Chemotherapy: An Overview

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This section contains overview information for policy related to billing for chemotherapy services, including infusion policy, authorization requirements for chemotherapy services and cancer clinical trials guidelines. Billing policy details about chemotherapy drugs can be found in the following Part 2 manual sections:

- *Chemotherapy: Drugs A-D Policy*
- *Chemotherapy: Drugs E-O Policy*
- *Chemotherapy: Drugs P-Z Policy*

Important Notice and TAR Requirement

All listed chemotherapy drugs may be approved for FDA-labelled 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 (22 CCR § 51313(4)). Billing codes and utilization management criteria are listed with each code. Experimental Services are not a benefit. Investigational Services are covered in accordance with statutory requirements (22 CCR § 51303(g)). Authorization is required for dosages exceeding the maximum recommended dosages as approved by the FDA.

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.

Reimbursement Methodology

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

Reimbursement is determined by the cost of the injection, plus the physician's injection administration fee for the first billed unit of drug. The price listed on the Medi-Cal Rates page of the Medi-Cal website for each physician-administered drug includes the one-time injection administration fee of $4.46. Since the injection administration fee is applied only once for each drug administered, subsequent units claimed will have the administration fee subtracted from the published rate.

Intravenous Infusion

CPT® codes 96413 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug) and 96415 (...each additional hour, one to eight hours) 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 in order 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 (chemotherapy administration, intravenous infusion technique; up to one hour, single or initial substance/drug).

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

Medi-Cal covers routine patient care costs for patients accepted into Phase I, Phase II, Phase III or Phase IV clinical trials for cancer when the following criteria are met:

1. The patient's treating physician, who must be providing health care services to the patient under the Medi-Cal program, recommends participation in the cancer clinical trial.
2. Participation in the cancer clinical trial must have a meaningful potential to benefit the patient, supported by the following documentation:
   - Conventional therapy will not adequately treat the intended patient's condition.
   - Medical literature supports a significant probability that the proposed treatment is active against the patient's cancer.
   - There is a reasonable expectation that the cancer treatment will benefit the patient. For example, the treatment may significantly prolong the intended patient's life or will maintain or restore a range of physical and social functions suited to activities of daily living.
3. The cancer clinical trial must not be to exclusively test toxicity but must have a therapeutic intent. The treating physician(s) must provide medical justification including:
   - A summary of or the actual research protocol.
   - Evidence that the patient meets the clinical trial entrance criteria and has been enrolled in the cancer clinical trial.
   - Documentation that the patient participating in a double-blind clinical trial is not receiving a placebo and no other acute cancer treatment.
4. A cancer clinical trial may not be authorized in the inpatient setting if the participating patient is not receiving acute care treatment, and hospitalization is desired solely because of participation in the clinical trial.

Routine Patient Care Costs Described

Routine patient care costs include the following:

- Health care services that would be provided in the absence of a clinical trial
- Health care services required for the provision of the investigational drug, item, device or service
- Health care services required for clinically appropriate monitoring of the cancer treatment
- Health care services provided for the prevention of complications arising from the cancer clinical trial
- Health care services needed for reasonable and necessary care arising from complications of the cancer clinical trial

The following services are excluded from routine patient care costs and are not Medi-Cal reimbursable:

- Drugs and devices associated with the cancer clinical trial that have not been approved by the FDA
- Services not directly associated with health care, such as travel, housing, companion expenses, and other non-clinical expenses associated with the cancer clinical trial
- Any item or service provided solely for data collection
- Health services associated with the cancer clinical trials that are excluded from coverage by the Medi-Cal program
- Health care services customarily provided by the research sponsors

Approved Clinical Trials

Medi-Cal reimburses for services rendered only in connection with approved clinical trials. Cancer clinical trials qualify for approval if they meet one of the following conditions:

- The trial involves a drug that is exempt under federal regulation from a new drug application, or
- The cancer clinical trial is approved by one of the following:
  - The National Institutes of Health
  - The FDA in the form of an investigational new drug application
  - The Department of Defense
  - The Department of Veterans Affairs

TAR Requirements

Cancer clinical trials are reimbursable in both inpatient and outpatient settings. TARs submitted for hospital admission of a patient participating in a cancer clinical trial will be adjudicated by Medi-Cal consultants in the same manner as for any patient requiring an acute level of care. Services requiring authorization may be approved for a patient diagnosed with cancer and accepted into a clinical trial, when the criteria listed above are met.

‹‹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.