

**Billing and Coding Guideline for CHEMO-001 Chemotherapy Drugs and their Adjuncts**  
LCD L37205

**Medicare Regulation Excerpts:**

PUB.100-20 One time Notification (OTN); Change Request (CR) 3818, 3631, 3028

*For services furnished on or after January 1, 2005, chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs and also to anti-neoplastic agents provided for the treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents and other biologic response modifiers. Administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration.*

**Excerpts from CMS internet only Manual (IOM):**

**Publications 100-02 Medicare Benefit Policy Manual, Chapter 15, Section 60.1, Incident to Physician Professional Services and A**

*Incident to a physician's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness.*

*To be covered, supplies, including drugs and biologicals, must be an expense to the physician or legal entity billing for the services or supplies. For example, where a patient purchases a drug and the physician administers it, the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.*

*Per CR 9749: Please use CPT G0498: Chemo extend IV infusion with pump: this is the single service that INCLUDES the chemotherapy administration AND the pump. G0498 will be inclusive for all of these costs, no other administration, pump charge, set up or disconnect charges would be allowed. Chemotherapy administration, intravenous infusion technique; initiation of infusion in the office/other outpatient setting using office/other outpatient setting pump/supplies, with continuation of the infusion in the community setting (e.g., home, domiciliary, rest home or assisted living) using a portable pump provided by the office/other outpatient setting, includes follow up office/other outpatient visit at the conclusion of the infusion. Effective 01/01/2016*

**Publications 100-04 Medicare Claims Processing Manual, Chapter 12, Section 30.5, Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions**

***D. Chemotherapy Administration***

*Chemotherapy administration codes apply to parenteral administration of nonradionuclide anti-neoplastic drugs; and also to anti-neoplastic agents provided for treatment of noncancer diagnoses (e.g., cyclophosphamide for auto-immune conditions) or to substances such as monoclonal antibody agents, and other biologic response modifiers. The following drugs are commonly considered to fall under the category of monoclonal antibodies: infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab. Drugs commonly considered to fall under the category of hormonal antineoplastics include leuprolide acetate and goserelin acetate. The drugs cited are not intended to be a complete list of drugs that may be administered using the chemotherapy administration codes. Local carriers may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare.*

*The administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration.*

*If performed to facilitate the chemotherapy infusion or injection, the following services and items are included and are not separately billable:*

- 1. Use of local anesthesia;*
- 2. IV access;*
- 3. Access to indwelling IV, subcutaneous catheter or port;*
- 4. Flush at conclusion of infusion;*
- 5. Standard tubing, syringes and supplies; and*
- 6. Preparation of chemotherapy agent(s).*

*Payment for the above is included in the payment for the chemotherapy administration service.*

*If a significant separately identifiable evaluation and management service is performed, the appropriate E & M code should be reported utilizing modifier 25 in addition to the chemotherapy code. For an evaluation and management service provided on the same day, a different diagnosis is not required.*

### **Publications 100-04 Medicare Claims Processing Manual, Chapter 17, Section 90.2, Drugs, Biologicals, and Radiopharmaceuticals**

***A. General Billing and Coding for Hospital Outpatient Drugs, Biologicals, and radiopharmaceuticals***  
*Hospitals should report charges for all drugs, biologicals, and radiopharmaceuticals, regardless of whether the items are paid separately or packaged, using the correct HCPCS codes for the items used. It is also of great importance that hospitals billing for these products make certain that the reported units of service of the reported HCPCS code are consistent with the quantity of a drug, biological, or radiopharmaceutical that was used in the care of the patient.*

*Payment for drugs, biologicals and radiopharmaceuticals under the OPSS is inclusive of both the acquisition cost and the associated pharmacy overhead or nuclear medicine handling cost. Hospitals should include these costs in their line-item charges for drugs, biologicals, and radiopharmaceuticals.*

*Under the OPSS, if commercially available products are being mixed together to facilitate their concurrent administration, the hospital should report the quantity of each product (reported by HCPCS code) used in the care of the patient. Alternatively, if the hospital is compounding drugs that are not a mixture of commercially available products, but are a different product that has no applicable HCPCS code, then the hospital should report an appropriate unlisted drug code (J9999 or J3490). In these situations, it is not appropriate to bill HCPCS code C9399. HCPCS code C9399, Unclassified drug or biological, is for new drugs and biologicals that are approved by FDA on or after January 1, 2004, for which a specific HCPCS code has not been assigned.*

*The HCPCS code list of retired codes and new HCPCS codes reported under the hospital OPSS is published quarterly via Recurring Update Notifications. The latest payment rates associated with each APC and HCPCS code may be found in the most current Addendum A and Addendum B, respectively, that can be found under the CMS quarterly provider updates on the CMS Web site at: <http://www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp>*

### **Publications 100-04 Medicare Claims Processing Manual, Chapter 14, Section 10.2, Ambulatory Surgery Center**

***Drugs, Biologicals, Surgical Dressings, Supplies, splints, Casts, Appliances, and Equipment***  
*Beginning January 1, 2008, the ASC facility payment for a surgical procedure includes payment for drugs and biologicals that are not usually self-administered and that are considered to be packaged into the payment for the surgical procedure under the OPSS. Also, beginning January 1, 2008, Medicare makes separate payment to ASCs for drugs and biologicals that are furnished integral to an ASC covered surgical procedure and that are separately payable under the OPSS.*

## **Publication 100-02 Medicare Benefit Policy Manual, Chapter 15, Section 50.4.5, Off Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen**

### **A. Overview**

*Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration- (FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below. A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer. Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. The contractor may maintain its own subscriptions to the listed compendia or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.*

### **Current compendia:**

*American Hospital Formulary Service-Drug Information (AHFS-DI)*

*Effective June 5, 2008 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium*

*Effective June 10, 2008 -Micromedex DrugDex*

*Effective July 2, 2008 - Clinical Pharmacology*

*Effective August 12, 2015- Lexi-Drugs*

In general, a use is identified by a compendium as medically accepted if the indication is a Category 1 or 2A in NCCN; or Class I, Class IIa, or Class IIb in DrugDex; or narrative text in AHFS or Clinical Pharmacology is supportive; or is listed in Lexi-Drugs as “Use: Off-Label” and rated as “evidence level A.”

*The listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as **medically accepted** if the:*

- 1. indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,*
- 2. narrative text in AHFS-DI or Clinical Pharmacology is supportive, or*
- 3. indication is listed in Lexi-Drugs as “Use: Off-Label” and rated as “Evidence Level A”*

*A use is **not medically accepted** by a compendium if the:*

- 1. indication is a Category 3 in NCCN or a Class III in DrugDex; or,*
- 2. narrative text in AHFS or Clinical Pharmacology is “not supportive,” or*
- 3. indication is listed in Lexi-Drugs as “Use: Unsupported”*

*The complete absence of narrative text on a use is considered neither supportive nor non-supportive*

**For National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22), please use the CMS.GOV/Medicare coverage website.**

### **Coding Guidelines**

1. Use the appropriate J code to report the drug being used.
2. True codes reflect the dosage of the drug; the number of units should indicate the total number of units given in 2400/SV1-04 data element of the ANSI 837 5010 or in item 24G of the CMS 1500 form.

3. NOC billing:

**Office/Clinic:**

When using a drug/radiopharmaceutical NOC code (J9999, J3490, or J3590) list the name of the drug, the amount of the drug that is administered and wasted if applicable; method of administration in the electronic narrative 2400/SV101-7 which is equivalent to line 19 of the CMS 1500 form. List the units of service as **one** in 2400/SV1-04 data element of the ANSI 837 5010 or in item 24G of the CMS 1500 form.

Occasionally, the strength of the drug will also be needed on NOC claims. If the NOC ASP pricing file lists the name of the drug with its strength it must also be included on line 19.

Example: Sodium Bicarbonate 8.4%.

**Hospital Outpatient Departments:**

Hospital outpatient departments are allowed to bill for new drugs, biologicals, and therapeutic radiopharmaceuticals that are approved by the FDA on or after January 1, 2004 for which pass-through status has not been approved and a C-code and APC payment have not been assigned using the “unclassified” drug/biological HCPCS code C9399 (Unclassified drugs or biological). Drugs, biologicals, and therapeutic radiopharmaceuticals that are assigned to HCPCS code C9399.

4. Coverage for medication is based on the patient’s condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia ratings listed below.
5. Self-administered drugs are not covered and should not be submitted to Medicare unless requested to do so by the beneficiary.
6. An invoice may be requested if pricing is not available on the Average Sales Price (ASP) pricing file. This file contains lists for NOC and true codes. This file can be located using the CMS.GOV/Medicare coverage website.

Electronic submitters should indicate they have additional documentation or an invoice, which Medicare may require, by indicating “DOCUMENTATION AVAILABLE UPON REQUEST” in the electronic equivalent of item 19. If the additional documentation or an invoice you have is needed for Medicare to make its payment determination, a development letter will be sent requesting the information. If you do not indicate the availability of the additional documentation, or the information is not returned timely, the claim will be returned as unprocessable.

7. To be covered, drugs and biologicals must be an expense to the physician or legal entity billing for the services or supplies. If the drug was supplied free to the physician, donated, or the patient brings in the drug to the physician office to be administered, **the drug would not be billable.** The administration of the drug would be covered **if the drug is given for a covered indication.**
  - a. When submitting a claim for the administration of a drug that was given for a covered indication, that the beneficiary brings in or was donated to them, indicate on line 19 the name of the drug. Failure to include the name of the drug in line 19 may result in denial.

- b. Drug administration services are not covered when the drug is given for a non-covered indication.
8. Requests for off label coverage consideration should be submitted via the LCD reconsideration process described on our WPS GHA website **or** submit a request with a copy of the compendia documenting the medically accepted category or narrative and or peer reviewed literature that is published in a CMS accepted journal supporting its use via e-mail to [policycomments@wpsic.com](mailto:policycomments@wpsic.com).

**Related Local Coverage Documents**

Article: Not Otherwise Classified Chemotherapy Agents (NOC)