**Influenza High Dose (IIV3-HD)**

Influenza vaccine, high dose (IIV3-HD), is a suspension of inactivated influenza viruses for intramuscular (IM) injection.

**Indications**

All ACIP-recommended indications

**Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

65 years of age and older

**Billing**

CPT code 90662 (influenza virus vaccine [IIV], split virus, preservative free, enhanced immunogenicity via increased antigen content, for intramuscular use)

## **Influenza Live (LAIV3) or (LAIV4)**

Influenza Vaccine Live (LAIV3) or (LAIV4) is a suspension of live, attenuated influenza subtypes A and type B viruses for intranasal (IN) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

2 through 49 years of age

### **«Billing**

CPT code 90672 (influenza virus vaccine, quadrivalent, live, [LAIV4], for intranasal use)»

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Influenza Recombinant (RIV 3) or (RIV4)**

Influenza Vaccine Recombinant (RIV3) or (RIV4) is a suspension of recombinant HA proteins of influenza virus subtypes A and type B.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

18 years of age and older

## Billing

CPT code 90673 (influenza virus vaccine, trivalent [RIV3], derived from recombinant DNA, hemagglutinin (HA) protein only, preservative and antibiotic free, for intramuscular use)

CPT code 90682 (influenza virus vaccine, quadrivalent [RIV4], derived from recombinant DNA, hemagglutinin [HA] protein only, preservative and antibiotic free, for intramuscular use)

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## Influenza Vaccine (ccIIV4)

Cell Culture Inactivated Influenza Vaccine, Quadrivalent (Cciiv4) is a suspension for Intramuscular Injection

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

<<6 month and older>>

## Billing

CPT 90674 (influenza virus vaccine, quadrivalent [ccIIV4], derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use)

CPT 90756 (influenza virus vaccine, quadrivalent [ccIIV4], derived from cell cultures, subunit, antibiotic free, 0.5 mL dosage, for intramuscular use)

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Japanese Encephalitis**

Japanese encephalitis vaccine is a reconstituted suspension of inactivated Japanese encephalitis virus for intramuscular (IM) injection.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

2 months and older

### **Billing**

CPT code 90738 (Japanese encephalitis virus vaccine, inactivated, for intramuscular use)

### **Required Modifier**

SK (member of a high-risk population)

## **«Meningococcal Conjugate (MenACWY-D and MenACWY-CRM)»**

Meningococcal (Groups A, C, Y, and W-135) conjugate vaccine is a suspension for intramuscular (IM) injection

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

2 months and older

## Billing

CPT code 90734 (meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, diphtheria toxoid carrier [MenACWY-D] or CRM197 carrier [MenACWY-CRM], for intramuscular use)

## Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## «Meningococcal Conjugate (MenACWY-TT)

Meningococcal (Groups A, C, Y, W) Conjugate vaccine is a solution for intramuscular (IM) injection.

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

2 years of age and older

## Billing

CPT code 90619 (Meningococcal conjugate vaccine, serogroups A, C, W, Y, quadrivalent, tetanus toxoid carrier (MenACWY-TT), for intramuscular use).

## Required Modifier

SK (member of a high-risk population).

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.»»

## **Meningococcal Group B (MenB-4C)**

Meningococcal Group B Vaccine (MenB-4C) is a suspension for intramuscular (IM) injection

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

10 to 25 years of age

### **Billing**

CPT code 90620 (meningococcal recombinant protein and outer membrane vesicle vaccine, serogroup B [MenB-4C], 2 dose schedule, for intramuscular use)

### **Required Modifier**

SK (member of a high-risk population)

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Meningococcal Group B (MenB-FHbp)**

Meningococcal Group B Vaccine (MenB-FHbp) is a suspension for intramuscular (IM) injection

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

10 to 25 years of age

## Billing

CPT code 90621 (meningococcal recombinant lipoprotein protein vaccine, serogroup B [MenB-FHbp], 2 or 3 dose schedule, for intramuscular use)

## Required Modifier

SK (member of a high-risk population)

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## Measles, Mumps, and Rubella (MMR)

Measles, Mumps, and Rubella Vaccine Live (MMR) is a reconstituted suspension for subcutaneous (SQ) administration.

## Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

12 months and older

## Billing

CPT code 90707 (measles, mumps, and rubella virus vaccine [MMR], live, for subcutaneous use)

## Required Modifier

<<SK (member of high-risk population).>>

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Measles, Mumps, Rubella, and Varicella (MMRV)**

Measles, mumps, rubella, and varicella vaccine (MMRV), live, is a reconstituted suspension for subcutaneous (SQ) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

12 months through 12 years (before the 13th birthday)

### **Billing**

CPT code 90710 (measles, mumps, rubella, and varicella vaccine [MMRV], live, for subcutaneous use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Polio**

Poliovirus Vaccine Inactivated (IPV) is a suspension for intramuscular (IM) or subcutaneous (SQ) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 weeks of age and older

## **Billing**

CPT code 90713 (poliovirus vaccine, inactivated [IPV] for subcutaneous or intramuscular use)

## **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Pneumococcal 13-Valent Conjugate (PCV13)**

Pneumococcal 13-valent Conjugate Vaccine (PCV13) is a suspension for intramuscular (IM) injection.

## **Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

## **Age Limits**

6 weeks of age and older

## **Billing**

CPT code 90670 (pneumococcal conjugate vaccine, 13 valent [PCV13], intramuscular use)

## **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **«Pneumococcal 15-Valent Conjugate (PCV15)**

Pneumococcal 15-valent Conjugate Vaccine (PCV15) is a suspension for intramuscular (IM) injection.

## **Indications**

All ACIP-recommended indications.»»

## «Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules.

### Age Limits

18 years of age and older

### Billing

CPT code 90671 (Pneumococcal conjugate vaccine, 15 valent (PCV15), for intramuscular use).

## **Pneumococcal 20-Valent Conjugate (PCV20)**

Pneumococcal 20-valent Conjugate Vaccine (PCV20) is a suspension for intramuscular (IM) injection.

### Indications

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

### Age Limits

18 years of age and older

### Billing

CPT code 90677 (Pneumococcal conjugate vaccine, 20 valent [PCV20], for intramuscular use).»

## **Pneumococcal Polysaccharide 23-Valent (PPSV23)**

Pneumococcal polysaccharide vaccine polyvalent (PPSV23) is a solution of purified capsular polysaccharides from 23 serotypes of *Streptococcus pneumoniae* for intramuscular (IM) or subcutaneous (SQ) injection.

### Indications

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

2 years and older

### **Billing**

CPT code 90732 (pneumococcal polysaccharide vaccine, 23-valent [PPSV23], adult or immunosuppressed patient dosage, when administered to individuals 2 years or older, for subcutaneous or intramuscular use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Rabies**

Rabies vaccine is a reconstituted suspension of inactivated rabies virus for intramuscular (IM) injection.

### **Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

All ages

### **Billing**

CPT code 90675 (rabies vaccine, for intramuscular use)

### **Required Modifier**

SK (member of a high-risk population)

## **Rotavirus (RV1)**

Rotavirus vaccine is a suspension of live, attenuated human (RV1) G1P [8] rotavirus for oral (PO) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 to 24 weeks of age

### **Billing**

CPT code 90681 (rotavirus vaccine, human, attenuated [RV1], 2 dose schedule, live, for oral use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Rotavirus (RV5)**

Rotavirus vaccine (RV5) is a solution of five live human-bovine reassortant rotaviruses for oral (PO) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 to 32 weeks of age

## **Billing**

CPT code 90680 (rotavirus vaccine, pentavalent [RV5], 3 dose schedule, live, for oral use)

## **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Tetanus and Diphtheria (Td)**

Tetanus and diphtheria toxoids adsorbed (Td) is a suspension for intramuscular (IM) administration

## **Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

## **Age Limits**

7 years and older

## **Billing**

CPT code 90714 (tetanus and diphtheria toxoids adsorbed [Td], preservative free, when administered to individuals 7 years or older, for intramuscular use)

## **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **Tetanus, Diphtheria, and Acellular Pertussis (Tdap)**

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) is a suspension for intramuscular (IM) administration

## **Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

7 years and older

### **Billing**

CPT code 90715 (tetanus, diphtheria toxoids and acellular pertussis vaccine [Tdap], when administered to individuals 7 years or older, for intramuscular use)

### **Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

## **«Tick-Borne Encephalitis (TBE)**

Tick-Borne Encephalitis Vaccine (TBE) is a suspension for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications.

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules.

### **Age Limits**

1 year of age and older.

### **Billing**

CPT code 90626 (Tick-borne encephalitis virus vaccine, inactivated; 0.25 mL dosage, for intramuscular use).

CPT code 90627 (Tick-borne encephalitis virus vaccine, inactivated; 0.5 mL dosage, for intramuscular use).

### **Required Modifier**

SK (member of high-risk population).»

## **Typhoid polysaccharide (ViCPs)**

Typhoid Vi capsular polysaccharide vaccine (ViCPs) is a solution containing the cell surface Vi polysaccharide extracted from *Salmonella enterica serovar Typhi*, *S typhi* Ty2 strain for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

2 years and older

### **Billing**

CPT code 90691 (typhoid vaccine, Vi capsular polysaccharide (ViCPs), for intramuscular use)

### **Required Modifier**

SK (member of high-risk population)

## **Typhoid Live Oral (Ty21a)**

Typhoid vaccine live oral (Ty21a) is a live, attenuated vaccine for oral administration. The vaccine contains the attenuated strain of serovar *Salmonella typhi* Ty21a.

### **Indications**

All ACIP-recommended indications

### **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

6 years and older

**Billing**

CPT code 90690 (typhoid vaccine, live, oral)

**Required Modifier**

SK (member of high-risk population)

**Varicella (VAR)**

Varicella Virus Vaccine Live (VAR) is a reconstituted suspension for subcutaneous (SQ) administration.

**Indications**

All ACIP-recommended indications

**Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

**Age Limits**

12 months and older

**Billing**

CPT code 90716 (varicella virus vaccine [VAR], live, for subcutaneous use)

**Required Modifier**

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program.

**Yellow Fever**

Yellow fever vaccine is a reconstituted suspension of live yellow fever virus for subcutaneous (SC) injection.

**Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

9 months and older

### **Billing**

CPT code 90717 (yellow fever vaccine, live, for subcutaneous use)

### **Required Modifier**

SK (member of a high-risk population)

## **Zoster Live (ZVL)**

Zoster Vaccine Live (ZVL) is a reconstituted suspension for subcutaneous (SQ) injection.

### **Indications**

All ACIP-recommended indications

## **Dosages and Dosing Schedules**

ACIP-recommended dosages and dosing schedules

### **Age Limits**

50 years and older

### **Billing**

CPT code 90736 (zoster [shingles] vaccine [HZV], live, for subcutaneous injection)

## **Zoster Recombinant (RZV)**

Zoster Vaccine Recombinant, Adjuvanted (RZV) is a reconstituted suspension for intramuscular (IM) administration.

### **Indications**

All ACIP-recommended indications

## Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

## Age Limits

«18 years and older»

## Billing

CPT code 90750 (zoster (shingles) vaccine (HZV), recombinant, subunit, adjuvanted, for intramuscular use)

## «Required Modifier (Ages less than 50)

SK (member of a high-risk population)»

## Immune Globulins, Serum, Or Recombinant Products

### Hepatitis B Immune Globulin (HBIG)

Hepatitis B Immune Globulin (HBIG) is a solution for intramuscular (IM) or intravenous (IV) administration.

#### Indications

All ACIP-recommended indications

#### Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

#### Age Limits

All ages

#### Billing

CPT code 90371 (hepatitis B immune globulin [HBIG], human, for intramuscular use)

HCPCS code J1571 (injection, hepatitis B immune globulin [HepaGam B], intramuscular, 0.5 ml)

HCPCS code J1573 (injection, hepatitis B immune globulin [HepaGam B], intravenous, 0.5 ml)

## **Immune Globulin (Human)**

Immune Globulin (Human) is a solution for intramuscular (IM) administration.

### Indications

All ACIP and FDA-recommended indications

### Dosages and Dosing Schedules

ACIP and FDA-recommended dosages and dosing schedules

### Age Limits

All ages

### Billing

HCPCS code J1460 (injection, Gamma Globulin, Intramuscular, 1 CC) or J1560 (injection, Gamma Globulin, Intramuscular, Over 10 CC)

Do not report claims with CPT code 90281 (immune globulin [Ig], human, for intramuscular use)

## **Palivizumab**

Palivizumab 50 mg, CPT code 90378 is reimbursable for passive immunization of certain infants as described below.

The following coverage policy was updated after the publication of the article titled, "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection" by American Academy of Pediatrics (AAP) in 2014.

Five monthly doses of palivizumab will provide more than six months (24 weeks) of protective serum antibody concentration. For children meeting the policy described below, up to five doses may be authorized for use between November and the following March. If prophylaxis is initiated in December, the fifth and final dose should be administered in April.

For the current RSV season only (2021 thru 2022), due to increased activity of RSV in California according to Center for Disease Control and Prevention's (CDC) National Respiratory and Enteric Virus Surveillance System, providers may administer more than five doses. For the current apparent RSV season only, effective August 19, 2021, providers may administer a maximum of 9 doses per child, in the event that the child receives the first dose in August and monthly doses from August through April, providing protection through May.

A maximum of five doses of palivizumab may be authorized during a typical RSV season, and 9 doses during the current RSV season only (2021 thru 2022).

The TAR criteria is as follows:

- Infants born before 29 weeks, 0 days gestation who are less than 12 months of age at the start of the RSV season
- During the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age less than 32 weeks, 0 days and a requirement for greater than 21 percent oxygen for at least the first 28 days after birth
- During the second year of life for preterm infants who develop chronic lung disease (CLD) of prematurity as defined above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six-month period before the start of the second RSV season
- Infants who are 12 months or younger with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension
- Infants with cyanotic heart defects in the first year of life may receive palivizumab prophylaxis if deemed warranted by the infant's pediatric cardiologist
- Children younger than two years who undergo cardiac transplantation during the RSV season
- An infant younger than 24 months receiving prophylaxis who undergoes cardiopulmonary bypass or extracorporeal membrane oxygenation and continues to require prophylaxis post-operatively may receive a post-operative dose of palivizumab (15 mg/kg)
- During the first year of life, infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
- Children younger than 24 months of age who are profoundly immunocompromised during the RSV season, as assessed by a qualified pediatric Infectious Disease or Immunologic specialist
- During the first year of life, infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise
- During the second year of life, infants with cystic fibrosis and manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile

**Note:** Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.

### Authorization Required

Palivizumab is given by intramuscular injection on a monthly basis during the RSV season. A TAR is required. Providers may request the amount of palivizumab needed for the entire RSV season on one TAR. The usual dosage is 15 mg/kg per injection. One unit equals 50 mg for Medi-Cal billing purposes. Providers may bill for one unit even if only part of the unit was given to the recipient and the remainder of the drug was discarded. It is reimbursable once in a 25-day period.

### Resources:

- [RSV PCR for CA \(3 week average\)](#)
- [RSV Antigen for CA \(3 week average\)](#)
- [Interim Guidance for Use of Palivizumab Prophylaxis to Prevent Hospitalization from Severe Respiratory Syncytial Virus Infection During the Current Atypical Interseasonal RSV Spread](#)
- [Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection](#)

## **Rabies Immune Globulins**

Rabies immune globulin is a solution of globulins dried from the plasma or serum of selected adult human donors who have been immunized with rabies vaccine and have developed high titers of rabies antibody.

### Indications

All ACIP-recommended indications

### Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

### Age Limits

All ages

### Required ICD-10 Diagnosis Codes

Z20.3 is a required DX and not a modifier for CPT codes 90375 and 90376

### Billing

CPT code 90375 (rabies immune globulin [Rig], human, for intramuscular use)

CPT code 90376 (rabies immune globulin, heat-treated [Rig-HT], human, for intramuscular and/or subcutaneous use)

CPT code 90377 (rabies immune globulin, heat – and solvent/detergent – treated [Rig-HT S/D], human, for intramuscular and/or subcutaneous use)

## **Tetanus Immune Globulin (Tlg)**

Tetanus immune globulin, human (Tlg), is solution for intramuscular (IM) administration.

### Indications

All ACIP-recommended indications

### Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

### Age Limits

All ages

### Billing

HCPCS code J1670 (injection, tetanus immune globulin, human, up to 250 units)

## **Varicella Zoster Immune Globulin**

Varicella Zoster immune globulin is a solution for intramuscular (IM) administration.

### Indications

All ACIP-recommended indications

### Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

### Age Limits

All ages

### Billing

CPT code 90396 (Varicella-zoster immune globulin, human, for intramuscular use)

## **Coronavirus Disease 2019 (COVID-19) Therapeutics (Vaccines and Monoclonal Antibodies)**

### **Comirnaty® COVID-19 Vaccine, mRNA/Pfizer-BioNTech COVID-19 Vaccine**

Comirnaty (COVID-19 Vaccine, mRNA) COVID-19 vaccine is approved by the U.S. Food and Drug Administration (FDA) and is made by Pfizer for BioNTech. It is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older.

The FDA also issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 5 through 11 years of age and 12 through 15 years of age.

Comirnaty/Pfizer-BioNTech COVID-19 vaccine may be prescribed through two methods:

1. FDA-approved Comirnaty for use as a two-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older.
2. EUA-authorized Pfizer-BioNTech COVID-19 vaccine for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome SARS-CoV-2 in individuals 5 through 11 years of age and 12 through 15 years of age.

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series for ages 12 and older.

**Note:** Pfizer-BioNTech COVID-19 vaccine supplied in a multiple dose vial with an orange cap and a label with an orange border is authorized for use to provide a two-dose primary series to individuals 5 through 11 years of age. It should not be used in individuals 12 years of age and older.

#### **1. Comirnaty FDA-Approved Usage**

Comirnaty (COVID-19 Vaccine, mRNA) is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older.

## **FDA-Approved Dosage**

### Primary Series:

A two-dose primary series in individuals 16 years of age and older.

Comirnaty is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

### 2. Pfizer-BioNTech COVID-19 Vaccine Authorized EUA Usage

Pfizer-BioNTech COVID-19 Vaccine is EUA authorized for active immunization to prevent COVID-19 in individuals 5 through 11 years of age and 12 through 15 years of age.

## **EUA-Authorized Dosage**

### Primary Series:

- Pediatric Use (Ages 5 through 11 years of age)
  - Two doses (0.2 mL each) administered intramuscularly 3 weeks apart to individuals 5 through 11 years of age
    - ❖ Each vial must be diluted before administration. For dilution and preparation instructions, see the [Fact Sheet for Healthcare Providers Administering Vaccine For 5 Through 11 Years of Age](#)
- Ages 12 years of age and older:
  - Two doses (0.3 mL each) administered intramuscularly 3 weeks apart to individuals 12 years of age or older.

### Additional Dose

A third primary series dose of Pfizer-BioNTech COVID-19 Vaccine given at least 28 days following the second dose to individuals 5 years of age and older who have been determined to be moderately to severely immunocompromised.

People are considered to be moderately or severely immunocompromised if they have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)

- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response
- If recommended by a healthcare provider for an individual's specific medical condition

### «Booster Doses

#### **First Booster Dose»**

At least **five months** after completing the primary series with Pfizer-BioNTech vaccine, a booster dose of the appropriate FDA-authorized or approved COVID-19 vaccine may be administered to eligible individuals 12 years and older.

- «A booster dose of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most situations»
- Only Pfizer-BioNTech Vaccine can be used as a booster in individuals 12 through 17 years of age

The following people **should** receive a booster:

- Everyone 12 years and older.

#### **«Second Booster Dose**

At least **four months** after receiving an initial booster of the appropriate FDA-authorized or approved COVID-19 vaccine, a secondary booster dose of the Pfizer-BioNTech vaccine may be administered to eligible individuals. The second booster **must** be an mRNA COVID-19 vaccine.

The following people **may choose** to receive a second booster:

- Adults 50 years and older who are not moderately or severely immunocompromised
- Individuals 12 years and older who are moderately immunocompromised, have undergone solid organ transplantation or who are living with conditions that are considered to have an equivalent level of immunocompromise.
  - Children and teens who are moderately or severely immunocompromised may receive a 2nd booster of only **Pfizer-BioNTech COVID-19** vaccine
- Adults 18 years and older who are not moderately or severely immunocompromised and who received 2 doses of J&J/Janssen vaccine.»

#### **Choosing the COVID-19 Booster Shot**

A booster dose may be administered as a heterologous (mix and match) dose after the completion of primary vaccination with another COVID-19 vaccine.

For instructions on preparation, administration and the Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors, see [Fact Sheet for Healthcare Providers Administering Vaccine](#) or [Fact Sheet for Healthcare Providers Administering Vaccine For 5 Through 11 Years of Age](#).

For the most recent Fact Sheets, visit the [Pfizer/BioNTech COVID Vaccine](#) website.

### Age Limits

Must be 5 years of age or older «for the first dose and 12 years of age or older for second booster dose»

### Billing

Vaccine codes:

- 91300 (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease (COVID-19)] vaccine, mRNA-LNP, spike protein, preservative free, 30 mcg/0.3ml dosage, diluent reconstituted, for intramuscular use)
- 91307 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, preservative free, 10 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use

Administration codes:

- «0001A (Pfizer-BioNTech COVID-19 Vaccine [Purple Cap] Administration – First Dose)
- 0002A (Pfizer-BioNTech COVID-19 Vaccine [Purple Cap] Administration – Second Dose)
- 0003A (Pfizer-BioNTech COVID-19 Vaccine [Purple Cap] Administration – Third Dose)
- 0004A (Pfizer-BioNTech COVID-19 Vaccine [Purple Cap] Administration – Booster)
- 0051A (Pfizer-BioNTech COVID-19 Vaccine Pre-Diluted [Gray Cap] Administration – First Dose)
- 0052A (Pfizer-BioNTech COVID-19 Vaccine Pre-Diluted [Gray Cap] Administration – Second Dose)
- 0053A (Pfizer-BioNTech COVID-19 Vaccine Pre-Diluted [Gray Cap] Administration – Third Dose)
- 0054A (Pfizer-BioNTech COVID-19 Vaccine Pre-Diluted [Gray Cap] Administration – Booster)
- 0071A (Pfizer-BioNTech COVID-19 Pediatric Vaccine [Orange Cap] - Administration – First dose)
- 0072A (Pfizer-BioNTech COVID-19 Pediatric Vaccine [Orange Cap] - Administration – Second dose»

- «0073A (Pfizer-BioNTech COVID-19 Pediatric Vaccine [Orange Cap] - Administration – Third Dose)»
- M0201 (COVID-19 vaccine administration inside a patient's home; reported only once per individual home, per date of service, when only COVID-19 vaccine administration is performed at the patient's home)

#### Important Billing Instructions:

- DHCS will follow CMS guidelines for the reimbursement of COVID-19 vaccines when administered in accordance with FDA EUA
- Since the initial supply of vaccines are purchased by the federal government and distributed free to providers, providers must not bill 91300 or 91307 for the cost of the vaccine
- DHCS is currently reimbursing for the vaccine administration. Providers must submit the appropriate vaccine administration codes for billing the first, second, third or booster vaccine dose as applicable
- M0201 is for an additional \$35 payment for administering the COVID-19 vaccine to certain patients in their homes who meet the defined criteria and are unable to travel to a vaccination site and should be reported in addition to the appropriate vaccine and dose-specific administration. For policy details regarding billing with M0201, see “Home Administration of COVID-19 Vaccine” on one of the pages below
- DHCS will provide future guidance for the billing and reimbursement of provider purchased vaccines at the appropriate time
- Providers must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their own systems within 24 hours and to the California Immunization Registry (CAIR2) within 24 hours
- Providers must administer the vaccine in accordance with the CDC and Advisory Committee on Immunization Practices (ACIP) requirement
- It is important to provide vaccine recipients with the EUA fact sheet for patients/caregivers and vaccination cards identifying the brand of vaccine administered and the date of their next vaccination (if applicable)

#### Resources

- [Fact Sheet for Healthcare Providers For 12 Years of Age And Older](#)
- [Fact Sheet for Recipients And Caregivers 12 Years of Age And Older](#)
- [Fact Sheet for Healthcare Providers For 5-11 Years of Age](#)
- [Fact Sheet for Recipients And Caregivers 5-11 Years of Age](#)
- [CDC Recommendations on COVID-19 Vaccine Booster Shot](#)

## «**SPIKEVAX (COVID-19 Vaccine, mRNA)/Moderna COVID-19 Vaccine**

Spikevax COVID-19 vaccine is approved by the U.S. Food and Drug Administration (FDA) and is made by Moderna. It is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.»

### Authorized Use

«Additionally, the FDA issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

Spikevax and Moderna COVID-19 Vaccine may be prescribed through two methods:

- Spikevax is FDA-approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 18 years of age and older. It is also authorized for the same use as the Moderna COVID-19 Vaccine.
- Moderna COVID-19 Vaccine is EUA-authorized for use as a two-dose primary series to individuals 18 years of age and older; a third primary series dose to individuals 18 years of age and older who are moderately to severely immunocompromised; a single booster dose to individuals 18 years of age and older who have completed a primary series with Moderna COVID-19 Vaccine or Spikevax (COVID-19 Vaccine, mRNA); and a single booster dose to individuals 18 years of age and older who have completed primary vaccination with another authorized or approved COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

FDA-approved Spikevax and the EUA-authorized Moderna COVID-19 Vaccine have the same formulation and can be used interchangeably without presenting any safety or effectiveness concerns.

Providers should note Moderna COVID-19 Vaccine has two types of packaging:

- Multiple-dose vial of Moderna COVID-19 Vaccine with a red cap and label with a light blue border which can be used for primary series doses and for a booster dose
- Multiple-dose vial of Moderna COVID-19 Vaccine with a dark blue cap and label with a purple border which can be used only for a booster dose

### FDA-Approved/EUA-Authorized Dosage

Spikevax and Moderna COVID-19 Vaccine are administered intramuscularly as a series of two doses (0.5 mL each) one month apart.»

## Additional Dose

«A third primary series dose of Spikevax or Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the second dose of the vaccine is authorized for administration to individuals 18 years of age or older who are moderately or severely immunocompromised.»

People are considered to be moderately or severely immunocompromised if they have:

- Been receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response
- If recommended by a healthcare provider for an individual's specific medical condition.

## «Booster Dose

### First Booster Dose»

The booster dose of the Moderna COVID-19 Vaccine is 0.25 mL

«At least **five months** after completing primary series with Spikevax or Moderna COVID-19 Vaccine, a booster dose of any FDA-authorized or approved COVID-19 vaccine may be administered to adults 18 years and older.

- A booster dose of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most situations»

The following people **should** receive a booster:

- Everyone 18 years and older

### «Second Booster Dose

At least **four months** after getting the first booster shot receiving the first booster with appropriate FDA-authorized or approved COVID-19 vaccine, a secondary booster dose of the Moderna COVID-19 vaccine may be administered to eligible individuals 18 years and older. The second booster **must** be an mRNA COVID-19 vaccine.»

«The following people **may choose** to receive a second booster:

- Adults 50 years and older who are not moderately or severely immunocompromised
- Adults 18 years and older who are moderately immunocompromised, have undergone solid organ transplantation or who are living with conditions that are considered to have an equivalent level of immunocompromise
- Adults 18 years and older who are not moderately or severely immunocompromised and who received 2 doses of J&J/Janssen vaccine»

### Choosing the COVID-19 Booster Shot

A booster dose may be administered as a heterologous (mix and match) dose after the completion of primary vaccination with another COVID-19 vaccine.

Providers may refer to the [Fact Sheet for Healthcare Providers Adminstrating Vaccine](#) for information on dose preparation, administration, storage and handling. For the most recent Fact Sheet, see [Vaccine Recipient Fact Sheet | EUA | Moderna COVID-19 Vaccine](#).

For a summary of instructions to COVID-19 vaccination providers and mandatory requirements for the Moderna COVID-19 Vaccine Administration under EUA, refer to the [Fact Sheet for Healthcare Providers Administering Vaccine](#).

### **«Age Limits**

Must be 18 years of age or older»

### Billing

#### **Vaccine codes:**

- 91301 (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease (COVID-19)] vaccine, mRNA-LNP, spike protein, preservative free, 100 mcg/0.5ml dosage, for intramuscular use)
- 91306 (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease (COVID-19)] vaccine, mRNA-LNP, spike protein, preservative free, 50 mcg/0.25 mL dosage, for intramuscular use)
- «91309 Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use»

#### **Administration codes:**

- «0011A (Moderna COVID-19 Vaccine [Red Cap] Administration – First Dose)
- 0012A (Moderna COVID-19 Vaccine [Red Cap] Administration – Second Dose)
- 0013A (Moderna COVID-19 Vaccine [Red Cap] Administration – Third Dose)»

- «0064A (Moderna COVID-19 Vaccine [Red Cap] [Low Dose] 50 mcg/0.25mL dosage Administration – Booster)
- 0094A (Moderna COVID-19 Vaccine [Blue Cap] 50mcg/0.5mL Administration – Booster)»
- M0201 (COVID-19 vaccine administration inside a patient’s home; reported only once per individual per date of service when only COVID-19 vaccine administration is performed at the patient’s home)

### **Important Billing Instructions:**

- DHCS will follow CMS guidelines for the reimbursement of COVID-19 vaccines when administered in accordance with FDA EUA
- Since the initial supply of vaccines are purchased by the federal government and distributed free to providers, providers must not bill 91301, 91306 «or 91309» for the cost of the vaccine
- DHCS is currently reimbursing for the vaccine administration. Providers must submit the appropriate vaccine administration codes for billing the first, second, third or booster vaccine dose as applicable
- M0201 is for an additional \$35 payment for administering the COVID-19 vaccine to certain patients in their homes who meet the defined criteria and are unable to travel to a vaccination site and should be reported in addition to the appropriate vaccine and dose-specific administration. For policy details regarding billing with M0201, see “*Home Administration of COVID-19 Vaccine*” on one of the pages below
- DHCS will provide future guidance for the billing and reimbursement of provider purchased vaccines at the appropriate time
- Providers must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their own systems within 24 hours and to the California Immunization Registry (CAIR2) within 24 hours
- Providers must administer the vaccine in accordance with the CDC and Advisory Committee on Immunization Practices (ACIP) requirements
- It is important to provide vaccine recipients the EUA fact sheet for patients/caregivers and vaccination cards identifying the brand of vaccine administered and the date of their next vaccination (if applicable)

### Resources

- «[Healthcare Providers](#)– labels with purple borders
- [Healthcare Providers](#)– labels with light blue borders»
- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [Fact Sheet for Recipients and Caregivers](#)

- [CDC Recommendations on COVID-19 Vaccine Booster Shot](#)

## Janssen COVID-19 Vaccine

«The Janssen COVID-19 Vaccine is authorized for use under an EUA for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.»

### EUA-Authorized Dosage

The primary vaccination regimen for the Janssen COVID-19 Vaccine is a single-dose (0.5 mL) administered to individuals 18 years of age and older.

### Additional Dose

No additional primary dose is recommended at this time

### **First Booster Dose**

A single Janssen COVID-19 Vaccine booster dose is 0.5 mL.

At least **2 months** after primary vaccination with the Janssen COVID-19 Vaccine, a single dose of another FDA-authorized or approved COVID-19 vaccine may be administered to «adults» 18 years of age and older. (for a total of two shots).

- «A booster dose of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) are preferred in most situations»

The following people **should** receive a booster:

- «Adults» 18 years and older

### **«Second Booster Dose**

A second booster shot may be administered at least **four months** after getting the first booster shot.

- The second booster must be either Pfizer-BioNTech or Moderna COVID-19 vaccine

The following people **may choose** to receive a second booster:

- Adults 50 years and older who are **not** moderately or severely immunocompromised
- Adults 18 years and older who are moderately or severely immunocompromised
- Adults 18 years and older who are **not** moderately or severely immunocompromised and who received two doses of J&J/Janssen vaccine»

See the [Fact Sheet for Healthcare Providers Administering Vaccine](#) for information on dose preparation, administration, storage and handling. For the most recent Fact Sheet, refer to the [Janssen COVID-19 Vaccine website](#).

For a summary of instructions to COVID-19 vaccination providers, warnings and mandatory requirements for the Janssen COVID-19 vaccine administration under Emergency Use Authorization (EUA), refer to the [Fact Sheet for Healthcare Providers Administering Vaccine](#).

### Age Limits

Must be 18 years of age or older

### Billing

#### **Vaccine Code:**

- 91303 (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [Coronavirus disease (COVID-19)] vaccine, DNA, spike protein, adenovirus type 26 [Ad26] vector, preservative free,  $5 \times 10^{10}$  viral particles/0.5ml dosage, for intramuscular use)

#### **Administration Codes:**

- <<0031A (Janssen Covid-19 Vaccine Administration – First Dose)
- 0034A (Janssen Covid-19 Vaccine Administration – Booster)>>
- M0201 (COVID-19 vaccine administration inside a patient's home; reported only once per individual home, per date of service, when only COVID-19 vaccine administration is performed at the patient's home)

#### **Important Billing Instructions:**

- DHCS will follow CMS guidelines for the reimbursement of COVID-19 vaccines when administered in accordance with FDA EUA.
- Since the initial supply of vaccines are purchased by the federal government and distributed free to providers, providers must not bill 91303 for the cost of the vaccine.
- DHCS is currently reimbursing for the vaccine administration billed with 0031A or 0034A for the primary or booster dose
- M0201 is for an additional \$35 payment for administering the COVID-19 vaccine to certain patients in their homes who meet the defined criteria and are unable to travel to a vaccination site and should be reported in addition to the appropriate vaccine and dose-specific administration. For policy details regarding billing with M0201, see “Home Administration of COVID-19 Vaccine” on one of the pages below
- DHCS will provide future guidance for the billing and reimbursement of provider purchased vaccines at the appropriate time
- Providers must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their own systems within 24 hours and to the California Immunization Registry (CAIR2) within 24 hours

- Providers must administer the vaccine in accordance with the CDC and Advisory Committee on Immunization Practices (ACIP) requirements
- It is important to provide vaccine recipients the EUA Fact Sheet for Recipients and Caregivers and vaccination cards identifying the brand of vaccine administered and the date of their next vaccination (if applicable)

#### Resources:

- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [Fact Sheet for Recipients and Caregivers](#)
- [CDC Recommendations on COVID-19 Vaccine Booster Shot](#)

### **Home Administration of COVID-19 Vaccine**

In addition to billing for the administration of a COVID-19 vaccine, providers may also bill for the administration of a COVID-19 vaccine at a beneficiary's home, so long as the beneficiary is unable to travel to a vaccination site themselves.

However, administering at the beneficiary's home is only reimbursable if the sole purpose of the visit is to administer a COVID-19 vaccine. In the instance of another service being a part of the visit, Medi-Cal will only reimburse the COVID-19 vaccine administration, and, if applicable, the other service; it will not reimburse for home administration.

The supplemental home administration fee is designed to target Medi-Cal beneficiaries that have difficulty leaving the home to get the vaccine, which could mean any of these:

- They have a condition, due to an illness or injury that restricts their ability to leave home without a supportive device or help from a paid or unpaid caregiver
- They have a condition that makes them more susceptible to contracting a pandemic disease like COVID-19
- They are generally unable to leave the home, and if they do leave home it requires a considerable and taxing effort
- The patient is hard-to-reach because they have a disability or face clinical, socioeconomic or geographical barriers to getting a COVID-19 vaccine in settings other than their home.

#### Definition of 'Home'

Locations that can qualify as a patient's home for the additional in-home payment amount, includes, but is not limited to, the following:

- A private residence
- Temporary lodging (for example, a hotel or motel, campground, hostel, or homeless shelter)

- An apartment in an apartment complex or a unit in an assisted living facility or group home
- When the Medicare patient's home has been made provider-based to a hospital during the COVID-19 Public Health Emergency (PHE)

However, the following locations are not considered "homes" that can qualify for the additional payment amount:

- Communal spaces of a multi-unit living arrangement
- Hospitals (except when the Medicare patient's home has been made provider-based to a hospital during the COVID-19 PHE)
- Skilled nursing facilities (SNFs), regardless of whether they are the patient's permanent residence
- Assisted living facilities participating in the CDC's Pharmacy Partnership for Long-Term Care Program when their residents are vaccinated through this program

### Frequency Restrictions

If a provider administers a single dose vaccine to fewer than ten Medi-Cal beneficiaries on the same day residing in the same home, Medi-Cal will reimburse the supplemental payment up to a maximum of five times when Medi-Cal patients are vaccinated in the same home.

For example, if a provider administers six vaccines to Medi-Cal patients in the same home, Medi-Cal will reimburse five payments of \$35.00 for the in-home vaccine administration rate, plus \$40.00 for each dose of the COVID-19 vaccine administered. For a total reimbursement of \$415.00.

### Billing

Providers using a *CMS-1500* or *UB-04* (or similar electronic transaction), should use HCPCS code M0201 (COVID-19 vaccine administration inside a patient's home; reported only once per individual per date of service when only COVID-19 vaccine administration is performed at the patient's home) to specify that a COVID-19 vaccine was administered in a home setting.

Pharmacy providers should use NDC 99999999995 in either a 30-1 or similar electronic transaction, to specify that a COVID-19 vaccine was administered in a home setting.

## Coronavirus 2019 Monoclonal Antibodies

### **Bebtelovimab, Monoclonal Antibodies**

Bebtelovimab is a recombinant neutralizing human IgG1k monoclonal antibody (mAb) to the spike protein of SARS-CoV-2 and is unmodified in the Fc region. Bebtelovimab binds the spike protein with a dissociation constant  $K_D$  equals 0.046 to 0.075 nM and blocks spike protein attachment to the human ACE2 receptor with an  $IC_{50}$  value of 0.39 nM (0.056 mcg/mL).

### Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of bebtelovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg):

- with positive results of direct SARS-CoV-2 viral testing, and
- who are at high risk for progression to severe COVID-19, including hospitalization or death, and
- for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate

Bebtelovimab may only be administered in settings in which healthcare providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

### **Limitations of Authorized Use**

Bebtelovimab is not authorized for treatment of mild-to-moderate COVID-19 in geographic regions where infection is likely to have been caused by a non-susceptible SARS-CoV-2 variant based on available information including variant susceptibility to this drug and regional variant frequency.

- FDA's determination and any updates will be available on the [Emergency Use Authorization](#) page on the FDA's website

Bebtelovimab is not authorized for use in patients, who:

- are hospitalized due to COVID-19, or
- require oxygen therapy and/or respiratory support due to COVID-19, or
- require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity

Bebtelovimab is not FDA-approved for any use, including for use as treatment of COVID-19.

### Dosage and Administration

#### **Dosage**

- The dosage in adults (18 years and older) and pediatric patients (12 years of age and older weighing at least 40 kg) 175 mg of bebtelovimab.
- Administer bebtelovimab as soon as possible after positive results of direct SARS-CoV-2 viral testing and within seven days of symptom onset.

- Bebtelovimab must be administered as a single intravenous injection over at least 30 seconds.

For Dose Preparation and Administration, Contraindications, Warnings and Precautions, see the [Bebtelovimab Fact Sheet for Health Care Providers](#).

### **Patient Monitoring Recommendations**

Clinically monitor patients for possible infusion-related reactions during administration and observe patients for at least 1 hour after injection is complete

For Required Reporting for Serious Adverse Events and Medication Errors, see the [Bebtelovimab Fact Sheet for Health Care Providers](#).

### **Age Limits**

Must be 12 years of age or older

### **Billing**

#### **HCPSC codes**

- Q0222, (injection, bebtelovimab, 175 mg)

#### **Administration codes**

- M0222 (intravenous injection, bebtelovimab, includes injection and post administration monitoring)
- M0223 (intravenous injection, bebtelovimab, includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency)

#### **Important billing instructions:**

- DHCS will follow CMS guidelines for the reimbursement of bebtelovimab when administered in accordance with the FDA EUA
- Since the initial supply of bebtelovimab is purchased by the federal government and distributed free to providers, providers must not bill code Q0222 for the cost of bebtelovimab
- DHCS will provide future guidance for the billing and reimbursement of provider purchased products at the appropriate time
- DHCS will reimburse for the cost of administration (infusion) when billed with the administration codes, M0222 or M0223
- Providers must maintain appropriate medical documentation that supports the medical necessity of the service, including documentation that supports that the terms of the EUAs are met. The documentation should also include the name of the provider who ordered or made the decision to administer the infusion

- It is important to provide monoclonal antibody recipients with the EUA fact sheet for patients/caregivers for the applicable product
- DHCS allows a broad range of providers and suppliers to administer these treatments, including but not limited to:
  - Freestanding and hospital-based infusion centers.
  - Home health agencies.
  - Nursing homes.
  - Entities with whom nursing homes contract to administer treatment

### Resources

[Bebtelovimab Fact Sheet for Health Care Providers](#)

[Bebtelovimab Fact Sheet for Patients, Parents and Caregivers](#)

### **Product Distribution Information**

COVID-19 monoclonal antibodies are currently being distributed by the U.S. Department of Health and Human Services (HHS) in coordination with state and territorial health departments.

- Providers can find public locations that have received shipments via [COVID-19 Therapeutics Locator](#).
- For California, see [Distribution and Ordering of Anti-SARS-CoV-2 Therapeutics](#) in CDPH website.

### **Tixagevimab Co-packaged with Cilgavimab (Evusheld) Monoclonal Antibodies**

Tixagevimab and cilgavimab are recombinant human IgG1κ monoclonal antibodies that bind to nonoverlapping epitopes of the spike protein receptor-binding domain of SARS-CoV-2, blocking attachment to the human ACE2 receptor. Tixagevimab and cilgavimab have amino acid substitutions to extend half-life, reduce antibody effector function, and minimize the potential risk of antibody-dependent disease enhancement.

### Authorized Use

#### **Treatment**

The U.S. FDA has issued an EUA for the emergency use of the unapproved product Evusheld (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and

- Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or,
- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s)

Evusheld is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

**Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:**

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts less than 200/mm<sup>3</sup>, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., greater than or equal to 20 mg prednisone or equivalent per day when administered for greater than or equal to 2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

### **Limitations of Authorized Use**

- Evusheld is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2
- Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination

- Individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination

## Dosages and Administration

### Initial Dosing

Adults and pediatric individuals (12 years of age and older weighing at least 40 kg): 300 mg of tixagevimab and 300 mg of cilgavimab administered as two separate consecutive intramuscular (IM) injections.

### Dosing for Individuals Initially Receiving 150 mg of Tixagevimab and 150 mg of Cilgavimab

Individuals who have already received the previously authorized dose (150 mg of tixagevimab and 150 mg of cilgavimab) should receive a second Evusheld dose (150 mg of tixagevimab and 150 mg of cilgavimab) as soon as possible. Any subsequent repeat dosing should be timed from the date of the second Evusheld dose.

### Repeat Dosing

Evusheld has only been studied in single-dose studies. There are no safety and efficacy data available with repeat dosing. Longer term data from the study PROVENT indicated that Evusheld may be effective for pre-exposure prophylaxis for 6 months post-administration for pre-Omicron SARS-CoV-2 variants. However, the neutralization activity of Evusheld against the Omicron subvariants (BA.1, and BA.1.1 [BA.1+R346K]) versus the reference strain decreases 12- to 424-fold, and consequently the duration of protection is not known and is likely reduced. Conversely, the neutralization activity of Evusheld against the Omicron BA.2 subvariant versus the reference strain is minimally impacted.

Because it is unclear which SARS-CoV-2 variant or Omicron subvariant will become dominant in the United States over the next few months, the recommended timing for repeat dosing cannot be provided at this time. The fact sheets will be revised with repeat dosing recommendations in the near future when more data are available to determine the appropriate timing of redosing (for example: a repeat dose with 150 mg of tixagevimab and 150 mg of cilgavimab three months or six months after the prior dose).

### Administration

- Tixagevimab and cilgavimab must be administered by a qualified healthcare provider
- Administer the two components of Evusheld consecutively
- Administer the IM injections at different injection sites, preferably one in each of the gluteal muscles, one after the other
  - For the 300 mg tixagevimab and 300 mg cilgavimab dose, ensure that the administration sites are appropriate for the volume (3 mL per injection)

For dose preparation, contraindications, warnings and precautions, see the [Fact Sheet for Health Care Providers](#).

### Patient Monitoring Recommendations

Clinically monitor individuals after injections and observe for at least one hour.

For required reporting for serious adverse events and medication errors for Evusheld administration under EUA, see the [Fact Sheet for Health Care Providers](#).

### **Age Limits**

Must be 12 years of age or older

### **Billing**

#### HCPCS Code

- Q0220 (injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID -19 vaccine(s) and/or covid-19 vaccine component(s), 300 mg)
- Q0221 (injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals (12 years of age and older weighing at least 40kg) with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID -19 vaccine is not recommended due to a history of severe adverse reaction to a COVID -19 vaccine(s) and/or covid-19 vaccine component(s), 600 mg)

### Administration Codes

- M0220 (injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals [12 years of age and older weighing at least 40kg] with no known SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), includes injection and post administration monitoring)

- M0221 (injection, tixagevimab and cilgavimab, for the pre-exposure prophylaxis only, for certain adults and pediatric individuals [12 years of age and older weighing at least 40kg] with no SARS-CoV-2 exposure, who either have moderate to severely compromised immune systems or for whom vaccination with any available COVID-19 vaccine is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s), includes injection and post administration monitoring in the home or residence; this includes a beneficiary's home that has been made provider-based to the hospital during the COVID-19 public health emergency)

### **Important Billing Instructions**

- DHCS will follow CMS guidelines for the reimbursement of tixagevimab and cilgavimab when administered in accordance with FDA EUA
- Since the initial supply of tixagevimab and cilgavimab is purchased by the federal government and distributed free to providers, providers must not bill codes Q0220 or Q0221 for the cost of Evusheld
- DHCS will provide future guidance for the billing and reimbursement of provider purchased products at the appropriate time
- DHCS will reimburse for the cost of administration (infusion) when billed with administration code M0220 or M0221
- Providers must maintain appropriate medical documentation that supports the medical necessity of the service, including documentation that supports that the terms of the EUAs are met. The documentation should also include the name of the provider who ordered or made the decision to administer the infusion
- It is important to provide monoclonal antibody recipients with the EUA fact sheet for patients/caregivers for the applicable product
- DHCS allows a broad range of providers and suppliers to administer these treatments, including but not limited to:
  - Freestanding and hospital-based infusion centers
  - Home health agencies
  - Nursing homes
  - Entities with whom nursing homes contract to administer treatment

## Resources

- [Fact Sheet for Health Care Providers](#)
- [Fact Sheet for Patients, Parents and Caregivers](#)

## Product Distribution Information

COVID-19 monoclonal antibodies are currently being distributed by the U.S. Department of Health and Human Services (HHS) in coordination with state and territorial health departments

- Providers can find public locations that have received shipments via [COVID-19 Therapeutics Locator](#) (arcgis.com)
- For California, see [Distribution and Ordering of Anti-SARS-CoV-2 Therapeutics](#) on the CDPH website

## **COVID-19 Convalescent Plasma**

COVID-19 convalescent plasma is human plasma collected by the U.S. Food and Drug Administration (FDA) registered or licensed blood establishments from individuals whose plasma contains high titers of anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. Convalescent plasma is qualified and labeled as having high titer anti-SARS-CoV-2 antibodies based on testing accepted by FDA under an Emergency Use Authorization (EUA). Qualification of COVID-19 convalescent plasma as high titer is based on serologic correlates of neutralizing activity, i.e., the ability of the donor antibodies to block infection by reference strains of the SARS-CoV-2 virus in laboratory tests.

**Note:** Policy for COVID-19 convalescent plasma (HCPCS code C9507 is located in the *Blood and Blood Derivatives* section of the provider manual

## **Legend**

Symbols used in the document above are explained in the following table.

<b>Symbol</b>	<b>Description</b>
«	This is a change mark symbol. It is used to indicate where on the page the most recent change begins.
»	This is a change mark symbol. It is used to indicate where on the page the most recent change ends.