Physician-Administered Drugs (PADs) Overview

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This section provides an overview of physician-administered drugs (PADs), including coverage policy, billing guidance and other resources for providers, consistent with *Welfare and Institutions Code* (W&I Code) Section 14105.456 and the federally approved California State Plan for Medicaid.

Note: This section combines and updates information from several previously separate sections, including for non-self-administered noninjectable drugs, injections, chemotherapy and ophthalmology.

Definitions

Administration Fee

The reimbursement paid to medical providers (for example, physicians, nurses, hospitals, etc.) submitting medical claims for administering a PAD (typically subcutaneously or intramuscularly), separate from the cost of the PAD itself. This is currently a flat-rate fee and is paid only once for each PAD administered. Pharmacy providers receive a professional dispensing fee as noted in this section.

Covered Outpatient Drugs

Consistent with Section 1927(k) of the Social Security Act (SSA) and codified in Title 42 of the *Code of Federal Regulations (CFR)* Section 447.502, covered outpatient drugs may be dispensed only upon a prescription if any one of the following applies:

- The covered drugs are approved by the federal Food and Drug Administration (FDA) for safety and effectiveness for certain medically accepted indications under Sections 505 or 507 of the Federal Food, Drug and Cosmetic Act (FFDCA), or under Section 505(i) (generic drugs) of the FFDCA.
- The covered drugs were commercially used or sold in the United States before 1962 and are not considered a "new drug" by the FDA.
- The covered drugs are a biological product (excluding vaccines) licensed under Section 351 of the Public Health Service Act.
- The covered drugs are insulin certified under Section 506 of the FFDCA.

Note: Covered outpatient drugs have National Drug Code (NDC) numbers (unique to the product), lot (batch) and expiration dates on the vial or box. Covered outpatient drugs may be either legend or non-legend., if they otherwise meet the definition in Section 1927(k) of the Social Security Act.

Legend Drugs

Drugs that are required by federal law to be dispensed only upon a prescription because they meet one or more of the following criteria:

- Habit-forming;
- Potentially harmful or toxic; and/or
- Requires supervision by a licensed practitioner for safe use, as specified in its new drug application.

Note: Examples include antibiotics and antidepressants. Legend drugs contain statements such as, “Caution: Federal law prohibits dispensing without prescription,” “Rx only” or similar wording.

Non-Legend Drugs

Over-the-counter (OTC) drugs that can be dispensed or sold without a prescription and are generally used for common, self-treatable conditions. Examples include OTC aspirin, allergy medications and multi-vitamins.

Note: Although non-legend drugs are available OTC, all drugs require a valid prescription from a provider in order to be eligible for Medi-Cal reimbursement.

Off-Label Use

Off-label use refers to prescribing a medication for a condition, indication, population, dose or route of administration not included in the FDA-approved labeling. The prescribing provider may exercise clinical judgement based upon evidence-based medicine and relevant practice guidelines when prescribing off label.

For example, a provider may prescribe a type 2 diabetes drug (such as Metformin) for polycystic ovary syndrome, or a seizure/nerve pain drug (such as Gabapentin) for anxiety.

Off-label use requires an approved *Treatment Authorization Request* (TAR) or Service Authorization Request (SAR) demonstrating medical necessity and must include supporting documentation of current standards of practice and current medical literature or treatment guidelines, in accordance with regulatory requirements (*California Code of Regulations* [CCR], Title 22, Section 51313(4)).

PAD

PADs are administered by injection or infusion, orally or through other methods, to Medi-Cal members (referred to as members in this section) by many different types of medical providers (for example, physicians, nurses, hospitals, etc.) in clinical settings such as medical offices, outpatient clinics, hospitals, etc., but they may also be provided in a member's home consistent with Medi-Cal policy. PADs may not be self-administered by members or administered by a parent, caregiver or guardian. PADs are often single-source (meaning, brand name only), high-cost, and/or biologics/specialty drugs. Examples include chemotherapy agents, oncology/immunotherapy agents, hematology agents, cell and gene therapies, etc.

Note: Most PADs are covered under Medi-Cal as a medical benefit. There are a small number of PADs that are covered under Medi-Cal as a pharmacy benefit (under Medi-Cal Rx). For more information, refer to coverage and billing information on the Medi-Cal Rx website.

Professional Dispensing Fee

The reimbursement paid to pharmacy providers submitting pharmacy claims for the cost of dispensing a prescription-covered outpatient drug, separate from the drug's ingredient cost. The professional dispensing fee is currently a two-tier fee based on volume of annual prescriptions and does not apply to PADs. PADs, which are billed on medical claims, instead receive the administration fee as noted above.

List of Covered PADs and HCPCS Codes

Medi-Cal maintains a complete list of covered PADs and associated billing codes, which is updated regularly. This information can be accessed in the *List of Physician-Administered Drugs and HCPCS Codes* manual section.

Coverage

Medi-Cal covers FDA-approved PADs, as prescribed by providers acting within their respective scope of practice and documented on a valid prescription, for all members in both the Medi-Cal fee-for-service and managed care delivery systems. Most PADs are billed on medical claims using the applicable HCPCS code. Medical claims are submitted using the *CMS-1500*, which is the standard paper claim form, or the 837P (Professional), which is the Health Insurance Portability and Accountability Act of 1996 (HIPAA)-mandated electronic transaction standard form (equivalent to the *CMS-1500*). In some cases, claims for PADs must be submitted using the *UB-04* form, particularly when administered in facility-based settings such as outpatient hospitals. For the small number of PADs able to be billed on pharmacy claims, pharmacy providers use the National Council for Prescription Drug Program (NCPDP) standard claim form. For more information, refer to coverage and billing information on the Medi-Cal Rx website.

Eligibility Requirements

Members must be eligible for and actively enrolled in full-scope Medi-Cal or a specialty program that covers PADs on the date of service to be eligible for coverage under this section. Specialty programs include, but are not limited to, the California Children's Services (CCS) program, the Genetically Handicapped Persons Program (GHPP) and the Family Planning, Access, Care and Treatment (Family PACT) Program. Providers must verify member eligibility prior to administering a PAD and submitting a claim for reimbursement.

Medi-Cal Fee-for-Service

Members enrolled in Medi-Cal fee-for-service will receive PADs directly from enrolled providers who bill the Department of Health Care Services (DHCS) directly.

Medi-Cal Managed Care

- Members enrolled in Medi-Cal managed care will receive most PADs from medical providers contracted with their assigned Medi-Cal Managed Care Plan (MCP).
- MCPs are required to provide or arrange for medically necessary PADs as a covered Medi-Cal benefit, unless the PAD is specifically carved out of the MCP contract or one of the small number of PADs coverable as a pharmacy benefit under Medi-Cal Rx.
- Certain PADs are fully carved out from MCPs and instead billed directly to DHCS. Examples of carved-out PADs include antipsychotics, HIV/AIDS drugs, substance use disorder drugs, blood factors and two drugs (LYFGENIA and CASGEVY) only when used to treat sickle cell disease under the Cell and Gene Therapy Access Model.

Note: Since each MCP is unique in its billing and utilization management control requirements, providers should contact individual MCPs for coverage and billing instructions.

Outpatient Hemodialysis

Under CCR, Title 22, Section 51313(f), drugs administered to members for chronic outpatient hemodialysis in renal dialysis centers and community hemodialysis units are covered, but are payable only when included in the all-inclusive rate set forth in CCR, Title 22, Section 51509.2. Therefore, PADs administered in renal dialysis centers and community hemodialysis units should not be billed separately to Medi-Cal. For more information, refer to the *Dialysis: Chronic Dialysis Services* section of this manual.

Inpatient Hospital or Nursing Facilities Coverage

PADs provided to members receiving inpatient hospital or nursing facility services, whether or not rendered in a hospital setting (CCR, Title 22, Sections 51510 and 51511), are not reimbursable and should not be separately billed to Medi-Cal. Therefore, PADs administered in these types of facilities should not be billed separately to Medi-Cal.

Note: Some exceptions exist to this policy. Refer to the section *Diagnosis-Related Groups (DRG): Inpatient Services* in this manual for information about separately reimbursable services for inpatient hospital stays. Refer to the Cell and Gene Therapy Access Model page of the DHCS website for information related specifically to the reimbursement of gene therapy drugs when used for sickle cell disease only in inpatient settings.

Reimbursement Methodology

For providers billing for members with Medi-Cal fee-for-service, PADs are reimbursed according to the methodology in California's Medicaid State Plan, which was approved by the federal Centers for Medicare & Medicaid Services (CMS). Under current policy, PADs are reimbursed at the Medicare rate of reimbursement when established and published by CMS, or the pharmacy rate of reimbursement when the Medicare rate is not available. The Medicare rate is currently defined as Medicare Part B rate for the product as published in the Medicare Fee Schedule at the time the service is rendered. The pharmacy rate is currently defined as the lower of:

- The National Average Drug Acquisition Cost (NADAC), or, when the NADAC is not available, the wholesaler acquisition cost (WAC) plus zero percent;
- The federal upper limit (FUL); or
- The maximum allowable ingredient cost (MAIC).

When the lowest drug ingredient cost is not available based on NADAC, WAC plus zero percent, FUL or MAIC, the reimbursement paid to the provider will be their invoice price. For more information on the pharmacy rate of reimbursement, refer to Supplement 2 to Attachment 4.19-B of the California State Plan Under Title XIX of the Social Security Act.

Note: Medical claims for PADs also receive an administration fee for the first billed unit of drug. PADs billed on medical claims do not receive a professional dispensing fee.

Additionally, for PADs purchased pursuant to the 340B program, a 340B-covered entity is required to bill and will be reimbursed an amount not to exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with Section 256b of Title 42 of the *United States Code*.

Note: Medical claims for 340B PADs also receive an administration fee for the first billed unit of drug. 340B PADs billed on medical claims do not receive a professional dispensing fee.

Policy Requirements & Claim Submission Guidelines

Authorization Requirements

An approved TAR/SAR may be required for claims for certain PADs, as indicated in the *List of Physician-Administered Drugs and HCPCS Codes* manual section, and whenever a PAD is used in quantities and/or frequencies in excess of FDA-approved labeling of that PAD. The product name on an approved TAR/SAR must be identical to the product name dispensed and the product name on the claim submitted for reimbursement. For additional TAR information, refer to the *TAR Completion* section of this manual. For further information, refer to the following sections in this manual:

- *List of Physician-Administered Drugs and HCPCS Codes*
- *California Children's Service (CCS) Program Service Authorization Request*
- *Genetically Handicapped Persons Program (GHPP)*

ICD-10-CM Diagnosis Code Requirement

Consistent with HIPAA and Medi-Cal policy requirements, all claims must include a clinically appropriate ICD-10-CM diagnosis code. Failure to include an ICD-10-CM diagnosis code may result in a claim denial. Additionally, some PADs may require providers to include a specific ICD-10-CM diagnosis code on the related claim, in accordance with Medi-Cal policy. An approved TAR/SAR must be referenced in PAD claims that do not contain the required ICD-10-CM diagnosis code for the PAD.

Pursuant to CCR, Title 22, Section 51476(c), the provider shall maintain readily retrievable documentation of the member's diagnostic or clinical condition information that fulfills the ICD-10-CM diagnosis code requirement as documented in the member's medical record. This information must be made available to DHCS upon request or in the event of state or federal audit.

For more information, refer to the *List of Physician-Administered Drugs and HCPCS Codes* spreadsheet for specific ICD-10-CM diagnosis code or other clinical requirements.

Claim Submission Guidelines

Providers must submit PAD claims in accordance with Medi-Cal policy, which may be found in this section as well as the *Physician-Administered Drugs – NDC* section in this manual. For physician claim form completion instructions, refer to the *Physician-Administered Drugs – NDC: CMS-1500 Billing Instructions*, or *Physician-Administered Drugs – NDC: UB-04 Billing Instructions* sections in this manual. Non-pharmacy providers must use the appropriate HCPCS injection codes and modifiers (when required) to bill for all PADs. For the small number of PADs able to be billed on pharmacy claims, pharmacy providers use the NCPDP standard claim form. For more information, refer to coverage and billing information on the Medi-Cal Rx website.

Note: The administration fee is paid only once for each PAD administered. Subsequent units claimed must have the administration fee subtracted from the current Medi-Cal fee-for-service reimbursement rate.

Weekly Injections

Billing weekly injections on the *CMS-1500* claim

Providers should enter the date the injection is administered as the “From” date of service and enter the date prior to the day the next injection is administered as the “To” date of service in the *Date(s) of Service* field (Box 24A). Refer to the *Injections: Billing Example for CMS-1500* section in this manual.

Billing weekly injections on the *UB-04* claim

Enter the date the injection is administered and enter the date prior to the day the next injection is administered in the *Serv. Date* field (Box 45). Refer to the *Injections: Billing Example for UB-04* section in this manual.

Injection Administered More Than Once in the Same Day

When the same injection is administered more than once in the same day, each injection must be listed on a separate claim line. The time of day the multiple injections are given must be included in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) to avoid a denial as a duplicate claim.

Unclassified Injections: J3490 and J3590

HCPCS Code J3490 Unclassified Drugs

Providers may submit claims for HCPCS code J3490 only when a specific billing code for the PAD is not available or does not exist. Claims submitted with J3490 for PADs that have a specific billing code may be denied. The claim form must include the following:

- ICD-10-CM diagnosis code
- NDC
- Name and strength of drug administered, and amount given, in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19), or on a separate attachment.

Note: One billed unit equals the total dose provided to the member.

HCPCS Code J3590 Unclassified Biologics

Providers may submit claims for HCPCS code J3590 only when a specific code for the PAD is not available or does not exist. Claims submitted with J3590 for PADs that have a specific billing code may be denied. The claim form must include the following:

- ICD-10-CM diagnosis code
- NDC
- Name and strength of drug administered, and amount given, in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim, or on a separate attachment.

HCPCS code J3590 requires an approved TAR/SAR for reimbursement. Providers must document the following on the TAR/SAR:

- Medical necessity for using the drug
- Name, strength and dosage of the drug
- ICD-10-CM diagnosis code
- NDC

Note: One billed unit equals the total dose administered to the member.

Unlisted Supplies/Drugs

HCPCS code Z7610 is used by providers billing for unlisted supplies and non-injectable drugs for a non-surgical procedure on the *UB-04* claim. For more information, refer to the *Supplies and Drugs for Outpatient Services* section in this manual.

CPT® code 99070 is used to bill for physicians' unlisted supplies and materials used in non-surgical procedures.

Note: Important additional instructions for CPT code 99070 appear in the *Supplies and Drugs for Medical Services* section of this manual.

Do not use HCPCS code Z7610 or CPT code 99070 when billing for unlisted supplies/drugs.

Experimental and Investigational Services

Experimental services are not a Medi-Cal benefit. Investigational services are covered in accordance with regulatory requirements (CCR, Title 22, Section 51303(g)). Providers submitting electronic TARs (eTARs) must select the Special Handling description "Cannot Bill Direct, TAR is Required," which is found in the *Patient Information* section of the eTAR application.

Additional Chemotherapy Services Information

Intravenous Infusion

CPT codes 96413 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug) and 96415 (chemotherapy administration, intravenous infusion technique; each additional hour) are reimbursable only when performed by a physician or by a qualified assistant under physician's direct supervision. The National Provider Identifier (NPI) must be entered in the *Attending* field (Box 76)/*Billing Provider Info and Phone Number* field (Box 33A) of the claim form for the claim to be reimbursed. Claims for code 96415 require medical justification if billed for more than one hour.

Place of Service Codes/Facility Type Codes

In addition, providers may only bill these codes with the following Place of Service or facility type codes:

***CMS-1500* Use Code**	***UB-04* Use Code**	**Facility Type/Place of Service**
11	79	Clinic
53, 71, 72	71, 73, 74, 75, 76	Clinic
24	83	Special Facility
22, 65	13, 72	Hospital/Clinic
23	14	Hospital
42	None	Ambulance (air or water)

These codes are not reimbursable when rendered to hospital inpatients, patients in a Nursing Facility Level A (NF-A), NF Level B (NF-B) or at home because a nurse usually performs intravenous infusion in these facilities.

Additional Hours: CPT Code 96415

CPT code 96415 is generally reimbursable for a maximum of one additional hour of administration. When code 96415 is billed in conjunction with cisplatin (HCPCS code J9060), a maximum of five additional hours may be reimbursed.

Additional Hours Multiple Sequential Infusions

Reimbursement for code 96415 is limited to a maximum of three hours when billed in conjunction with multiple-sequential chemotherapy drugs administered by infusion technique. The first hour of infusion services is billed with code 96413.

Claims submitted with code 96415 must include documentation that states the names of the drugs administered, the individual infusion time for each and a statement that “multiple chemotherapeutic agents were administered sequentially.” This information should appear in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim or on an attachment.

Prolonged Intravenous Infusion (More than Eight Hours): “By Report” Billing Required

“By Report” billing is required for CPT code 96416 (chemotherapy administration, intravenous infusion technique, initiation of prolonged chemotherapy infusion [more than eight hours], requiring the use of a portable or implantable pump). A report with enough information to manually price the procedure must be attached to the claim or written in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19) of the claim. The report must detail the physician’s services including, but not limited to, the number of hours spent attending to the patient.

Cancer Clinical Trials Guidelines

Pursuant to Section 1396d(gg)(2) of Title 42 of the *United States Code*, Medi-Cal covers routine patient care costs for beneficiaries participating in a qualifying clinical trial. Refer to the *Clinical Trials Policy* section of this manual for details.

Coverage of PADs Not Listed

Medi-Cal may cover PADs not listed in this section or other sections of the provider manual with an approved TAR/SAR demonstrating medical necessity. For information on how to submit a TAR, refer to the Treatment Authorization Request page on the DHCS website.

Additional Resources

Refer to the following additional resources for more information.

- For guidance on NDC requirements and *CMS 1500*/*UB-04*, see *Physician-Administered Drugs – NDC* in this manual.
- For guidance on Other Health Coverage (OHC), see:
  - *Other Health Coverage (OHC)* in this manual
  - *Other Health Coverage (OHC) Guidelines for Billing* in the Part 1 provider manual.
- *Medicare/Medi-Cal Crossover Claims: CMS-1500* in this manual.
- For guidance on modifiers see:
  - *Modifiers*
  - *Modifiers Used with Procedure Codes*
- For guidance on NDCs, see the National Drug Code: FAQs page on the Medi-Cal Providers website.
- For the small number of PADs able to be billed on pharmacy claims, refer to coverage and billing information on the Medi-Cal Rx website.

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.