CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 13012	**Date: December 19, 2024**
	Change Request 13904

SUBJECT: Internet Only Manual (IOM) Update to 100-04 Chapter 12, Section 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to add additional clarifying language to the IOM 100-04 Chapter 12, Section 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions.

EFFECTIVE DATE: January 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2025

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	12/30.5/Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 13012	Date: December 19, 2024	Change Request: 13904

SUBJECT: Internet Only Manual (IOM) Update to 100-04 Chapter 12, Section 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

EFFECTIVE DATE: January 1, 2025
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 2, 2025

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to add additional clarifying language to the IOM 100-04 Chapter 12, Section 30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions.

II. GENERAL INFORMATION

A. Background: For the CY 2025 PFS final rule, CMS-1807-F, CMS finalized a policy to add clarifying language with increased detail to IOM 100-04 Chapter 12, Section 30.5. This additional language is in response to concerns from external parties regarding down coding of complex non-chemo drug administration services.

B. Policy: Add additional language to IOM 100-04 Chapter 12, Section 30.5 that provides increased detail and considerations of complexity for Medicare Administrative Contractors (MACs) to use when determining payment for complex non-chemotherapeutic drug administration services.

III. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
13904.1	Contractors shall be in compliance with the revisions in Publication 100-04, Chapter 12, Section 30.5 contained in this change request.	X	X	X						

IV. PROVIDER EDUCATION

Medicare Learning Network® (MLN): CMS will develop and release national provider education content and market it through the MLN Connects® newsletter shortly after we issue the CR. MACs shall link to relevant information on your website and follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 for distributing the newsletter to providers. When you follow this manual section, you don't need to separately track and report MLN content releases. You may supplement with your local educational content after we release the newsletter.

Impacted Contractors: A/B MAC Part A, A/B MAC Part B, A/B MAC Part HHH

V. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information:N/A

VI. CONTACTS

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VII. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

30.5 - Payment for Codes for Chemotherapy Administration and Nonchemotherapy Injections and Infusions

(Rev. 13012; Issued: 12-19-24; Effective: 01-01-25; Implementation: 01-02-25)

A. General

Codes for Chemotherapy administration and nonchemotherapy injections and infusions include the following three categories of codes in the American Medical Association's Current Procedural Terminology (CPT):

1. Hydration;
2. Therapeutic, prophylactic, and diagnostic injections and infusions (excluding chemotherapy); and
3. Chemotherapy administration.

Physician work related to hydration, injection, and infusion services involves the affirmation of the treatment plan and the supervision (pursuant to incident to requirements) of nonphysician clinical staff.

B. Hydration

The hydration codes are used to report a hydration IV infusion which consists of a pre-packaged fluid and /or electrolytes (e.g. normal saline, D5-1/2 normal saline +30 mg EqKC1/liter) but are not used to report infusion of drugs or other substances.

C. Therapeutic, prophylactic, and diagnostic injections and infusions (excluding chemotherapy)

A therapeutic, prophylactic, or diagnostic IV infusion or injection, other than hydration, is for the administration of substances/drugs. The fluid used to administer the drug (s) is incidental hydration and is not separately payable.

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

1. Use of local anesthesia;
2. IV start;
3. Access to indwelling IV, subcutaneous catheter or port;
4. Flush at conclusion of infusion; and
5. Standard tubing, syringes and supplies.

Payment for the above is included in the payment for the chemotherapy administration or nonchemotherapy injection and infusion 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 administration or nonchemotherapy injection and infusion service. For an evaluation and management service provided on the same day, a different diagnosis is not required.

The CPT 2006 includes a parenthetical remark immediately following CPT code 90772 (Therapeutic, prophylactic or diagnostic injection; (specify substance or drug); subcutaneous or intramuscular.) It states, "Do not report 90772 for injections given without direct supervision. To report, use 99211."
This coding guideline does not apply to Medicare patients. If the RN, LPN or other auxiliary personnel furnishes the injection in the office and the physician is not present in the office to meet the supervision requirement, which is one of the requirements for coverage of an incident to service, then the injection is not covered. The physician would also not report 99211 as this would not be covered as an incident to service.

D. Chemotherapy Administration

Chemotherapy administration codes apply to parenteral administration of non-radionuclide 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. A/B MACs (B) may provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare. *A/B MACs should consider multiple factors when determining if the level of intensity for a complex drug administration service has been met, rather than just the drug name alone. Chemotherapy administration is considered highly complex and requires physician or qualified health professional work and monitoring well beyond the level of the therapeutic, prophylactic, and diagnostic injections and infusions code series (96360-96379) due to the high incidence of potentially adverse reactions for the patient. This service typically requires direct supervision from qualified health professionals and/or clinical staff with advanced practice training in the special considerations of preparation, dosage, and disposal and often involves frequent monitoring of the patient and conferring with a physician.*

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.

E. Coding Rules for Chemotherapy Administration and Nonchemotherapy Injections and Infusion Services

Instruct physicians to follow the CPT coding instructions to report chemotherapy administration and nonchemotherapy injections and infusion services with the exception listed in subsection C for CPT code 90772. The physician should be aware of the following specific rules.

When administering multiple infusions, injections or combinations, the physician should report only one "initial" service code unless protocol requires that two separate IV sites must be used. The initial code is the code that best describes the key or primary reason for the encounter and should always be reported irrespective of the order in which the infusions or injections occur. If an injection or infusion is of a subsequent or concurrent nature, even if it is the first such service within that group of services, then a subsequent or concurrent code should be reported. For example, the first IV push given subsequent to an initial one-hour infusion is reported using a subsequent IV push code.
If more than one "initial" service code is billed per day, the A/B MAC (B) shall deny the second initial service code unless the patient has to come back for a separately identifiable service on the same day or has two IV lines per protocol. For these separately identifiable services, instruct the physician to report with modifier 59.

The CPT includes a code for a concurrent infusion in addition to an intravenous infusion for therapy, prophylaxis or diagnosis. Allow only one concurrent infusion per patient per encounter. Do not allow payment for the concurrent infusion billed with modifier 59 unless it is provided during a second encounter on the same day with the patient and is documented in the medical record.
For chemotherapy administration and therapeutic, prophylactic and diagnostic injections and infusions, an intravenous or intra-arterial push is defined as: 1.) an injection in which the

healthcare professional is continuously present to administer the substance/drug and observe the patient; or 2.) an infusion of 15 minutes or less.

The physician may report the infusion code for "each additional hour" only if the infusion interval is greater than 30 minutes beyond the 1 hour increment. For example if the patient receives an infusion of a single drug that lasts 1 hour and 45 minutes, the physician would report the "initial" code up to 1 hour and the add-on code for the additional 45 minutes.

Several chemotherapy administration and nonchemotherapy injection and infusion service codes have the following parenthetical descriptor included as a part of the CPT code, "List separately in addition to code for primary procedure." Each of these codes has a physician fee schedule indicator of "ZZZ" meaning this service is allowed if billed with another chemotherapy administration or nonchemotherapy injection and infusion service code.

Do not interpret this parenthetical descriptor to mean that the add-on code can be billed only if it is listed with another drug administration primary code. For example, code 90761 will be ordinarily billed with code 90760. However, there may be instances when only the add-on code, 90761, is billed because an "initial" code from another section in the drug administration codes, instead of 90760, is billed as the primary code. Pay for code 96523, "Irrigation of implanted venous access device for drug delivery systems," if it is the only service provided that day. If there is a visit or other chemotherapy administration or nonchemotherapy injection or infusion service provided on the same day, payment for 96523 is included in the payment for the other service.

F. Chemotherapy Administration (or Nonchemotherapy Injection and Infusion) and Evaluation and Management Services Furnished on the Same Day

For services furnished on or after January 1, 2004, do not allow payment for CPT code 99211, with or without modifier 25, if it is billed with a nonchemotherapy drug infusion code or a chemotherapy administration code. Apply this policy to code 99211 when it is billed with a diagnostic or therapeutic injection code on or after January 1, 2005.

Physicians providing a chemotherapy administration service or a nonchemotherapy drug infusion service and evaluation and management services, other than CPT code 99211, on the same day must bill in accordance with §30.6.6 using modifier 25. The A/B MACs (B) pay for evaluation and management services provided on the same day as the chemotherapy administration services or a nonchemotherapy injection or infusion service if the evaluation and management service meets the requirements of section §30.6.6 even though the underlying codes do not have global periods. If a chemotherapy service and a significant separately identifiable evaluation and management service are provided on the same day, a different diagnosis is not required.

In 2005, the Medicare physician fee schedule status database indicators for therapeutic and diagnostic injections were changed from T to A. Thus, beginning in 2005, the policy on evaluation and management services, other than 99211, that is applicable to a chemotherapy or a nonchemotherapy injection or infusion service applies equally to these codes.