
Immunizations

Page updated: December 2020

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 please refer to the Pharmacy provider manual section titled Reimbursement.

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.

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

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

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

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

Vaccine Immunization Administration Codes

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

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

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

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

Free Vaccines For Children (VFC) Program

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

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

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

Free Vaccines from Source Other than VFC Program

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

BCG Vaccine

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

Indications

All ACIP-recommended indications

«Dosages and Dosing Schedules»

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Billing

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

Required Modifier

SK (member of a high-risk population)

Cholera

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

18 to 64 years of age

Billing

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

Required Modifier

SK (member of a high-risk population)

«Coronavirus 2019 Therapeutics (Vaccines and Monoclonal Antibodies)**Coronavirus 2019 Vaccines****Coronavirus 2019 Vaccine (Pfizer-BioNTech)**

Pfizer-BioNTech COVID-19 vaccine is for use for active immunization to prevent Coronavirus Disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. It is an investigational vaccine not licensed for any indication.

Authorized Use

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent COVID-19 caused by severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Dosages and Dosing Schedules

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) three weeks apart.»

«Providers may refer to the [Fact Sheet for Healthcare Providers](#) for information on dose preparation, administration, storage and handling. For the most recent Fact Sheet, please see www.cvdvaccine.com.

There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Providers may refer to the [Fact Sheet for Healthcare Providers](#) for contraindications, warnings, adverse reactions and use with other vaccines.

Summary of Instructions For COVID-19 Vaccination Providers

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine. See “Mandatory Requirements for Pfizer-Biontech COVID-19 Vaccine Administration Under Emergency Use Authorization” for reporting requirements.

Mandatory Requirements for Pfizer-Biontech COVID-19 Vaccine Administration Under Emergency Use Authorization

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of Pfizer-BioNTech COVID-19 Vaccine, the following items are required. Use of unapproved Pfizer-BioNTech COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

- Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.
- The vaccination provider must communicate to the individual receiving the Pfizer-BioNTech COVID-19 Vaccine or their caregiver, information consistent with the [“Fact Sheet for Recipients and Caregivers”](#) prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine.
- The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
- The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events (irrespective of attribution to vaccination),
 - cases of MIS in adults and children, and
 - cases of COVID-19 that result in hospitalization or death.

«Serious Adverse Events

Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report.

- The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine to recipients.

Other Adverse Event Reporting To Vaers And Pfizer Inc.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website: www.pfizersafetyreporting.com

Fax: 1-866-635-8337

Telephone: 1-800-438-1985

Additional Information

For general questions, visit the website or call the telephone number provided below.

Global Website: www.cvdvaccine.com

Telephone: 1-877-829-2619 (1-877-VAX-CO19)

Age Limits

Must be 16 years of age or older»»

«Billing

Vaccine code:

- 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)

Administration codes:

- 0001A (Pfizer-Biontech COVID-19 Vaccine Administration – First Dose)
- 0002A (Pfizer-Biontech COVID-19 Vaccine Administration – Second Dose)

Important Billing Instructions:

- Since the initial supply of vaccines are purchased by the federal government and distributed free to providers, providers must not bill 91300 for the cost of the vaccine.
- DHCS is currently reimbursing for the vaccine administration. Providers must submit the appropriate vaccine administration codes for billing the first and second vaccine doses as applicable.
- 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 72 hours. They must verify through CAIR2 that the vaccine for the second dose is the same brand that was administered for the first dose.
- 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 emergency use authorization fact sheet for patients/caregivers and vaccination cards identifying the brand of vaccine administered and the date of their second vaccination (if applicable).

Prescribing Restriction(s)

Frequency of billing = two doses of 0.3 mL/ 1 unit each, three weeks apart.

Resources:

- [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers](#)
- [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers»](#)

«Coronavirus 2019 Vaccine (Moderna)

The Moderna COVID-19 Vaccine has not been approved or licensed by the US FDA, but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older.

Authorized Use

Moderna 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.

Dosages and Dosing Schedules

The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart. Providers may refer to the [Fact Sheet for Healthcare Providers](#) for information on dose preparation, administration, storage and handling. For the most recent Fact Sheet, please see www.cvdvaccine.com.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of the Moderna COVID-19 Vaccine should receive a second dose of the Moderna COVID-19 Vaccine to complete the vaccination series.

Providers may refer to the [Fact Sheet for Healthcare Providers](#) for Contraindications, Warnings, Adverse Reactions and use with other vaccines.

Summary of Instructions For COVID-19 Vaccination Providers

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of the Moderna COVID-19 Vaccine. See “Mandatory Requirements for Moderna COVID-19 Vaccine Administration Under Emergency Use Authorization” for reporting requirements.

Mandatory Requirements for Moderna COVID-19 Vaccine Administration Under Emergency Use Authorization

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the Moderna COVID-19 Vaccine, the following items are required. Use of unapproved Moderna COVID-19 Vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements must be met):

- Moderna COVID-19 Vaccine is authorized for use in individuals 16 years of age and older.>>

- «The vaccination provider must communicate to the individual receiving the Moderna COVID-19 Vaccine or their caregiver, information consistent with the “[Fact Sheet for Recipients and Caregivers](#)” prior to the individual receiving the Moderna COVID-19 Vaccine.
- The vaccination provider must include vaccination information in the state/local jurisdiction’s Immunization Information System (IIS) or other designated system.
- The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
 - vaccine administration errors whether or not associated with an adverse event,
 - serious adverse events (irrespective of attribution to vaccination),
 - cases of MIS in adults and children, and
 - cases of COVID-19 that result in hospitalization or death. Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html> or by calling 1-800-822-7967. The reports should include the words “Moderna COVID-19 Vaccine EUA” in the description section of the report.
- The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of Moderna COVID-19 Vaccine to recipients

Serious Adverse Events

Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Other Adverse Event Reporting To Vaers And Modernatx, Inc.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to ModernaTX, Inc. using the contact information below or by providing a copy of the VAERS form to ModernaTX, Inc.

«Email: ModernaPV@modernatx.com

Fax: 1-866-599-1342

Telephone: 1-866-663-3762 (1-866-MODERNA)

Additional Information

For general questions, visit the website or call the telephone number provided below. To access the most recent Moderna COVID-19 Vaccine Fact Sheets, please visit the website provided below.

Website: <https://www.modernatx.com/covid19vaccine-eua/>

Telephone: 1-866-663-3762 (1-866-MODERNA)

Age Limits

Must be 18 years of age or older

Billing

Vaccine code:

- 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)

Administration codes:

- 0011A (Moderna COVID-19 Vaccine Administration – First Dose)
- 0012A (Moderna COVID-19 Vaccine Administration – Second Dose)

Important Billing Instructions:

- Since the initial supply of vaccines are purchased by the federal government and distributed free to providers, providers must not bill 91301 for the cost of the vaccine
- DHCS is currently reimbursing for the vaccine administration. Providers must submit the appropriate vaccine administration codes for billing the first and second vaccine doses as applicable.
- 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 72 hours. They must verify through CAIR2 that the vaccine for the second dose is the same brand that was administered for the first dose.>>

- «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 emergency use authorization fact sheet for patients/caregivers and vaccination cards identifying the brand of vaccine administered and the date of their second vaccination (if applicable).

Prescribing Restriction(s)

Frequency of billing = 2 doses of 0.5 mL/ 1 unit each, 4 weeks apart

Resources

- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [Fact Sheet for Recipients and Caregivers](#)»

«Coronavirus 2019 Monoclonal Antibodies

Coronavirus 2019 Monoclonal Antibody (Bamlanivimab)

Bamlanivimab is a recombinant neutralizing human IgG1 κ monoclonal antibody (mAb) to the spike protein of SARS-CoV-2 and is unmodified in the Fc region. Bamlanivimab binds to spike protein with a dissociation constant $KD = 0.071$ nM and blocks spike protein attachment to the human ACE2 receptor with an IC_{50} value of 0.025 μ g/mL.

Authorized Use

Bamlanivimab is authorized for use under an EUA for treatment of mild to moderate 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 progressing to severe COVID-19 and/or hospitalization. Bamlanivimab is not FDA-approved for these uses.

Limitations of Authorized Use

Bamlanivimab is not authorized for use in patients:

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

Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.»

«Dosages and Dosing Schedules

Patient Selection

Bamlanivimab should be administered as soon as possible after positive viral test for SARS-CoV-2 and within 10 days of symptom onset in adults and pediatric patients (12 to 10 years of age and older weighing at least 40 kg), who are at high risk for progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) greater than or equal to 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are greater than or equal to 65 years of age
- Are greater than or equal to 55 years of age and have
 - cardiovascular disease, or
 - hypertension, or
 - chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12 to 17 years of age and have
 - BMI greater than or equal to 85th percentile for their age and gender based on [CDC growth charts](#), or
 - sickle cell disease, or
 - congenital or acquired heart disease, or neurodevelopmental disorders, for example, cerebral palsy, or a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), or
 - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

Dosage

The dosage of bamlanivimab in adults and pediatric patients (12 years of age and older weighing at least 40 kg) is bamlanivimab 700 mg. Administer bamlanivimab as soon as possible after positive results of direct SARS-CoV2 viral testing and within 10 days of symptom onset. Bamlanivimab must be diluted and administered as a single IV infusion over at least 60 minutes.

For information on use in specific populations, see [Fact Sheet for Healthcare Providers](#).»

«Administration

- Bamlanivimab may only be administered in settings in which health care 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.
- Bamlanivimab is available as concentrated solution and must be diluted prior to administration.
- Administer bamlanivimab 700 mg via I.V. infusion over at least 60 minutes via pump or gravity.
- Clinically monitor patients during infusion and observe patients for at least one hour after infusion is complete.
- Patients treated with bamlanivimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.

For more information on dose preparation and administration, storage, etc., see the [Fact Sheet for Healthcare Providers](#).

Mandatory Requirements for Bamlanivimab Administration Under EUA

In order to mitigate the risks of using this unapproved product under the EUA and to optimize the potential benefit of bamlanivimab, the following items are required.

Use of bamlanivimab under this EUA is limited to the following (all requirements must be met):

- Treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization (see *Limitations of Authorized Use*).
 - As the healthcare provider, communicate to your patient or parent/caregiver, as age appropriate, information consistent with the “[Fact Sheet for Patients, Parents and Caregivers](#)” prior to the patient receiving bamlanivimab. Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient’s medical record that the patient/caregiver has been: Given the “[Fact Sheet for Patients, Parents and Caregivers](#),”
 - Informed of alternatives to receiving authorized bamlanivimab, and

Informed that bamlanivimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.

- Patients with known hypersensitivity to any ingredient of bamlanivimab must not receive bamlanivimab.>>

- «The prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to bamlanivimab treatment within 7 calendar days from the onset of the event. The reports should include unique identifiers and the words “Bamlanivimab treatment under Emergency Use Authorization (EUA)” in the description section of the report.

Submit adverse event reports to FDA MedWatch using one of the following methods:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm, or by using a postage-paid Form FDA 3500 (available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>) and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form

Submitted reports should include in the field name, “Describe Event, Problem, or Product Use/Medication Error” the statement “Bamlanivimab treatment under Emergency Use Authorization (EUA)”

Serious Adverse Events

Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event,
- hospitalization, disability, or congenital anomaly.

The prescribing health care provider and/or the provider’s designee are/is to provide mandatory responses to requests from FDA for information about adverse events and medication errors following receipt of bamlanivimab.

Other Reporting Requirements

In addition, provide a copy of all FDA MedWatch forms to: Eli Lilly and Company, Global Patient Safety. Fax: 1-317-277-0853 E-mail: mailindata_gsmtindy@lilly.com. Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events.»

«Instructions for Healthcare Providers

Healthcare providers must communicate to their patient or parent/caregiver, as age appropriate, information consistent with the “Fact Sheet for Patients, Parents and Caregivers” (and provide a copy of the Fact Sheet) prior to the patient receiving bamlanivimab, including:

- FDA has authorized the emergency use of bamlanivimab for the treatment of mild to moderate 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 progressing to severe COVID-19 and/or hospitalization [see *Limitations of Authorized Use*].
- The patient or parent/caregiver has the option to accept or refuse bamlanivimab.
- The significant known and potential risks and benefits of bamlanivimab, and the extent to which such potential risks and benefits are unknown.
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.
- Patients treated with bamlanivimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.

For information on clinical trials that are testing the use of bamlanivimab for COVID-19, please see www.clinicaltrials.gov.

Age Limits

Must be 12 years of age or older

Billing

HCPCS code:

- Product code: Q0239 (injection, bamlanivimab-xxxx, 700 mg)

Administration code:

- M0239 (intravenous infusion, bamlanivimab-xxxx, includes infusion and post administration monitoring)

Important Billing Instructions:

- DHCS will follow CMS guidelines for the reimbursement of bamlanivimab when administered in accordance with FDA EUA.
- Since the initial supply of bamlanivimab is purchased by the federal government and distributed free to providers, providers must not bill Q0239 for the cost of bamlanivimab.>>

- «DHCS will provide future guidance for the billing and reimbursement of provider purchased products at the appropriate time.
- DHCS will reimburse for the cost of administration (infusion) when billed with the administration code, M0239

Suggested ICD-10 Diagnosis Codes

U07.1, U07.2

Resources:

- [Fact Sheet for Healthcare Providers](#)
- [Fact Sheet for Patients, Parents and Caregivers](#)
- [Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19](#)
- [Bamlanivimab Distribution Fact Sheet](#)»

«Coronavirus 2019 Monoclonal Antibody (Casirivimab and Imdevimab)

Casirivimab (IgG1 κ) and imdevimab (IgG1 λ) are two recombinant human mAbs which are unmodified in the Fc regions. Casirivimab and imdevimab bind to non-overlapping epitopes of the spike protein receptor binding domain (RBD) of SARS-CoV-2 with dissociation constants $K_D = 45.8$ pM and 46.7 pM, respectively. Casirivimab, imdevimab and the casirivimab +imdevimab combination blocked RBD binding to the human ACE2 receptor with IC_{50} values of 56.4 pM, 165 pM and 81.8 pM, respectively.

Authorized Use

Casirivimab and imdevimab are authorized to be administered together for use under an EUA for the treatment of mild to moderate 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 progressing to severe COVID-19 and/or hospitalization. Casirivimab and imdevimab are not FDA-approved for these uses.

Limitations of Authorized Use

Casirivimab and imdevimab are not authorized for use in patients:

- who are hospitalized due to COVID-19, or
- who require oxygen therapy due to COVID-19, or
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity»

«Benefit of treatment with casirivimab and imdevimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation with COVID-19.

Dosages and Dosing Schedules

Patient Selection

The optimal dosing regimen for treatment of COVID-19 has not yet been established. The recommended dosing regimen may be updated as data from clinical trials become available.

Patient Selection and Treatment Initiation

Casirivimab and imdevimab are to be administered together, for the treatment of mild to moderate 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 progressing to severe COVID-19 and/or hospitalization.

High risk is defined as patients who meet at least one of the following criteria:

- Have a body mass index (BMI) greater than or equal to 35
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are greater than or equal to 65 years of age
- Are greater than or equal to 55 years of age AND have
 - cardiovascular disease, or
 - hypertension, or
 - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 to 17 years of age and have
 - BMI greater than or equal to 85th percentile for their age and gender based on [CDC growth charts](#), or
 - sickle cell disease, or
 - congenital or acquired heart disease, or neurodevelopmental disorders, for example, cerebral palsy, or
 - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), or»

- «asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

Dosage

The dosage of casirivimab and imdevimab is 1,200 mg of casirivimab and 1,200 mg of imdevimab administered together as a single intravenous infusion. Casirivimab and imdevimab solutions must be diluted prior to administration. Casirivimab and imdevimab should be given as soon as possible after a positive viral test for SARS-CoV-2 and within 10 days of symptom onset. For information on use in specific populations, see [Fact Sheet for Healthcare Providers](#).

Administration

- Casirivimab and imdevimab may only be administered in settings in which health care 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. Casirivimab and imdevimab must be administered together after dilution by intravenous (iv) infusion only.
- Administer 1,200 mg of casirivimab and 1,200 mg of imdevimab together as a single I.V. infusion over at least 60 minutes via pump or gravity.
- Clinically monitor patients during infusion and observe patients for at least 1 hour after infusion is complete.
- Patients treated with casirivimab and imdevimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.

For more information on dose preparation and administration, storage, etc., see [Fact Sheet for Healthcare Providers](#).

Mandatory Requirements for Casirivimab And Imdevimab Administration Under Emergency Use Authorization

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of casirivimab and imdevimab to be administered together, the following items are required. Use of casirivimab and imdevimab under this EUA is limited to the following (all requirements must be met):

- Treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization (see *Limitations of Authorized Use*).»

- «Providers must communicate with their patient or parent/caregiver, as age appropriate, information consistent with the “[Fact Sheet for Patients, Parents and Caregivers](#)” prior to the patient receiving casirivimab and imdevimab. Healthcare providers (to the extent practicable given the circumstances of the emergency) must document in the patient’s medical record that the patient/caregiver has been:
 - Given the “[Fact Sheet for Patients, Parents and Caregivers](#)”
 - Informed of alternatives to receiving authorized casirivimab and imdevimab, and
 - Informed that casirivimab and imdevimab is an unapproved drug that is authorized for use under this Emergency Use Authorization.
- Patients with known hypersensitivity to any ingredient of casirivimab and imdevimab must not receive casirivimab and imdevimab. The prescribing health care provider and/or the provider’s designee are/is responsible for mandatory reporting of all medication errors and serious adverse events potentially related to casirivimab and imdevimab treatment within seven calendar days from the onset of the event. The reports should include unique identifiers and the words “Casirivimab and imdevimab treatment under Emergency Use Authorization (EUA)” in the description section of the report

Submit adverse event reports to FDA MedWatch using one of the following methods:

- Complete and submit the report online at <http://www.fda.gov/medwatch/report.htm>, or
- By using a postage-paid Form FDA 3500 (available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf>) and returning by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form
- Submitted reports should include in the field name, “Describe Event, Problem, or Product Use/Medication Error” the statement “Casirivimab and imdevimab treatment under Emergency Use Authorization (EUA)”

Serious Adverse Events

Serious Adverse Events are defined as:

- death;
- a life-threatening adverse event;
- inpatient hospitalization or prolongation of existing hospitalization;
- a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- a congenital anomaly/birth defect;
- a medical or surgical intervention to prevent death, a life-threatening event,»

- «hospitalization, disability, or congenital anomaly.

Other Reporting Requirements

In addition, please provide a copy of all FDA MedWatch forms to: Eli Lilly and Company, Global Patient Safety.

Fax: 1-317-277-0853

E-mail: mailindata_gsmtindy@lilly.com

Or call Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921) to report adverse events

Instructions for Healthcare Providers

Healthcare providers must communicate to their patient or parent/caregiver, as age appropriate, information consistent with the “Fact Sheet for Patients, Parents and Caregivers” (and provide a copy of the Fact Sheet) prior to the patient receiving casirivimab and imdevimab, including:

- FDA has authorized the emergency use of casirivimab and imdevimab for the treatment of mild to moderate 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 progressing to severe COVID-19 and/or hospitalization (see *Limitations of Authorized Use*).
- The patient or parent/caregiver has the option to accept or refuse casirivimab and imdevimab. The significant known and potential risks and benefits of casirivimab and imdevimab, and the extent to which such potential risks and benefits are unknown.
- Information on available alternative treatments and the risks and benefits of those alternatives, including clinical trials.
- Patients treated with casirivimab and imdevimab should continue to self-isolate and use infection control measures (e.g., wear mask, isolate, social distance, avoid sharing personal items, clean and disinfect “high touch” surfaces, and frequent handwashing) according to CDC guidelines.

For information on clinical trials that are testing the use of casirivimab and imdevimab for COVID-19, please see www.clinicaltrials.gov.

Age Limits

Must be 12 years of age or older

Billing

HCPCS code:

- Product Code: Q0243 (injection, casirivimab and imdevimab, 2,400 mg)»

<<Administration code:

- M0243 (intravenous infusion, casirivimab and imdevimab includes infusion and post administration monitoring)

Important billing instructions:

- DHCS will follow CMS guidelines for the reimbursement of casirivimab and imdevimab when administered in accordance with FDA EUA.
- Since the initial supply of casirivimab and imdevimab is purchased by the federal government and distributed free to providers, providers must not bill Q0243 for the cost of casirivimab and imdevimab
- DHCS will provide future guidance for the billing and reimbursement of provider purchased products at the appropriate time.
- DHCS will reimburse for the cost of administration (infusion) when billed with the administration code, M0243.

Suggested ICD-10 Diagnosis Codes

U07.1, U07.2

Resources

- [Health Care Provider Fact Sheet](#)
- [Fact Sheet for Patients, Parents and Caregivers](#)
- [Guidance for Hospitals Regarding Allocation of Scarce Medications for COVID-19](#)>>

Diphtheria and Tetanus (DT)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

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

Billing

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

Required Modifier

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

Diphtheria, Tetanus, and Acellular Pertussis (DTaP)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

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

Billing

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

Required Modifier

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

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

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

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

Billing

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

Required Modifier

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

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

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

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

Billing

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

Required Modifier

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

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

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

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

Billing

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

Required Modifier

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

Hepatitis A (HepA)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

12 months and older

Billing

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

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

Required Modifier

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

Hepatitis A-Hepatitis B (HepA-HepB)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

18 years and older

Billing

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

Required Modifier

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

Hepatitis B (HepB)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Billing

CPT code 90739 (Hepatitis B vaccine (HepB), adult dosage, 2 dose schedule, for intramuscular use)

CPT code 90740 (Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 3 dose schedule, for intramuscular use)

CPT code 90743 (Hepatitis B vaccine (HepB), adolescent, 2 dose schedule, for intramuscular use)

CPT code 90744 (Hepatitis B vaccine (HepB), pediatric/adolescent dosage, 3 dose schedule, for intramuscular use)

CPT code 90746 (Hepatitis B vaccine (HepB), adult dosage, 3 dose schedule, for intramuscular use)

CPT code 90747 (Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 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.

Haemophilus b Conjugate (Hib (PRP-OMP))

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 weeks and older

Billing

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

Required Modifier

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

Haemophilus b Conjugate (Hib (PRP-T))

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 weeks and older

Billing

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

Required Modifier

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

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

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

9 to 45 years of age

Billing

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

Influenza Vaccine

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

Influenza Inactivated (IIV3) or (IIV4)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 months of age and older

Billing

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

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

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

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

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

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

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

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

Required Modifier

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

Influenza Inactivated (IIV3) or (IIV4)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

18 years of age and older

Billing

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

CPT 90630 (Influenza virus vaccine, quadrivalent (IIV4), split virus, preservative free, for intradermal use)

Required Modifier

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

Influenza Adjuvanted (aIIV3) or (aIIV4)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

65 years of age and older

Billing

CPT code 90653 (Influenza vaccine, inactivated (IIV), subunit, adjuvanted, for intramuscular use)

CPT 90694 (Influenza virus vaccine, quadrivalent (aIIV4), inactivated, adjuvanted, preservative free, 0.5 mL dosage, for intramuscular use)

Influenza High Dose (IIV3-HD)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

65 years of age and older

Billing

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

Influenza Live (LAIV3) or (LAIV4)

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

Indications

All ACIP-recommended indications

«Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

2 through 49 years of age

Billing

CPT code 90660 (Influenza virus vaccine, trivalent, live (LAIV3) for intranasal use)

CPT code 90672 (Influenza virus vaccine, quadrivalent, live, (LAIV4), for intranasal use)

Required Modifier

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

Influenza Recombinant (RIV 3) or (RIV4)

Influenza Vaccine Recombinant (RIV 3) or (RIV4) is a suspension of recombinant HA proteins of influenza virus subtypes A and type B.

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

18 years of age and older

Billing

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

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

Required Modifier

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

Influenza Vaccine (ccIV4)

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

4 years of age and older

Billing

CPT 90674 (Influenza virus vaccine, quadrivalent (ccIV4), derived from cell cultures, subunit, preservative and antibiotic free, 0.5 mL dosage, for intramuscular use)

CPT 90756 (Influenza virus vaccine, quadrivalent (ccIV4), derived from cell cultures, subunit, antibiotic free, 0.5 mL dosage, for intramuscular use)

Required Modifier

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

Japanese Encephalitis

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

2 months and older

Billing

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

Required Modifier

SK (member of a high-risk population)

Meningococcal Conjugate (MenACWY)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

2 months and older

Billing

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

Required Modifier

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

Meningococcal Group B (MenB-4C)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

10 to 25 years of age

Billing

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

Required Modifier

SK (member of a high-risk population)

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

Meningococcal Group B (MenB-FHbp)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

10 to 25 years of age

Billing

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

Required Modifier

SK (member of a high-risk population)

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

Measles, Mumps, and Rubella (MMR)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

12 months and older

Billing

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

Required Modifier

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

Measles, Mumps, Rubella, and Varicella (MMRV)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

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

Billing

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

Required Modifier

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

Polio

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 weeks of age and older

Billing

CPT code 90713 (Poliovirus vaccine, inactivated (IPV) for subcutaneous or intramuscular use)

Required Modifier

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

Pneumococcal 13-Valent Conjugate (PCV13)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 weeks of age and older

Billing

CPT code 90670 (Pneumococcal conjugate vaccine, 13 valent (PCV13), intramuscular use)

Required Modifier

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

Pneumococcal Polysaccharide 23-Valent (PPSV23)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

2 years and older

Billing

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

Required Modifier

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

Rabies

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Billing

CPT code 90675 (Rabies vaccine, for intramuscular use)

Required Modifier

SK (member of a high-risk population)

Rotavirus (RV1)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 to 24 weeks of age

Billing

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

Required Modifier

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

Rotavirus (RV5)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 to 32 weeks of age

Billing

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

Required Modifier

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

Tetanus and Diphtheria (Td)

Tetanus and Diphtheria Toxoids Adsorbed (Td) is a suspension for intramuscular (IM) administration

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

7 years and older

Billing

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

Required Modifier

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

Tetanus, Diphtheria, and Acellular Pertussis (Tdap)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

7 years and older

Billing

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

Required Modifier

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

Typhoid polysaccharide (ViCPs)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

2 years and older

Billing

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

Required Modifier

SK (member of high-risk population)

Typhoid Live Oral (Ty21a)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

6 years and older

Billing

CPT code 90690 (Typhoid vaccine, live, oral)

Required Modifier

SK (member of high-risk population)

Varicella (VAR)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

12 months and older

Billing

CPT code 90716 (Varicella virus vaccine (VAR), live, for subcutaneous use)

Required Modifier

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

Yellow Fever

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

9 months and older

Billing

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

Required Modifier

SK (member of a high-risk population)

Zoster Live (ZVL)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

50 years and older

Billing

CPT code 90736 (Zoster (shingles) vaccine (HZV), live, for subcutaneous injection)

Zoster Recombinant (RZV)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

50 years and older

Billing

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

Immune Globulins, Serum, Or Recombinant Products

Hepatitis B Immune Globulin (HBIG)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Billing

CPT code 90371 (Hepatitis B immune globulin (HBIG), human, for intramuscular use

HCPCS code J1571 (Injection, hepatitis B immune globulin (HepaGam B), intramuscular, 0.5 ml)

HCPCS code J1573 (Injection, hepatitis B immune globulin (HepaGam B), intravenous, 0.5 ml)

Immune Globulin (Human)

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

Indications

All ACIP and FDA-recommended indications

Dosages and Dosing Schedules

ACIP and FDA-recommended dosages and dosing schedules

Age Limits

All ages

Billing

HCPCS code J1460, Injection, Gamma Globulin, Intramuscular, 1 CC or J1560, Injection, Gamma Globulin, Intramuscular, Over 10 CC

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

Palivizumab

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

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

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

A maximum of five doses of palivizumab may be authorized as follows:

- Infants born before 29 weeks, 0 days gestation who are less than 12 months of age at the start of the RSV season
- During the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age less than 32 weeks, 0 days and a requirement for greater than 21 percent oxygen for at least the first 28 days after birth
- During the second year of life for preterm infants who develop chronic lung disease (CLD) of prematurity as defined above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six-month period before the start of the second RSV season
- Infants who are 12 months or younger with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension

- Infants with cyanotic heart defects in the first year of life may receive palivizumab prophylaxis if deemed warranted by the infant's pediatric cardiologist
- Children younger than two years who undergo cardiac transplantation during the RSV season
- An infant younger than 24 months receiving prophylaxis who undergoes cardiopulmonary bypass or extracorporeal membrane oxygenation and continues to require prophylaxis post-operatively may receive a post-operative dose of palivizumab (15 mg/kg)
- During the first year of life, infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
- Children younger than 24 months of age who are profoundly immunocompromised during the RSV season, as assessed by a qualified pediatric Infectious Disease or Immunologic specialist
- During the first year of life, infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise
- During the second year of life, infants with cystic fibrosis and manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile

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

Authorization Required

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

Rabies Immune Globulins

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Required ICD-10 Diagnosis Codes

Z20.3 is a required modifier for CPT codes 90375 and 90376 only

Billing

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

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

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

Tetanus Immune Globulin (Tlg)

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Billing

HCPCS code J1670, Injection, tetanus immune globulin, human, up to 250 units

Do not report claims for J1670 with CPT code 90389 Tetanus immune globulin (Tlg), human, for intramuscular use

Varicella Zoster Immune Globulin

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

Indications

All ACIP-recommended indications

Dosages and Dosing Schedules

ACIP-recommended dosages and dosing schedules

Age Limits

All ages

Billing

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

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.