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); one vaccine (single or combination vaccine/toxoid)
- 90473 Immunization administration by intranasal or oral route; one 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.

‹‹Bacillus Calmette-Guerin (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 (Vaxchora)››

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

Two to 64 years of age

Billing

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

Required Modifier

SK (member of a high-risk population)

‹‹Dengue Tetravalent Vaccine, Live (Dengvaxia)››

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

Nine 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 Pediatric)››

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

six weeks through six years of age (prior to seventh birthday)

Billing

CPT code 90702 (Diphtheria and tetanus toxoids adsorbed (DT) when administered to individuals younger than seven 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) (Tripedia®, Daptacel®, Infarix®)››

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

six weeks through six years of age (prior to seventh birthday)

Billing

CPT code 90700 (Diphtheria, tetanus toxoids, and acellular pertussis vaccine (DTaP), when administered to individuals younger than seven 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) (Pediarix®)››

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

six weeks through six years of age (prior to seventh 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) (Kinrix®, Quadracel®)››

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 four through six years of age (prior to seventh 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) (Pentacel)››

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

six weeks through four years of age (prior to the fifth birthday)

Billing

CPT code 90698 (Diphtheria, tetanus toxoids, and acellular pertussis vaccine, *Haemophilus influenza* 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) (Vaxelis™)››

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

Six weeks through four years of age (prior to the fifth 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) (Vaqta®, Havrix®)››

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 (Ervebo®)››

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) (Twinrix®)››

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

CPT Code	Description	Age Limits
90739	‹‹Hepatitis B vaccine (HepB), CpG-adjuvanted, adult dosage, 2 dose or 4 dose schedule for intramuscular use (Heplisav-B®)››	18 years of age and older
90740	‹‹Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 3 dose schedule, for intramuscular use (Recombivax HB®)››	18 years of age and older
90743	‹‹Hepatitis B vaccine (HepB), adolescent, 2 dose schedule, for intramuscular use (Recombivax HB)››	11 through 15 years of age
90744	‹‹Hepatitis B vaccine (HepB), pediatric/adolescent dosage, 3 dose schedule, for intramuscular use (Recombivax HB Energix-B)››	Birth through 19 years of age
90746	‹‹Hepatitis B vaccine (HepB), adult dosage, 3 dose schedule, for intramuscular use (Recombivax HB) Energix-B)››	20 years of age and older
90747	‹‹Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 4 dose schedule, for intramuscular use (Recombivax HB (dialysis))››	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]) (PedvaxHIB®)››

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

Six 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]) (ActHIB®, Hiberex)››

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

Six 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) (Gardasil-9®)››

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

Nine 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 (IIV4) Afluria Quad, Fluarix Quad, Flulaval Quad, Fluzone Quad)››

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 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 (IIV4) (Fluzone Quad Intradermal)››

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 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 (allV4) (FLUAD®)

Influenza vaccine, adjuvanted 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 (IIV4-HD) (Fluzone High-Dose)

Influenza vaccine, high dose (IIV4-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 (LAIV4) (FluMist® Quadrivalent)

Influenza Vaccine Live (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

Two 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 (RIV4) (Flublok Quad)››

Influenza Vaccine Recombinant (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 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) (Flucelvax Quad)››

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

Six 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 (IXIARO)››

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

Two 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-CRM) (Menveo®)››

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

Two 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) (MenQuadfi®)››

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

Two 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) (Bexsero®)››

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) (Trumenba®)››

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) (M-M-R II®)››

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) (ProQuad®)››

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 (IPOL®)››

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

Six 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) (Prevnar 13™)››

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

Six 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) (Vaxneuvance™)››

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

‹‹6 weeks of age and older.››

Billing

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

‹‹Required Modifier

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

Pneumococcal 20-Valent Conjugate (PCV20) (Prevnar 20™)

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) (Pneumovax®23)

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

Two 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 (Imovax, RabAvert)

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) (Rotarix®)››

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

Six 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) (RotaTeq®)››

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

Six 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) (Tenivac®, TDVAX™)

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

Seven years and older.

Billing

CPT code 90714 (tetanus and diphtheria toxoids adsorbed [Td], preservative free, when administered to individuals seven 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) (Boostrix®) (Adacel®)››

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

Seven years and older

Billing

CPT code 90715 (tetanus, diphtheria toxoids and acellular pertussis vaccine [Tdap], when administered to individuals seven 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) (TicoVac®)››

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

One 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) (Typhim Vi®)››

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

Two 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) (Vivotif®)››

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

Six years and older.

Billing

CPT code 90690 (typhoid vaccine, live, oral).

Required Modifier

SK (member of high-risk population).

‹‹Varicella (VAR) (VARIVAX®)››

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 (YF-VAX)››

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

Nine months and older.

Billing

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

Required Modifier

SK (member of a high-risk population)

‹‹Zoster Recombinant (RZV) (Shingrix®)››

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) (HepaGam B, HyperHEP B, Nabi-HB)››

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) (GAMASTAN)››

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 (Synagis®)

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

Guidance for Current Apparently Atypical RSV Season (2022-2023)

For the current apparent Respiratory Syncytial Virus (RSV) season only (2022-2023), more than five doses of Palivizumab may be administered; providers may administer up to a maximum of six doses per child if the child receives the first dose in October. Monthly doses from October through April will provide protection through May.

This policy update is due to tracking RSV infection test positivity rates by California Children's Services (CCS) Program and the California Department of Public Health (CDPH), which receives RSV test positivity data from regional sentinel laboratories across California from which CDPH prepares aggregate RSV test positivity reports. These reports, along with those of the National Respiratory and Enteric Virus Surveillance System (NREVSS), suggests an earlier start to the RSV season than in typical years.››

‹‹Guidance for a Typical RSV Season

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.

TAR Requirement

A *Treatment Authorization Request* (TAR) is required for reimbursement during typical and atypical seasons.

TAR criteria

Palivizumab is considered medically necessary for the RSV prophylaxis under one of the following conditions:

- 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 tenth 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.

Administration and Billing Information

- Palivizumab is given by intramuscular injection on a monthly basis during the RSV season.
- 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

National Respiratory and Enteric Virus Surveillance System (NREVSS)

CCS Numbered Letter 13-0914

‹‹Rabies Immune Globulins (HyperRAB)››

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 (TIg) (HyperTET)››

Tetanus immune globulin, human (TIg), 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 (VariZIG)››

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) is a monovalent COVID-19 vaccine that is approved by the U.S. Food and Drug Administration (FDA) for the prevention of COVID-19 in individuals 12 years of age and older.

Pfizer-BioNTech COVID-19 Vaccine is a monovalent COVID-19 vaccine that is authorized for emergency use to prevent COVID-19 as:

- The first two doses of the three-dose primary series for children 6 months through 4 years of age.
- A two-dose primary series for individuals 5 years of age and older.
- A third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.

Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for emergency use to prevent COVID-19 as:

- The third dose of the three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age.
- A single booster dose at least two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

Providers must ensure that they use the most age-appropriate COVID-19 Vaccine package. For details please refer to the Pfizer BioNTech COVID-19 Vaccines webpage.

Comirnaty FDA-Approved Dosage

Primary Series

A two-dose primary series in individuals 12 years of age and older.

Administer intramuscularly as a series of two doses (0.3 mL each) three weeks apart.››

‹‹Pfizer-BioNTech COVID-19 Vaccine EUA-Authorized Dosage

Primary Series

Pediatric Use (6 months through 4 years of age)

Three doses (0.2 mL each): Dose 1 and Dose 2 are administered intramuscularly three to eight weeks apart followed by Dose 3 at least eight weeks after Dose 2.

The 3-dose primary series are administered as follows:

- Dose 1: Pfizer-BioNTech COVID-19 Vaccine
- Dose 2: Pfizer-BioNTech COVID-19 Vaccine
- Dose 3: Pfizer-BioNTech COVID-19 Vaccine, Bivalent
  - Each vial must be diluted before administration. For dilution and preparation instructions, see the age-appropriate Pfizer-BioNTech COVID-19 Vaccines Fact Sheets››

Pediatric Use (five through 11 years of age)

- ‹‹Two doses (0.2 mL each) administered intramuscularly three to eight weeks apart
  - Each vial must be diluted before administration. For dilution and preparation instructions, see the age-appropriate Pfizer BioNTech COVID-19 Vaccines Fact Sheets››
- Ages 12 years of age and older:
  - Two doses (0.3 mL each) administered intramuscularly three weeks apart

Third/Additional Dose

‹‹A third primary series dose of Pfizer-BioNTech COVID-19 Vaccine given at least four weeks following the second dose to individuals 6 months of age and older who have been determined to be moderately to severely immunocompromised (at least eight weeks following second dose for individuals 4 months through 4 years [Bivalent Vaccine dose]).››

People are considered to be moderately or severely immunocompromised based on any of the following:

- 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 therapy or hematopoietic cell transplant (HCT) (within two years of transplantation or taking immunosuppressive therapy)
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)

- Advanced or untreated HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (for example, 20 or more mg of prednisone or equivalent per day when administered for two or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
- If recommended by a healthcare provider for an individual's specific medical condition

Booster Doses

Bivalent Booster Dose

A single booster dose for ages 5 years through 11 years is 0.2 mL

A single booster dose for ages 12 years and older is 0.3 mL

At least **two months** after completion of either the primary vaccination or most recent booster dose with any authorized/approved monovalent COVID-19 vaccine. The following people can receive the Bivalent booster dose:

- Individuals 5 years of age (Pfizer-BioNTech booster only)
- Individuals 6 through 11 years (Pfizer-BioNTech or Moderna booster)
- Individuals 12 years and older (Pfizer-BioNTech or Moderna booster)

Note: The monovalent Pfizer-BioNTech COVID-19 Vaccine is no longer authorized as a booster dose for individuals 5 years and older.

‹‹Children 6 months to 4 years who received a three-dose primary series regardless which vaccine (monovalent or bivalent) was administered for Dose 3 are not recommended for a booster.››

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. Additionally, the updated booster dose does not need to be from the same manufacturer as the primary vaccination or previous monovalent booster.

For instructions on preparation, administration and the Requirements and Instructions for Reporting Adverse Events and Vaccine Administration Errors, see the applicable Fact Sheet for Healthcare Providers.

For the most recent Fact Sheets, visit the Pfizer-BioNTech COVID Vaccine website.

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)
- 91308 (Severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [coronavirus disease (COVID-19)] vaccine, mRNALNP, spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use)
- 91312 (Severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [coronavirus disease (COVID-19)] vaccine, mRNA-LNP, bivalent spike protein, preservative free, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use)
- ‹‹91317 (Severe acute respiratory syndrome coronavirus 2 [SARSCoV-2] [coronavirus disease (COVID-19)] vaccine, mRNALNP, bivalent spike protein, preservative free, 3 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)
- 0074A (Pfizer-BioNTech COVID-19 Pediatric Vaccine [Orange Cap] - Administration – Booster)
- 0081A (Pfizer-BioNTech COVID-19 Pediatric Vaccine (Aged 6 months through 4 years) (Maroon Cap) - Administration - First dose)
- 0082A (Pfizer-BioNTech COVID-19 Pediatric Vaccine (Aged 6 months through 4 years) (Maroon Cap) - Administration - Second dose)
- 0083A (Pfizer-BioNTech COVID-19 Pediatric Vaccine (Aged 6 months through 4 years) (Maroon Cap) - Administration - Third dose)
- 0124A (Pfizer-BioNTech COVID-19 Vaccine Administration – Bivalent Booster Dose)
- 0154A (Pfizer-BioNTech COVID-19 Vaccine, Bivalent Product (Aged 5 years through 11 years) (Orange Cap) Administration – Booster Dose)

- ‹‹0173A (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, bivalent spike protein, preservative free, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, 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, 91307, 91308, 91312 or 91317 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 primary 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

- ‹‹Pfizer-BioNTech COVID-19 Vaccines Fact Sheets
- CDC Recommendations on COVID-19 Vaccine Booster Shot
- Summary Document for Interim Clinical Considerations
- COVID-19 Vaccine Interim COVID-19 Immunization Schedule for 6 Months of Age and Older (cdc.gov)

SPIKEVAX (COVID-19 Vaccine, mRNA)/Moderna COVID-19 Vaccine

Spikevax COVID-19 vaccine is approved by the U.S. Food and Drug Administration (FDA) 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 emergency use to provide:

- A two-dose primary series to individuals 12 years through 17 years of age.
- A third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.

Moderna COVID-19 Vaccine is a monovalent COVID-19 vaccine that is authorized for emergency use to prevent COVID-19 as a:

- Two-dose primary series for individuals 6 months of age and older.
- Third primary series dose for individuals 6 months of age and older who have been determined to have certain kinds of immunocompromise.

Moderna COVID-19 Vaccine, Bivalent authorized for use as a single booster dose to prevent COVID-19, administered at least 2 months after.

- Completion of primary vaccination with the monovalent Moderna COVID-19 Vaccine in children 6 months through 5 years of age, or
- Completion of primary vaccination with any authorized or approved COVID-19 vaccine in individuals 6 years of age and older, or
- Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 6 years of age and older.

Providers must ensure that they use the most age-appropriate Moderna COVID-19 Vaccine package. For details, please refer to the Moderna COVID-19 Vaccines FDA webpage.››

FDA-Approved Dosage

Primary Series

Spikevax and Moderna COVID-19 Vaccine are administered intramuscularly as a series of two doses (0.5 mL each) one month apart in individuals 18 years of age and older.

EUA-Authorized Dosage

Primary Series

Pediatric Use (6 months through 5 years of age)

- ‹‹A two-doses (0.25 mL each) administered intramuscularly four to eight weeks apart.››

Pediatric Use (6 years through 11 years of age)

- ‹‹Two doses (0.5 mL each) four to eight weeks apart.

Pediatric Use (12 years of age and older)

- Two doses (0.5 mL each) four to eight weeks apart.

For dose preparation and administration, refer to the age-appropriate Moderna COVID-19 Vaccines Fact Sheets››.

Third/Additional Dose of primary series

‹‹A third primary series dose of Moderna COVID-19 Vaccine is administered at least 4 weeks after the second dose to individuals 6 months of age and older with certain kinds of immunocompromise››

- 0.25 mL to individuals 6 months through 5 years of age.
- 0.5 mL to individuals 6 years through 11 years of age.
- 0.5 mL to individuals at least 12 years of age.

‹‹A third primary series dose of Spikevax or Moderna COVID-19 Vaccine (0.5 mL) administered at least four weeks following the second dose of the vaccine is authorized for administration to individuals 12 years of age or older who are moderately or severely immunocompromised.››

People are moderately or severely immunocompromised based on any of the following:

- 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 therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)

- Moderate or severe primary immunodeficiency (for example, DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts less than 200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (for example, 20 or more mg of prednisone or equivalent per day when administered for two or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory
- If recommended by a healthcare provider for an individual's specific medical condition.

Booster Dose

Bivalent Booster Dose

- ‹‹A single booster dose for individuals 6 months through 5 years of age is 0.2 mL››
- A single booster dose for ages 6 years through 11 years is 0.25 mL
- A single booster dose for ages 12 years and older is 0.5 mL

At least **two months** after completion of either the primary vaccination or most recent booster dose with any authorized/approved monovalent COVID-19 vaccine. The following people can receive the Bivalent booster dose:

- ‹‹Individuals 6 months through 5 years of age.››
- Individuals 6 years of age and older.

‹‹**Note:** Only Moderna Bivalent Booster may be used in individuals 6 months through 5 years of age.››

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. Additionally, the updated booster dose does not need to be from the same manufacturer as the primary vaccination or previous monovalent booster.

‹‹Providers may refer to the age-appropriate Moderna COVID-19 Vaccines Fact Sheets 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 Moderna COVID-19 Vaccines Fact Sheets.››

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)
- 91311 (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] [coronavirus disease (COVID-19)] vaccine, mRNA-LNP, spike protein, preservative free, 25 mcg/0.25 mL dosage, for intramuscular use)
- 91313 (severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 50 mcg/0.5 mL dosage, for intramuscular use)
- ‹‹91316 (severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, bivalent, preservative free, 10 mcg/0.2 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)
- 0091A (Moderna COVID-19 Pediatric Vaccine (aged six years through 11 years) (Blue Cap with purple border) - administration - first dose)
- 0092A (Moderna COVID-19 Pediatric Vaccine (aged six years through 11 years) (Blue Cap with purple border) - administration - second dose)
- 0093A (Moderna COVID-19 Pediatric Vaccine (aged six years through 11 years) (Blue Cap with purple border) - administration - third dose)
- 0094A (Moderna COVID-19 Vaccine [Blue Cap] 50mcg/0.5mL Administration – Booster)
- 0134A (Moderna COVID-19 Vaccine Administration – Bivalent Booster Dose [Dark Blue Cap with Grey Borders])
- 0144A (Moderna COVID-19 Vaccine, Bivalent [Aged 6 years through 11 years] [Dark Blue Cap with gray border] Administration – Booster Dose)
- 0111A (Moderna COVID-19 Pediatric Vaccine [Aged 6 months through 5 years] [Blue Cap with magenta border] – Administration - First dose)
- 0112A (Moderna COVID-19 Pediatric Vaccine [Aged 6 months through 5 years] [Blue Cap with magenta border] – Administration - Second dose)
- 0113A (Moderna COVID-19 Pediatric Vaccine [Aged 6 months through 5 years] [Blue Cap with magenta border] – Administration - Third dose)
- ‹‹0164A (Immunization administration by intramuscular injection of sever acute respiratory syndrome coronavirus 2 (SARSCoV-2) (coronavirus disease [COVID-19]) vaccine, mRNALNP, spike protein, bivalent, preservative free, 10 mcg/0.2mL dosage, booster dose)››
- 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, 91309, 91311, 91313 or 91316 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 primary or booster vaccine doses 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

- ‹‹Moderna COVID-19 Vaccines Fact Sheets
- CDC Recommendations on COVID-19 Vaccine Booster Shot
- Summary Document for Interim Clinical Considerations
- Moderna COVID-19 Vaccine At-A-Glance (cdc.gov)
- COVID-19 Vaccine Interim COVID-19 Immunization Schedule for 6 Months of Age and Older (cdc.gov)››

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.

Booster Dose

Bivalent Booster Dose

At least **two months** after completion of either the primary vaccination or most recent booster dose with any authorized/approved monovalent COVID-19 vaccine. The following people can receive the Bivalent booster dose:

- Individuals 18 years and older (Pfizer-BioNTech or Moderna)

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, $5x10^{10}$ 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 vaccine 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

Novavax COVID-19 Vaccine

The Novavax COVID-19 Vaccine, Adjuvanted is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

EUA-Authorized Dosage

The Novavax COVID-19 Vaccine, Adjuvanted is administered intramuscularly as a primary series of two doses (0.5 mL each) three weeks apart. The CDC recommends an interval of three to eight weeks between the first and second dose.

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 http://www.NovavaxCovidVaccine.com.

For a summary of instructions to COVID-19 vaccination providers, warnings and mandatory requirements for the Novavax COVID-19 vaccine administration under EUA, refer to the Fact Sheet for Healthcare Providers Administering Vaccine.

Additional Dose

No additional primary dose is recommended at this time.

First (Monovalent) Booster Dose

At least six months after completion of primary vaccination with an authorized or approved COVID-19 vaccine, the following individuals 18 years and older can receive a booster dose of 0.5 ml:

- For whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate; or
- Who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

Bivalent Booster Dose

At least **two months** after completion of either the primary vaccination or most recent booster dose with any authorized/approved monovalent COVID-19 vaccine. The following people can receive the Bivalent booster dose:

- Individuals 12 through 17 years of age (can receive either Pfizer-BioNTech or Moderna bivalent booster).

Age Limits

Must be 12 years of age or older.

Billing

Vaccine code

- 91304 (severe acute respiratory syndrome coronavirus 2 [SARSCoV-2] [coronavirus disease COVID-19] vaccine, recombinant spike protein nanoparticle, saponin-based adjuvant, preservative free, 5 mcg/0.5 mL dosage, for intramuscular use).

Administration Codes

- 0041A (Novavax Covid-19 Vaccine Administration – first dose)
- 0042A (Novavax Covid-19 Vaccine Administration – second dose)
- 0044A Novavax COVID-19 Vaccine, Adjuvanted 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 91304 for the cost of the vaccine
- ‹‹DHCS is currently reimbursing for the vaccine administration billed with 0041A, 0042A or 0044A for the primary or booster vaccine doses.››
- 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

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 IgG1κ 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 KD equals 0.046 to 0.075 nM and blocks spike protein attachment to the human ACE2 receptor with an IC50 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

HCPCS 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.
- On August 15,2022, the manufacturer, Eli Lilly, started the commercial distribution of bebtelovimab. DHCS will reimburse the provider-purchased product in accordance with the reimbursement methodology for physician-administered drugs, at the pharmacy rate, 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).
  - DHCS will reimburse provider-purchased product when billed with product code Q0222.

- Providers may have both free federal-purchased and provider-purchased products.
  - For dates of service on or after August 15, 2022, providers are to only bill DHCS for product reimbursement using Q0222 if a provider-purchased product is administered. Providers must not bill for federal-purchased free products.
- Providers are to continue to bill for administering either type of product using administration codes M0222 or M0223.
- Providers are instructed to check the batch number on the vial. If the batch number is D534422, the product was commercially purchased. For news on additional batch numbers, refer to the Eli Lilly website.
- 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

HHS Update: Bebtelovimab Commercial Transition

Product Distribution Information

Bebtelovimab has become available for purchase from the distributor AmerisourceBergen (ABC) beginning the week of August 15, 2022. Distribution of bebtelovimab that was purchased by the federal government and distributed to providers through state allocation has ended.

Note: For details regarding the transition to commercial supply and the timeline for the transition, providers are to refer to webpage HHS Update: Bebtelovimab Commercial Transition.

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 two 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/mm3, 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 two 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 Cligavimab

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 six 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 Codes

- 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.

‹‹Monkeypox and Smallpox Vaccines

Guidance on the Use of JYNNEOS and ACAM2000® Vaccines for Monkeypox (Mpox)

JYNNEOS and ACAM2000 are the two vaccines that may be used for the prevention of monkeypox disease.

- JYNNEOS vaccine is approved by the U.S. Food and Drug Administration (FDA) for the prevention of monkeypox and smallpox disease. The standard regimen for JYNNEOS involves a subcutaneous (SUBQ) route of administration. It is the primary vaccine for this monkeypox outbreak.
  - The standard regimen is authorized for people aged 18 years or younger under an Emergency Use Authorization (EUA)
  - An alternative regimen involving intradermal (ID) administration is authorized for ages 18 and older to increase JYNNEOS doses by up to five fold.
- ACAM2000 is approved by FDA for use against smallpox and allowed for use against monkeypox under an Expanded Access Investigational New Drug (IND) protocol.
  - Requires informed consent and submission of additional forms.
  - ACAM2000 vaccine is an alternative to JYNNEOS.
- CDC recommends that individuals whose jobs may expose them to orthopoxviruses, such as monkeypox, should get vaccinated with either JYNNEOS or ACAM2000.
- Either JYNNEOS or ACAM2000 can be used for Post Exposure Prophylaxis (PEP), Expanded Post-Exposure Prophylaxis (PEP++) or Pre-Exposure Prophylaxis (PrEP), following risk-benefit discussions and a review of any conditions that could increase risk for serious adverse events.
- People with a severe allergy to any component of ACAM2000 or with a severely weakened immune system should not receive this vaccine.

Requirements For Mpox Vaccination

- The Advisory Committee on Immunization Practices (ACIP) recommends vaccination for those at high risk following a confirmed monkeypox exposure.
- JYNNEOS doses are prioritized if patient is at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions)››.

‹‹Dose Prioritization: Current Qualifying Criteria

Due to a limited supply, the California Department of Public Health (CDPH) is currently prioritizing Jynneos vaccine for the following individuals:

- Known close contacts of people who have Mpox (called PEP).
- People with certain risk factors who are more likely to have been recently exposed, even if they don't have a documented exposure (called PEP++). This can include people who attended a setting where there was a known/possible Mpox exposure.
- People at higher risk due to their job**.** According to the ACIP guidance, this includes laboratory workers who perform Mpox testing (called PrEP). Clinicians and people who work in laboratories not performing Mpox testing, are not advised to receive Mpox PrEP. Health care providers who may have unusual exposures to Mpox in the workplace should consult with their local health department about vaccination.

For the most recent dose prioritization information or availability of additional doses and expansion of vaccination to a larger group, see the guidance from CDPH on its Monkeypox homepage

General requirements

- Patient must be determined to be at high risk for smallpox or monkeypox infection.

Pre-Exposure Prophylaxis (PrEP) To Prevent Monkeypox

People who should get PrEP include:

- Clinical laboratory personnel who perform diagnostic testing for orthopoxviruses.
- Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans.
- Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes

People who can get PrEP if they want to.

- Healthcare personnel who administer ACAM2000 or anticipate caring for many patients with monkeypox.››

‹‹Post Exposure Prophylaxis (PEP) for Monkeypox Virus

• CDC recommends administration of vaccine within 4 days from the date of exposure in order to prevent onset of the disease.

- If given between four and fourteen days after the date of exposure, vaccination may reduce the symptoms of disease but may not prevent the disease.

Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++

People with certain risk factors are more likely to be exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox.

Revaccination After Exposure

Revaccination for persons exposed to the monkeypox virus and who have not received the smallpox vaccine within the last three years. The vaccine will be more effective the sooner it is administered.

Booster Schedule

CDC recommends booster doses every two or 10 years for persons who remain at continued exposure to monkeypox or other orthopoxviruses.

Smallpox and Monkeypox Vaccines (JYNNEOS, Imvamune or Imvanex)

Smallpox and monkeypox vaccines are an attenuated vaccinia virus, live, non-replicating, preservative free suspension for subcutaneous use.

Dosages and Dosing Schedules

Ages 18 years and older

- Alternative regimen: Intradermal: 0.1 mL per dose given as two doses separated by 28 days (EUA-authorized).
- Standard regimen: SUBQ: 0.5 mL per dose given as two doses separated by 28 days.

Ages 18 years and younger

- Standard regimen: SUBQ: 0.5 mL per dose given as two doses separated by 28 days (EUA-authorized).››

‹‹People of any age with a history of keloid scars

- SUBQ: 0.5 mL per dose given as two doses separated by 28 days.

Note: Based on available data, the second dose may be given from 24 days to up to 35 days after the first dose.

Interchangeability of Dosing Regimens (CDC 2022)

- Adults 18 years and older who received one JYNNEOS dose subcutaneously. The second dose may be administered intradermally if necessary to complete the series.
- A person whose 18th birthday occurs between their first and second dose may complete the series with the alternative regimen.

Smallpox (Vaccinia) Vaccine (ACAM2000)

ACAM2000 is a live, lyophilized preparation of smallpox vaccine for percutaneous scarification.

Dosages and Dosing Schedules

Individuals one year and older

- Percutaneous, delivered using a bifurcated needle: 0.0025 mL droplet of reconstituted vaccine
- A single dose is recommended.

Who should not receive ACAM2000

ACAM2000 should not be given to people who have the following health conditions:

- Three or more cardiac risk factors (hypertension, diabetes, hypercholesterolemia, heart disease at age equal to or greater than 50 years in a first-decree relative, or smoking).
- Eye disease treated with topical steroids.
- Congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people living with HIV, atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions.
- Atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions.
- Infants less than 12 months of age.››

- ‹‹Pregnancy or breast feeding.
- Persons with severe allergy to any component of the vaccine.

Note: For Qualifying Criteria for Smallpox (FDA-approved indication), see the CDC Guidance on Smallpox for details.

Billing

Vaccine codes

- Jynneos: CPT code 90611 (smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use)
- ACAM2000: CPT code 90622 (Vaccinia (smallpox) virus vaccine, live, lyophilized, 0.3 mL dosage, for percutaneous use)

Administration code

CPT code 90472 (administration of vaccine)

Required Modifier

SL (state-supplied vaccine)

Suggested ICD-10 Diagnosis Codes

B04 (Monkeypox)

Important Billing Instructions

- Monkeypox/Smallpox vaccines are a Medi-Cal benefit when administered in accordance with FDA approval/authorization and CDC and ACIP recommendations.
- Since the vaccines are supplied free by the federal government and made available through the public health departments, providers will not be reimbursed for the cost of the vaccine.
- DHCS will reimburse for the vaccine administration when billed with CPT code 90472.
- Providers must also bill the vaccine codes 90611 or 90622 with modifier SL (state-supplied vaccine) for documentation only (reimbursed at $0.01).
- Providers must submit both the vaccine and administration codes for appropriate reimbursement and documentation.››

- ‹‹Providers are to submit vaccine CPT code 90611 for the administration of either the 0.5 ml or the 0.1 ml dose of JYNNEOS to report the vaccine product that was administered.
- All administering providers must comply with the terms of the CDC Monkeypox Vaccination Program Provider Agreement.
- Providers must meet storage and recordkeeping requirements, including recording the administration of the vaccine to patients in their medical record system within 24 hours and to the California Immunization Registry (CAIR2) within 72 hours.

Product Availability

- There are currently two monkeypox vaccines available in the United States via the Strategic National Stockpile (SNS).
- Vaccines are currently not available to providers but are provided to states through CDC and SNS.
- At this time, the federal government has allocated a limited number of JYNNEOS vaccine doses to Californians. CDPH is working with local health departments to make these doses available to protect against monkeypox.
- Providers may consult with their local health services/offices to identify available locations in the area that may have vaccines to administer.
- For the most recent information on dose prioritization or availability of additional doses and expansion of vaccination to a larger group, see the guidance from CDPH on its Monkeypox Vaccination homepage.
- CDC will work with jurisdictions that request ACAM2000 vaccine to help decide who is eligible to receive it, and to make sure people who are considering getting the vaccine are fully informed of its benefits and risks prior to receiving it.››

‹‹Resources

- Monkeypox webpage (CDPH)
- Monkeypox and Smallpox Vaccine Guidance (CDC)
- Information For Healthcare Professionals (CDC)
- Fact Sheet for Healthcare Providers Administering Jynneos
- Fact Sheet For Recipients and Caregivers About Jynneos
- JYNNEOS Package Insert
- ACAM2000 Package Insert››

Legend

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

Symbol	Description
‹‹	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.