Immunizations

Page updated: November 2023

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).››

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 Limit

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).

‹‹Chikungunya (IXCHIQ)

Chikungunya Vaccine is a live attenuated solution for intramuscular (IM) administration.

Indications

All ACIP-recommended indications.››

‹‹Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules.

Age Limit

Must be 18 years of age and older.

Billing

CPT code 90589 (Chikungunya virus vaccine, live attenuated, for intramuscular use).

Required Modifier

SK (member of a high-risk population).

Required Documentation

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.››

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 Limit.

Must be 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 Limit

Must be 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, 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 Limit

Must be 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 Limit

Must be 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 Limit

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 Limit

Must be 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 Limit

Must be 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 Limit

Must be 12 months of age 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-two 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 Limit

Must be 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 Limit

Must be 18 years of age 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, two dose or four dose schedule for intramuscular use (Heplisav-B®)››	18 years of age and older
90740	‹‹Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, three dose schedule, for intramuscular use (Recombivax HB®)››	18 years of age and older
90743	‹‹Hepatitis B vaccine (HepB), adolescent, two dose schedule, for intramuscular use (Recombivax HB)››	11 through 15 years of age
90744	‹‹Hepatitis B vaccine (HepB), pediatric/adolescent dosage, three dose schedule, for intramuscular use (Recombivax HB Energix-B)››	Birth through 19 years of age
90746	‹‹Hepatitis B vaccine (HepB), adult dosage, three 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, four 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, three 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 Limit

Must be six weeks of age and older.

Billing

CPT code 90647 (Haemophilus influenza type b vaccine [Hib] PRP-OMP conjugate, three 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 Limit

Must be 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 Limit

Must be 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], two or three dose schedule for intramuscular use).

Required Modifier

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

Influenza Vaccine

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

‹‹Influenza Inactivated (IIV3 or IIV4) Afluria Fluarix, Flulaval Fluzone››

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 Limit

Must be six months of age and older.

Billing

CPT codes

- ‹‹90656 (influenza virus vaccine, trivalent [IIV3], split virus, preservative free, 0.5 mL dosage, for intramuscular use)
- 90657 (influenza virus vaccine, trivalent [IIV 3] split virus, 0.25 ml dosage for intramuscular use)
- 90658 (influenza virus vaccine, trivalent [IIV 3], split virus, 0.5 mL dosage, for intramuscular use)››

- 90685 (influenza virus vaccine, quadrivalent [IIV4], split virus, preservative free, 0.25 mL dosage, for intramuscular use)
- 90686 (influenza virus vaccine, quadrivalent [IIV 4], split virus, preservative free, 0.5 mL dosage, for intramuscular use)
- 90687 (influenza virus vaccine, quadrivalent [IIV 4], split virus, 0.25 mL dosage, for intramuscular use)
- 90688 (influenza virus vaccine, quadrivalent [IIV 4], 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 Limit

Must be18 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 Limit

Must be 65 years of age and older.

Billing

CPT codes

- 90653 (influenza vaccine, inactivated [IIV], subunit, adjuvanted, for intramuscular use).
- 90694 (influenza virus vaccine, quadrivalent [a IIV4], 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 Limit

Must be 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 Limit

Must be 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 Limit

Must be 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 (ccIIV3 or ccIIV4) (Flucelvax)

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 Limit

Must be six month of age and older.

Billing

CPT codes

- ‹‹90661 (influenza virus vaccine, trivalent (cc IIV3), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use).››
- 90674 (influenza virus vaccine, quadrivalent [cc IIV4], derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use).
- 90756 (influenza virus vaccine, quadrivalent [cc IIV4], 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 Limit

Must be two months of age 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 Limit

Must be two months of age 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 Limit

Must be 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 Groups A, B, C, W and Y Vaccine (PENBRAYA™)

Meningococcal pentavalent vaccine, conjugated Men A, C, W, Y-tetanus toxoid carrier, and Men B-FHbp is a suspension for intramuscular injection.

Indications

All ACIP-recommended indications.

Dosages

ACIP-recommended dosages and dosing schedules.

Age Limit

Must be 10 to 25 years of age.

Billing

CPT code 90623 (meningococcal pentavalent vaccine, conjugated Men A, C, W, Y- tetanus toxoid carrier, and Men B-FHbp, 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 Limit

Must be 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 Limit

Must be 10 to 25 years of age.

Billing

CPT code 90621 (meningococcal recombinant lipoprotein protein vaccine, serogroup B [MenB-FHbp], two or three 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 Limit

Must be 12 months of age 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 Limit

Must be 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 Limit

Muat be 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 Limit

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 Limit

Must be six 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 Limit

Must be six weeks 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 Limit

Must be two years of age 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 Limit

All ages.

Billing

CPT code 90675 (rabies vaccine, for intramuscular use).

Required Modifier

SK (member of a high-risk population).

Respiratory Syncytial Virus (RSV) Vaccine, Adjuvanted (AREXVY)

Respiratory Syncytial Virus Vaccine, Recombinant, Adjuvanted is a suspension for intramuscular (IM) administration.

Indications

All ACIP-recommended indications.

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules.

Age Limit

Must be 60 years of age and older.

Billing

CPT code 90679 (respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use).

Note: CDC recommends that adults 60 years of age and older may receive a single dose of RSV vaccine using shared clinical decision-making (SCDM). The intent of the SCDM is to allow providers and patients flexibility based on what is best for each individual patient.

Respiratory Syncytial Virus (RSV) Vaccine (ABRYSVO)

Respiratory Syncytial Virus Bivalent Vaccine is a solution for intramuscular (IM) administration.

Indications

All ACIP-recommended indications.

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules.

Age Limit

- Pregnant individuals at 32 through 36 weeks gestational age
- 60 years and older

Billing

CPT code 90678 (respiratory Syncytial Virus vaccine, preF, subunit, bivalent, for intramuscular use).

Required Modifier

SL (state-supplied vaccine) must be used when administering vaccine supplied by the Vaccines for Children (VFC) program for pregnant individuals less than 19 years old.

Note: CDC recommends maternal RSV vaccine for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants.

CDC also recommends that adults 60 years of age and older may receive a single dose of RSV vaccine using shared clinical decision-making (SCDM). The intent of the SCDM is to allow providers and patients flexibility based on what is best for each individual.

Required Documentation

Providers must document in the Remarks field (Box 80)/Additional Claim Information field (Box 19), or on an attachment to the claim the gestational age in pregnant individuals.

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 Limit

Must be 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 Limit

Must be 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®)››

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.

‹‹Medi-Cal does reimburse for the Td vaccine (CPT code 90714). 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.

Providers may use tetanus and diphtheria vaccine (Td) off-label for children less than seven years of age who develop a contraindication to pertussis-containing vaccine. Providers must document in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19), or on an attachment to the claim, justification for use in individuals less than seven years of age.››

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 Limit

Must be seven years of age 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 Limit

Must be 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 Limit

Must be two years of age 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 Limit

Must be six years of age 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 Limit

Must be 12 months of age 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 Limit

Must be nine months of age 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 Limit

Must be 18 years of age 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 Limit

All ages.

Billing

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

HCPCS codes

- J1571 (injection, hepatitis B immune globulin [HepaGam B], intramuscular, 0.5 ml).
- 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 Limit

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).

Respiratory Syncytial Virus (RSV)

Palivizumab (Synagis®) and Nirsevimab-alip (Beyfortus™)

The use of Nirsevimab and Palivizumab for the prevention of Respiratory Syncytial Virus (RSV) Disease in infants and children during 2023-2024.

California Children's Services (CCS) issued guidance for use of palivizumab in Numbered Letter (N.L.) 13-0914 and most recently updated palivizumab guidance in CCS Information Notice (I.N.) 22-04.

Nirsevimab-alip (Beyfortus)

Nirsevimab, is a long-acting monoclonal antibody product to reduce risk of both hospitalizations and healthcare visits for RSV. It is recommended by the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control (CDC) and Prevention as indicated by FDA and is now a benefit under the Vaccines for Children (VFC) program. On August 15, 2023, the American Academy of Pediatrics (AAP) released recommendations for the use of nirsevimab for prevention of RSV disease.

Guidance for RSV Prevention Within the CCS and Medi-Cal Programs

Use of nirsevimab and palivizumab for prevention of RSV disease in infants and children should conform to existing CCS guidance and ACIP and AAP recommendations quoted in the TAR Criteria.

TAR Requirement

A *Treatment Authorization Request* (TAR) is required for reimbursement.

TAR Criteria

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

- If nirsevimab is unavailable or not feasible to administer, infants at high risk for RSV disease (as specified in CCS N.L.13-0914) should receive palivizumab, **as specified in this policy**, until nirsevimab becomes available.
  - Additionally, a new group has been identified for whom second-season prophylaxis is recommended, differing from the existing palivizumab recommendations: American Indian and Alaska Native children
  - If palivizumab was administered initially for the season and less than five doses were administered, the infant should receive one dose of nirsevimab. No further palivizumab should be administered
- If an infant receives nirsevimab, then palivizumab should not be administered later that season.
- If palivizumab was administered in season one and the child is eligible for RSV prophylaxis in season two, the child should receive nirsevimab in season two if available. If nirsevimab is not available, palivizumab should be administered as recommended in this guidance.

Timing of Nirsevimab Administration

- Providers should aim for nirsevimab administration in the first week of life for infants born shortly before and during the RSV season. Administration can occur during the birth hospitalization or in the outpatient setting.
  - Infants with prolonged birth hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge
- Nirsevimab should be administered shortly before the start of the RSV season for infants younger than eight months.

- Nirsevimab should be administered shortly before the start of the RSV season for infants and children eight through 19 months of age who are at increased risk of severe RSV disease as previously specified in the TAR Criteria.
- Nirsevimab may be given to age-eligible infants and children who have not yet received a dose at any time during the season.
- Only children who meet high-risk criteria should receive more than one dose of nirsevimab – one dose in their first RSV season and one dose in their second RSV season. Healthy newborns born at the end of the RSV season who received nirsevimab around the time of delivery (first RSV season) should not receive a second dose entering their second season even if they are less than eight months of age; conversely, healthy infants born at the end of their first RSV season who did NOT receive nirsevimab and are less than eight months of age entering their second RSV season may receive one dose of nirsevimab.
- On the basis of pre-pandemic RSV infection patterns, nirsevimab may be administered from October through the end of March. Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules on the basis of local RSV activity in the community.

Maternal Vaccination Against RSV

- The CDC recommends the recently approved maternal RSV vaccine (Pfizer's bivalent RSVpreF vaccine – trade name Abrysvo TM) for pregnant people during 32 through 36 weeks gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. The CDC also voted to approve Pfizer's bivalent RSVpreF vaccine for the Vaccines for Children Program (applying to pregnant people under 19 years of age).
  - Most infants whose mother receives Pfizer's RSVpreF vaccine will not need nirsevimab.
- To maximize protection for babies after birth, the CDC recommends seasonal administration of one dose of RSV vaccine for pregnant people during weeks 32 through 36 of pregnancy.
- 14 days or more from time of maternal vaccination are likely needed for development and transplacental transfer of maternal antibodies to protect the infant; therefore, nirsevimab is recommended for infants born within 14 days of vaccination.
- Thus, the earliest an infant can be born and have maternal vaccine induced protection is at 34 weeks gestation.
- Infants born at less than 34 weeks gestation should receive nirsevimab.

- Protection from maternal vaccination may begin to wane after three or more months.
  - However, because maternal RSV vaccine administration is recommended during September through January, most infants of vaccinated mothers will be born during RSV season (i.e., born during October–March)
- Mothers of most infants born outside of RSV season (i.e., born during April through September) will not have been vaccinated, and nirsevimab is recommended for these infants.

Co-administration with Routine Childhood Vaccines

- In accordance with the CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.

Billing Information

CPT codes

- 90380 (respiratory syncytial virus, monoclonal antibody, seasonal dose; 0.5 mL dosage for intramuscular use).
- 90381 (respiratory syncytial virus, monoclonal antibody, seasonal dose; 1 mL dosage for intramuscular use).

Billing as a Vaccines for Children (VFC) benefit:

The administration fee for the RSV monoclonal antibody is billed with either CPT code 90380 or 90381, and modifier SL (state-supplied vaccine) for appropriate reimbursement.

Resources

Redbook Online. ACIP and AAP Recommendations for Nirsevimab. American Academy of Pediatrics. Accessed August 15, 2023.

Palivizumab (Synagis®)

Guidance for Palivizumab Prophylaxis 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.

CPT Code: 90378, (respiratory syncytial virus, monoclonal antibody recombinant, for intramuscular use, 50 mg each).

Resources

Palivizumab for Immunoprophylaxis of Respiratory Syncytial Virus Infection during 2022-2023.

ACIP and AAP Recommendations for the use of the Monoclonal Antibody Nirsevimab for the Prevention of RSV Disease

Proposed clinical considerations for maternal RSVPreF vaccine and nirsevimab (Centers for Disease Control and Prevention) (2023).

CDC recommends new vaccine to help protect babies against severe respiratory syncytial virus (RSV) illness after birth. Centers for Disease Control and Prevention; 2023.

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 Limit

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) Vaccines

What You Need to Know

- ‹‹2023–2024 updated COVID-19 vaccines are recommended by CDC: Pfizer-BioNTech, Moderna, or Novavax, to protect against serious illness from COVID-19.
- Individuals aged five years and older should get 1 dose of an updated COVID-19 vaccine to protect against serious illness from COVID-19.
- Children aged six months to four years need multiple doses of COVID-19 vaccines to be up to date, including at least one dose of updated COVID-19 vaccine.
- Individuals who are moderately or severely immunocompromised may get additional doses of updated COVID-19 vaccine.
- Individuals aged 65 years and older who received one dose of any updated 2023-2024 COVID-19 vaccine (Pfizer-BioNTech, Moderna or Novavax) should receive one additional dose of an updated COVID-19 vaccine at least four months after the previous updated dose.
- People who are up to date have lower risk of severe illness, hospitalization and death from COVID-19 than people who are unvaccinated or who have not completed the doses recommended for them by CDC.››

Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY® (COVID-19 Vaccine, mRNA)

The U.S. Food and Drug Administration (FDA) has amended the emergency use authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine, to include the 2023-2024 formula. The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) includes a monovalent (single) component that corresponds to the Omicron variant XBB.1.5 of SARS-CoV-2. The Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is authorized for all doses administered to individuals 6 months through 11 years of age to prevent COVID-19. The Pfizer-BioNTech COVID-19 Vaccine, Bivalent is no longer authorized for use in the United States.

Additionally, FDA approved COMIRNATY® (COVID-19 Vaccine, mRNA) 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.

Pfizer-BioNTech COVID-19 Vaccine EUA-Authorized Dosages

Vaccination Series:

Those who are unvaccinated or got the previous Pfizer-BioNTech COVID-19 vaccine.

Children aged six months through four years:

- **Unvaccinated should receive three updated Pfizer-BioNTech vaccines**.
  - Dose one and Dose two: three weeks apart; Dose 2 and Dose 3: At least 8 weeks apart.
- **One dose** of previous Pfizer-BioNTech COVID-19 vaccine should receive two updated Pfizer-BioNTech vaccines.
  - Dose one: three weeks after previous dose; Dose one and Dose two: At least eight weeks apart.
- **Two to Four doses** of the previous Pfizer-BioNTech COVID-19 vaccine should receive one updated Pfizer-BioNTech vaccine.
  - At least eight weeks after last dose of Pfizer-BioNTech vaccine.
- Each dose is 0.3 mL from the vial with a yellow cap. For preparation instructions, see the see the age-appropriate Pfizer-BioNTech COVID-19 Vaccines Fact Sheets.

Children aged five years through 11 years of Age Irrespective of COVID-19 Vaccination Status:

- Should receive a single dose.
  - At least eight weeks after last dose of COVID-19 vaccine.

COMIRNATY® FDA-Approved Dosages

Ages 12 years and older:

For individuals previously vaccinated with any COVID-19 vaccine:

- Should receive a single dose.
  - At least eight weeks after the last dose of COVID-19 vaccine.
- Each dose is 0.3 mL administered intramuscularly.

Additional Dose

- People who are moderately or severely immunocompromised may receive additional dose(s) of age-appropriate COVID-19 vaccine (2023-2024 Formula) after the last updated COVID-19 vaccine.
  - For additional information, see the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

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

- Active treatment for solid tumor and hematologic malignancies.
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia).
- Receipt of solid-organ transplant or an islet 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 (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Advanced 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) or untreated HIV infection.
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more 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 (e.g., B-cell-depleting agents).
- If recommended by a healthcare provider for an individual’s specific medical condition.

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

- 91318 (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, 3 mcg/0.2 mL dosage, diluent reconstituted, tris-sucrose formulation, for intramuscular use)
- 91319 (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, 10 mcg/0.2 mL dosage, tris-sucrose formulation, for intramuscular use)
- 91320 (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, spike protein, 30 mcg/0.3 mL dosage, tris-sucrose formulation, for intramuscular use)

Administration codes

- 90480 (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, single 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

- These instructions are for the commercialized, provider-purchased vaccines.
- DHCS will follow CMS guidelines for the reimbursement of COVID-19 vaccines when administered in accordance with FDA EUA or approval.
- Providers will be reimbursed for both the administration fee and the cost of the vaccine by billing the appropriate CPT codes.
- 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.
- 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).

Billing Instructions for Vaccines for Children (VFC) Program

- Providers must submit both the vaccine and administration CPT codes for appropriate reimbursement.
- Each vaccine code must be listed with a modifier "SL," which identifies the dose as a "state-supplied vaccine".
- The total reimbursement will be at the Medicare rate for administration only.
  - DHCS will not reimburse for the cost of the vaccine supplied free under the VFC program.

Resources

- Pfizer-BioNTech COVID-19 Vaccines Fact Sheets
- Comirnaty Package Insert
- Stay Up to Date with COVID-19 Vaccines | CDC
- Clinical Guidance for COVID-19 Vaccination | CDC

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

The FDA has issued an EUA for the emergency use of Moderna COVID-19 Vaccine (2023-2024 Formula) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals six months through 11 years of age.

Additionally, FDA approved SPIKEVAX 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.

Moderna COVID-19 Vaccine EUA-Authorized Dosage

Vaccination Series:

Children aged 6 months to 4 years:

- Unvaccinated should receive two updated Moderna vaccines; Dose one and Dose two: four weeks apart.
- One dose any previous Moderna should receive one bivalent dose four weeks after last previous dose.
- Two or more doses of previous doses of Moderna should receive one updated dose at least eight weeks after last previous dose of Moderna COVID-19 vaccine.
- Each dose is 0.25 mL from the vial with dark blue cap administered intramuscularly.

Children five-11 years:

- If previously unvaccinated:
  - At least eight weeks after last previous dose of COVID-19 vaccine.
  - Single dose, 0.25 mL from the vial with dark blue cap administered intramuscularly.

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

SPIKEVAX FDA-Approved Dosages:

Children 12 years and older:

- If previously vaccinated with any COVID-19 vaccine, administer one dose of SPIKEVAX.
  - At least eight weeks after last COVID-19 vaccine dose.
  - Each dose is 0.5 mL administered intramuscularly.

Additional Dose:

- People who are moderately or severely immunocompromised may receive additional dose(s) of age-appropriate COVID-19 vaccine (2023-2024 Formula) after the last updated COVID-19 vaccine.
  - For additional information, see the COVID-19 vaccination schedule for people 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.
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia).
- Receipt of solid-organ transplant or an islet 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 (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome).
- Advanced 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) or untreated HIV infection.
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more 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 (e.g., B-cell-depleting agents).
- If recommended by a healthcare provider for an individual's specific medical condition.

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

- 91321 (Severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 25 mcg/0.25 mL dosage, for intramuscular use).
- 91322 (Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]) vaccine, mRNA-LNP, 50 mcg/0.5 mL dosage, for intramuscular use).

Administration codes

- 90480 (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) (coronavirus disease [COVID-19]) vaccine, single 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

- These instructions are for the commercialized, provider-purchased vaccines.
- DHCS will follow CMS guidelines for the reimbursement of COVID-19 vaccines when administered in accordance with FDA EUA or approval.
- Providers will be reimbursed for both the administration fee and the cost of the vaccine by billing the appropriate CPT codes.
- 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.
- 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).

Billing Instructions for Vaccines for Children (VFC) Program

- Providers must submit both the vaccine and administration CPT codes for appropriate reimbursement.
- Each vaccine code must be listed with a modifier “SL,” which identifies the dose as a “state-supplied vaccine”.
- The total reimbursement will be at the Medicare rate for administration only.
  - DHCS will not reimburse for the cost of the vaccine supplied free under the VFC program.

Resources

- Moderna COVID-19 Vaccines Fact Sheets
- Spikevax Package Insert
- Stay Up to Date with COVID-19 Vaccines | CDC
- Clinical Guidance for COVID-19 Vaccination | CDC

Novavax COVID-19 Vaccine

FDA has issued an Emergency Use Authorization (EUA) for the emergency use of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) 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.

Vaccination Series

Ages 12 years of age and older.

- Individuals who did NOT previously receive any COVID-19 vaccine(s) should get two doses of updated Novavax vaccine to be up to date.
  - Dose one and dose two: at least three to eight weeks apart
- For individuals who received previous COVID-19 vaccine(s) before September 12, 2023:
  - One updated Novavax COVID-19 vaccine at least eight weeks after the last dose of COVID-19 vaccine. Administer 0.5 mL/5 µg rS and 50 µg of Matrix-M™ adjuvant vaccine from a vial with a blue cap: blue labelPeople Who are Moderately to Severely Immunocompromised
- People who are moderately or severely immunocompromised may receive additional dose(s) of age-appropriate COVID-19 vaccine (2023-2024 Formula) after the last updated COVID-19 vaccine.
  - For additional information, see the COVID-19 vaccination schedule for people who are moderately or severely immunocompromised.

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.

Age Limit

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

- 90480 (Immunization administration by intramuscular injection of severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2]) (coronavirus disease [COVID-19]) vaccine, single 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

- These instructions are for the commercialized, provider-purchased vaccines.
- DHCS will follow CMS guidelines for the reimbursement of COVID-19 vaccines when administered in accordance with FDA EUA or approval.
- Providers will be reimbursed for both the administration fee and the cost of the vaccine by billing the appropriate CPT codes.
- 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.
- 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 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).

Billing Instructions for Vaccines for Children (VFC) Program

- Providers must submit both the vaccine and administration CPT codes for appropriate reimbursement.
- Each vaccine code must be listed with a modifier “SL,” which identifies the dose as a “state-supplied vaccine”.
- The total reimbursement will be at the Medicare rate for administration only.
  - DHCS will not reimburse for the cost of the vaccine supplied free under the VFC program.

Resources

- Novavax HCP Fact Sheet
- COVID-19 Vaccination Recommendations Infographic
- COVID-19 Vaccination Recommendations Infographic (Immunocompromised)
- Clinical Guidance for COVID-19 Vaccination | CDC

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.

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.