AVGEMSI™
(gemcitabine) Injection

BILLING & CODING GUIDE

If you have additional billing and coding questions, please call your Field Reimbursement Manager or AVYXASSIST™ at 866-939-8927. Our Patient Access Specialists are available to assist Monday through Friday, 8 AM to 8 PM ET.

Please see Important Safety Information on pages 3 and 15-16 and full Prescribing Information for AVGEMSI™.

AVYXA

TABLE OF CONTENTS

The contents herein provide general coverage, coding, and payment information about AVGEMSI™ (gemcitabine) injection. The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA™ does not guarantee coverage or payment. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

Please see Important Safety Information on pages 3 and 15-16 and full Prescribing Information for AVGEMSI™.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

Ovarian Cancer

AVGEMSI™ in combination with carboplatin is indicated for the treatment of patients with advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

Breast Cancer

AVGEMSI in combination with paclitaxel is indicated for the first-line treatment of patients with metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.

Non-Small Cell Lung Cancer

AVGEMSI in combination with cisplatin is indicated for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC).

Pancreatic Cancer

AVGEMSI is indicated as first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. AVGEMSI is indicated for patients previously treated with fluorouracil.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATION

AVGEMSI is contraindicated in patients with a known hypersensitivity to gemcitabine. Reactions include anaphylaxis.

WARNINGS AND PRECAUTIONS

Schedule-Dependent Toxicity: In clinical trials evaluating the maximum tolerated dose of gemcitabine, prolongation of the infusion time beyond 60 minutes or more frequent than weekly dosing resulted in an increased incidence of clinically significant hypotension, severe flu-like symptoms, myelosuppression, and asthenia. The half-life of gemcitabine is influenced by the length of the infusion.

Myelosuppression: Myelosuppression manifested by neutropenia, thrombocytopenia, and anemia, occurs with gemcitabine as a single agent and the risks are increased when gemcitabine is combined with other cytotoxic drugs. In clinical trials, Grade 3-4 neutropenia, anemia, and thrombocytopenia occurred in 25%, 8%, and 5%, respectively of the 979 patients who received single agent gemcitabine. The frequencies of Grade 3-4 neutropenia, anemia, and thrombocytopenia varied from 48% to 71%, 8% to 28%, and 5% to 55%, respectively, in patients receiving gemcitabine in combination with another drug.

Prior to each dose of AVGEMSI, obtain a complete blood count (CBC) with a differential and a platelet count. Modify the dosage as recommended.

Severe Cutaneous Adverse Reactions (SCARs): SCARs, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with gemcitabine treatment. Monitor patients for signs and symptoms of severe cutaneous adverse reactions. Permanently discontinue gemcitabine in patients who develop SCARs.

AVGEMSI™
(gemcitabine) Injection

Ordering Information

To order AVGEMSI™ (gemcitabine) injection, please contact one of these authorized specialty distributors and use the appropriate order number:

1 g/26.3 mL
NDC: 83831-0123-01

2 g/52.6 mL
NDC: 83831-0124-01

Institutions/Hospitals	1 g/26.3 mL	2 g/52.6 mL
Cardinal Health Specialty	6044630	6044648
CENCORA - ASD Healthcare	10301985	10301983
McKesson Plasma & Biologics	3048402	3048428
Physician Offices	**1 g/26.3 mL**	**2 g/52.6 mL**
Cardinal Health Specialty	6044630	6044648
Oncology Supply	10301906	10301908
McKesson Specialty Health	5020581	5020582

Highlights

- Supplied in multiple-dose vials as 1 g/26.3 mL and 2 g/52.6 mL
- Free from mannitol, sodium acetate, and hydrochloric acid
- No reconstitution required
- Partially used multiple-dose vials are stable for up to 14 days when stored in the original cartons refrigerated at 2°C to 8°C (36°F to 46°F)
- Ready to add to intravenous infusion solution with 0.9% Sodium Chloride Injection, USP

J-CODE

J9999

Unique J-Code Coming January 1, 2026

AVYXASSIST™

Simplifying Patient Access, Providing Comprehensive Support.

AVYXASSIST™ can offer support to qualifying patients in need. The program provides the following services*

- Benefit verification
- Prior authorization requirements
- Appeals process information
- Referrals to 501(c)(3) foundations when applicable
- Free product assistance (uninsured or underinsured), bridge supply (coverage delays)
- Product replacement
- Copay assistance

COPAY ASSISTANCE PROGRAM

Eligible patients may pay as little as **$0** per dose*

TO ENROLL, PLEASE CHOOSE ONE OF THE FOLLOWING OPTIONS

Phone

866-939-8927
Monday through Friday
8 AM to 8 PM ET

CALL NOW

OR

Online

Click on the link below to begin your online enrollment

ENROLL NOW

OR

Fax

Download, print and fax the completed enrollment form to 833-852-3420

DOWNLOAD NOW

*For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

AVGEMSI™ Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA™ concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA™ does not recommend using any particular diagnosis code in billing situations for AVGEMSI™ (gemcitabine) Injection. The below codes are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs[1]

AVGEMSI™ NDC	Strength	Package
83831-0123-01	1 g/26.3 mL (38 mg/mL)	1 multiple-dose vial in 1 carton
83831-0124-01	2 g/52.6 mL (38 mg/mL)	1 multiple-dose vial in 1 carton

HCPCS Code

HCPCS Level II codes are used to identify most drugs and biologics administered in the office. Correct coding requires reporting the most specific code to accurately describe the service.[2] Not otherwise classified (NOC) codes are used only when a more specific HCPCS code is not available or assigned.

AVGEMSI™ J-Code	Description
J9999	Not otherwise classified, antineoplastic drug

To correctly process a claim using a NOC code, you may need to include invoice and clinical notes[3].

J-Code Billing Unit Conversion

Not Otherwise Classified (NOC) codes, such as J9999, are priced manually. When billing unlisted codes, the unit of service equals one (1), and the following details must be entered into Item 19 of the CMS-1500 or electronic claim equivalent:

- Name of the drug
- Dose administered (mg, cc, etc.) and strength of dosage, if appropriate.
- Route of administration (IV, IM, SC, PO, etc.)
- National Drug Code (NDC)

Until a permanent J-Code is assigned, AVGEMSI™ is billed using one (1) service unit.

Important: List one unit of service in the 2400/SV1-04 data element or in item 24G of the CMS 1500 form. Do not quantity-bill NOC drugs and biologicals even if multiple units are provided. Medicare determines the proper payment of NOC drugs and biologicals by the narrative information, not the number of units billed.[4]

Example:

AVGEMSI™ is indicated as first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas. AVGEMSI™ is indicated for patients who have previously received treatment with fluorouracil.[5]

The recommended dosage of AVGEMSI™ is 1,000 mg/m^2 intravenously over 30 minutes.[6] An individual with a body surface area of 1.9 m^2 receives 1900 mg of AVGEMSI™ in over 30 minutes. The service unit is one (1), and an example of supplemental information to include in Item 19 is:

AVGEMSI™ 1900 mg IV 83831012301

CPT Drug Administration Codes

CPT codes are used to bill drug administration services in the physician's office and other outpatient settings.[7] AVGEMSI™ has a 30-minute intravenous infusion time for differing indications. However, please code according to the start and stop times listed in the patient's medical chart.[8]

AVGEMSI™ is supplied as a multiple-dose vial. Medicare will not pay for drug waste on multiple-dose vials, so the JW and JZ modifiers are not applicable in the billing of AVGEMSI™.[9,10]

CPT Code	Description	Place of Service (POS)[10]
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance drug[11]	• Physician Office (11) • Off-Campus Outpatient Hospital (19) • On-Campus Outpatient Hospital (22)
96417	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug), up to 1 hour[12]	

Revenue Codes

Claim Item	Revenue Code	Description	Place of Service (POS)
AVGEMSI™	0636	Drugs Requiring Detailed Coding[13]	• Off-Campus Outpatient Hospital (19) • On-Campus Outpatient Hospital (22)
Drug Administration	0335	Chemotherapy Administration – IV[14]	

ICD Diagnosis Codes

AVGEMSI™ is a nucleoside metabolic inhibitor indicated:

- in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.
- in combination with paclitaxel, for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated.
- in combination with cisplatin, for the treatment of non-small cell lung cancer.
- as a single agent for the treatment of pancreatic cancer.[15]

For drugs with multiple indications, it is best practice to code the most specific ICD-10-CM Code within the indication to justify medical necessity.

International Classification of Disease, 10th Edition, Clinical Modification Codes for AVGEMSI™	
Indication	**ICD-10-CM Codes**
Ovarian Cancer[16]	C56.1, C65.2, C56.3, C56.9
Breast Cancer[17]	C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119,C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329,C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929
Non-Small Cell Lung Cancer[18]	C33, C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91, C34.92
Pancreatic Cancer[19]	C25.0, C25.1, C25.2, C25.3, C25.4, C25.7, C25.8, C25.9

ICD Diagnosis Codes by Indication

ICD-10-CM coding for AVGEMSI™ Injection varies greatly by payer. Please check with each payer to ascertain the best coding for AVGEMSI™ Injection according to their policy.

Ovarian Cancer: ICD-10-CM Diagnosis Coding	
ICD-10 Code	**Descriptor**
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary

Breast Cancer: ICD-10-CM Diagnosis Coding	
ICD-10 Code	**Descriptor**
C50.011 - C50.019	Malignant neoplasm of nipple and areola, female
C50.021 - C50.029	Malignant neoplasm of nipple and areola, male
C50.111 - C50.119	Malignant neoplasm of central portion of breast, female
C50.121 - C50.129	Malignant neoplasm of central portion of breast, male
C50.211 - C50.219	Malignant neoplasm of upper-inner quadrant of breast, female

Breast Cancer: ICD-10-CM Diagnosis Coding	
ICD-10 Code	**Descriptor**
C50.221 - C50.229	Malignant neoplasm of upper-inner quadrant of breast, male
C50.311 - C50.319	Malignant neoplasm of lower-inner quadrant of breast, female
C50.321 - C50.329	Malignant neoplasm of lower-inner quadrant of breast, male
C50.411 - C50.419	Malignant neoplasm of upper-outer quadrant of breast, female
C50.421 - C50.429	Malignant neoplasm of upper-outer quadrant of breast, male
C50.511 - C50.519	Malignant neoplasm of lower-outer quadrant of breast, female
C50.521 - C50.529	Malignant neoplasm of lower-outer quadrant of breast, male
C50.611 - C50.619	Malignant neoplasm of axillary tail of breast, female
C50.621 - C50.629	Malignant neoplasm of axillary tail of breast, male
C50.811 - C50.819	Malignant neoplasm of overlapping sites of breast, female
C50.821 - C50.829	Malignant neoplasm of overlapping sites of breast, male
C50.911 - C50.919	Malignant neoplasm of breast of unspecified site, female
C50.921 - C50.929	Malignant neoplasm of breast of unspecified site, male

Non-Small Cell Lung Cancer: ICD-10-CM Diagnosis Coding	
ICD-10 Code	**Descriptor**
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung

Non-Small Cell Lung Cancer: ICD-10-CM Diagnosis Coding	
ICD-10 Code	**Descriptor**
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of right bronchus or lung

Pancreatic Cancer: ICD-10-CM Diagnosis Coding	
ICD-10 Code	**Descriptor**
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of body of pancreas
C25.3	Malignant Neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of the pancreas
C25.9	Malignant neoplasm of pancreas, unspecified

Sample Claim Form CMS-1450 (UB-04)

Form Locator (FL) 42

(Electronic Claim Form = Loop 2400, Segment Type SV201):

List the appropriate revenue code for the drug. Match the descriptor for AVGEMSI™ injection to your revenue code, 0636.

Additionally, enter an appropriate revenue code for the administration service, such as 0335 for chemotherapy administration - IV or others based on the cost center where the service was performed.

FL 43

(NOT REQUIRED BY MEDICARE):

Enter the description of the procedure for the Revenue Code billed.

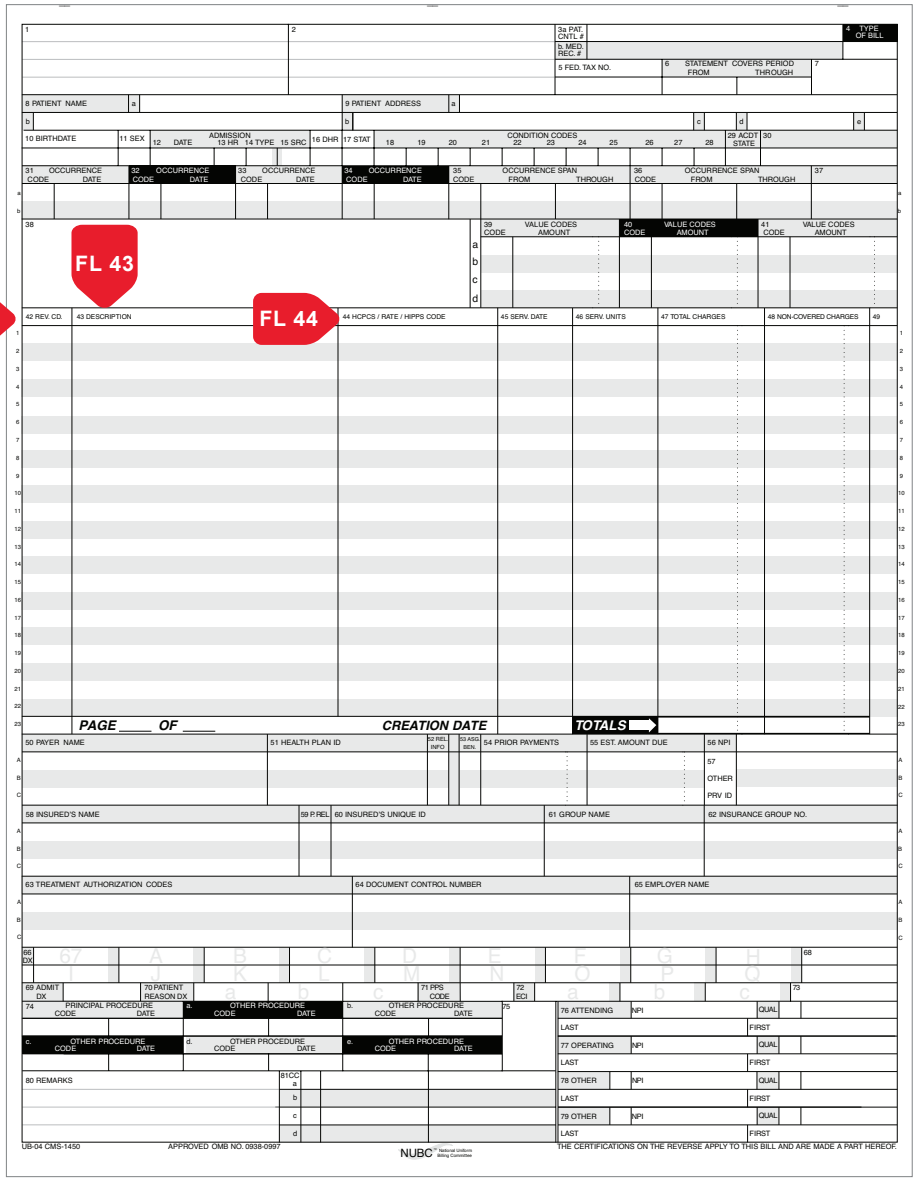
If required, list the N4 indicator first, then the 11-digit NDC code. In the third place, list the NDC unit measurement code and, last, the quantity. Check with other payers for their requirements.

FL 44

(Electronic Claim Form = Loop 2400, SV202-2 (SV202-1=HC/HP):

Enter the appropriate HCPCS code: **J9999, Not otherwise classified, antineoplastic drug**

For administration, enter the appropriate code or codes for intravenous administration. As an example, chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance drug requires CPT code 96413.[1]



FL 45

(Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46

(Electronic Claim Form = Loop 2400, SV205):

Enter the units for the HCPCS code billed.
Enter the number of service units for each item.

FL 63

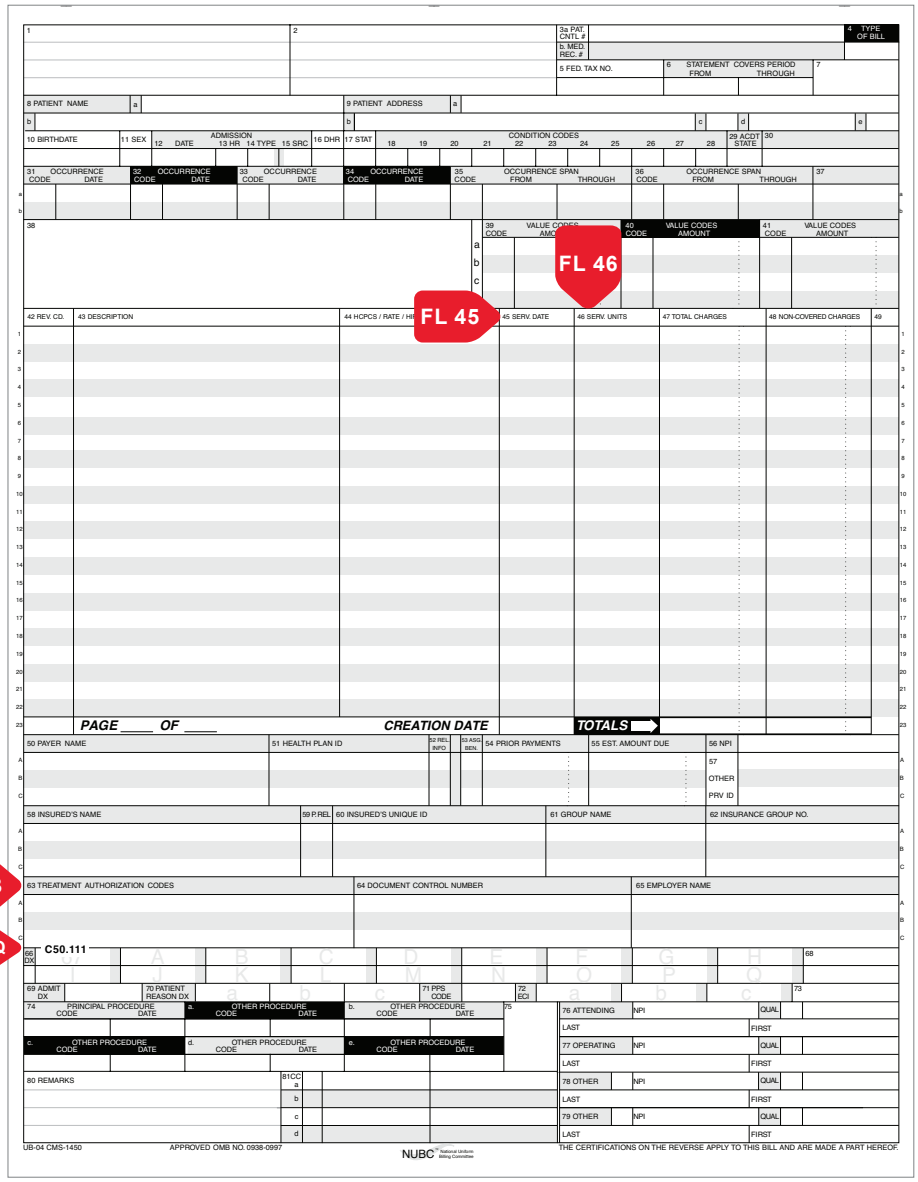
(Electronic Claim Form = Loop 2300,REF/G1/02):

Enter treatment authorization code.

FL 67A-Q

(Electronic Claim Form = Loop 2300, HI01-2 (HI01-1=BK)):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible. The code listed here is an example: ***C25.0 Malignant neoplasm of head of pancreas***



[1] CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

Electronic Claims Reference: *ASC 837I Version 5010A2 Institutional Health Care Claim to theCMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf*

Sample Claim Form CMS-1500

Item 19

(Electronic Claim Form = Loop 2400, Segment SV101-2) Additional claim information

When billing an NOC code, providers must indicate the following. The name of the drug, total dosage (plus strength of dosage, if appropriate), and method of administration. Some payers may require an NDC number.

Item 21

(Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2):

Enter the patient's diagnosis from the patient's medical record. An example code for this drug is *C25.0 Malignant neoplasm of head of pancreas.* Use Box 21 B-L fields for secondary diagnoses.

Item 23

(Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

Item 24D

(Electronic Claim Form = Loop 2400, Segment SV101):

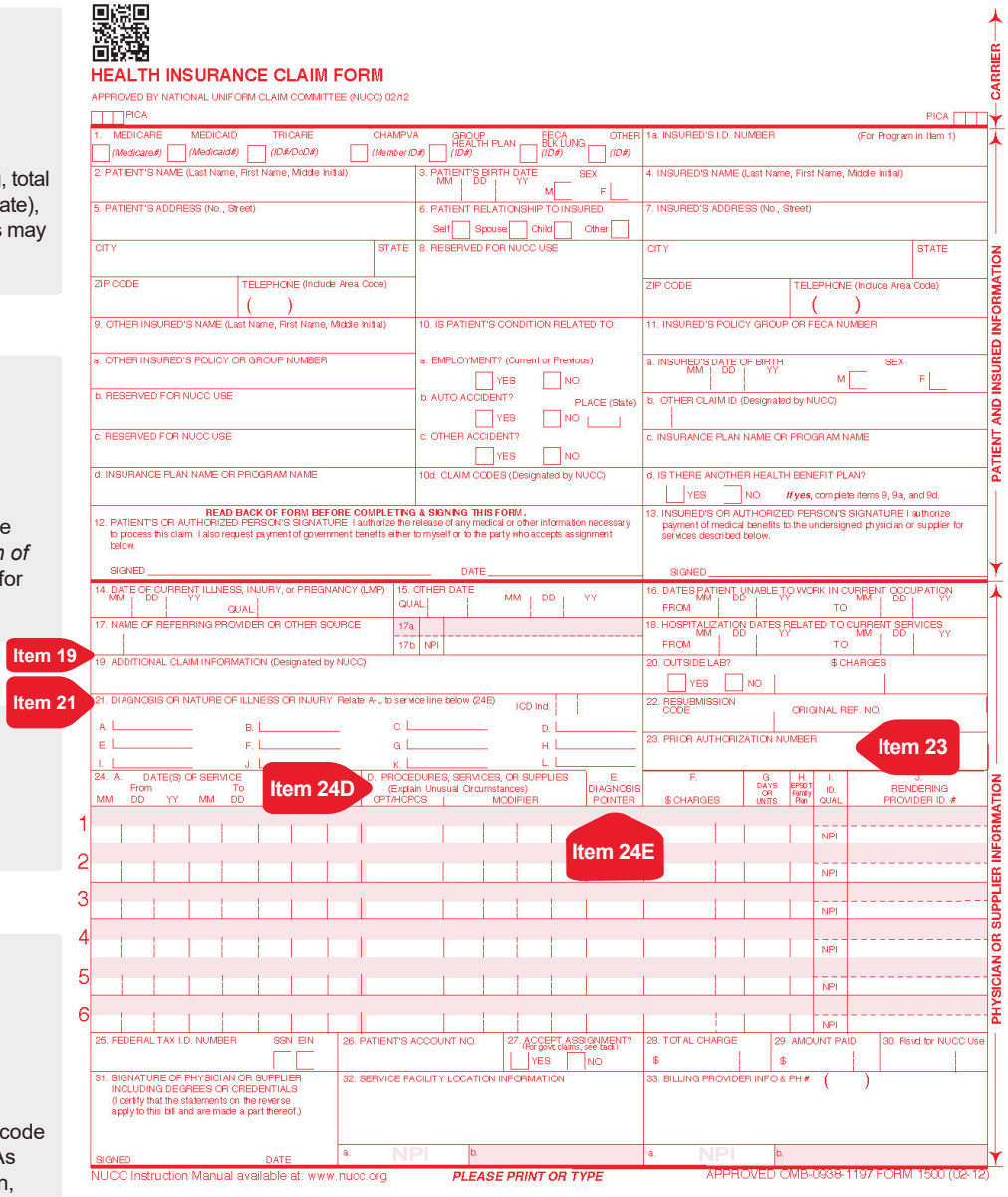
Enter the appropriate HCPCS code: **J9999, Not otherwise classified, antineoplastic drug**

For administration, enter the appropriate code or codes for intravenous administration. As an example, chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance drug requires CPT code 96413.[1]

Item 24E

(Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Box 21.



Item 24A-B

(Electronic Claim Form:
Item 24A (Electronic Claims = Loop 2400, DTP02;
Item 24 B (Loop 2300/2400, Segment CLM05-1/SV105))

In the non-shaded area, enter the appropriate date of service and place of service code.

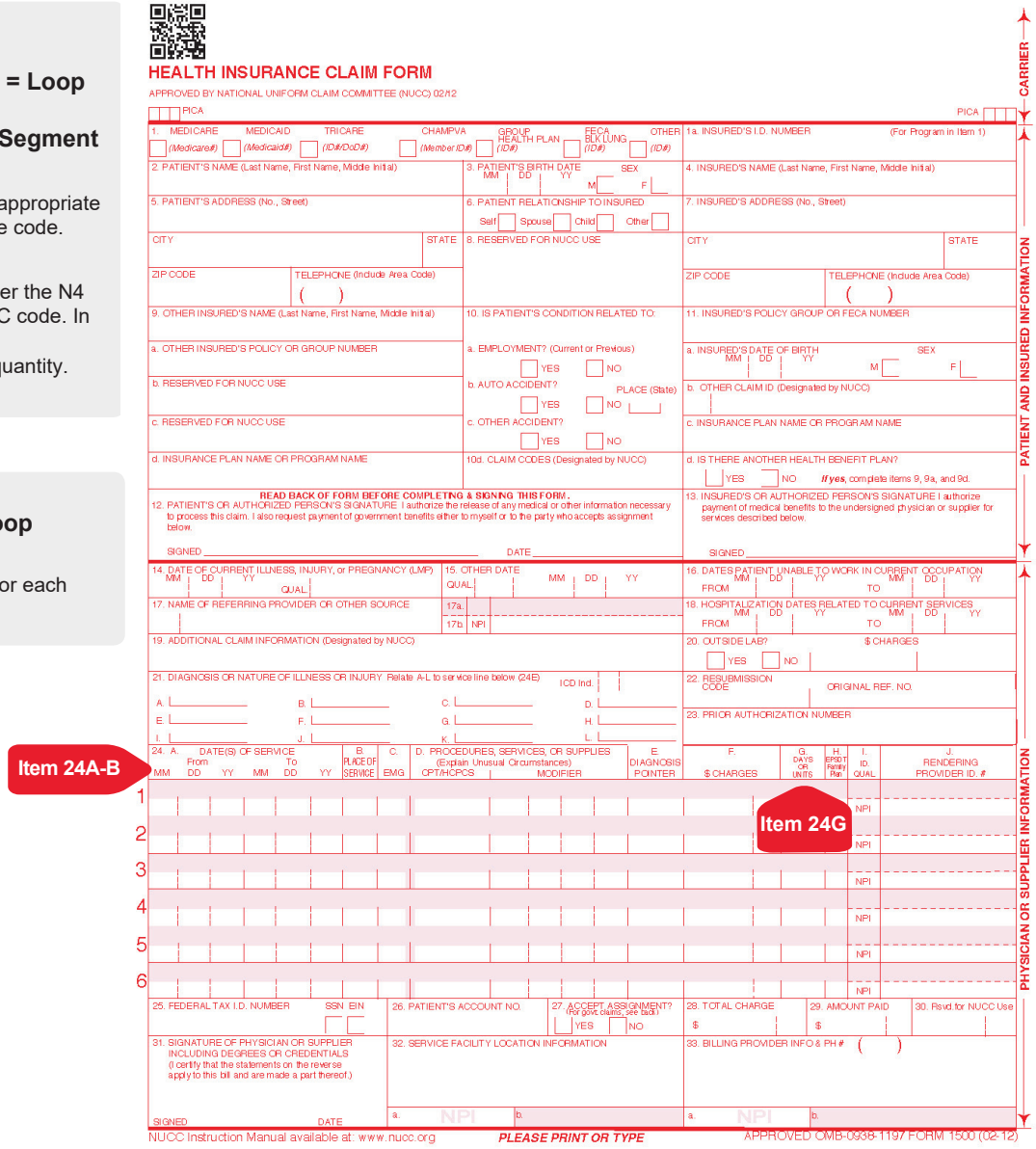
Example: Physician Office = 11.

If required, in the shaded area, enter the N4 indicator first, then the 11-digit NDC code. In the third space, list the NDC unit measurement code, and last, the quantity.

Item 24G

(Electronic Claim Form = Loop 2400, SV104):

Enter the number of service units for each item.



[1] CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

Electronic Claims Reference: *ASC 837I Version 5010A2 Institutional Health Care Claim to theCMS-1450 Claim Form Crosswalk. Palmettogba.com. Palmetto GBA, Accessed April 3, 2023. https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf*

IMPORTANT SAFETY INFORMATION (CONTINUED)

Pulmonary Toxicity and Respiratory Failure: Pulmonary toxicity, including interstitial pneumonitis, pulmonary fibrosis, pulmonary edema, and adult respiratory distress syndrome (ARDS), has been reported. In some cases, these pulmonary events can lead to fatal respiratory failure despite the discontinuation of therapy. The onset of pulmonary symptoms may occur up to 2 weeks after the last dose of gemcitabine.

Permanently discontinue AVGEMSI in patients who develop unexplained dyspnea, with or without bronchospasm, or evidence of severe pulmonary toxicity.

Hemolytic Uremic Syndrome (HUS): HUS, including fatalities from renal failure or the requirement for dialysis, can occur with gemcitabine. In clinical trials, HUS occurred in 0.25% of 2429 patients. Most fatal cases of renal failure were due to HUS. Serious cases of thrombotic microangiopathy other than HUS have been reported with gemcitabine.

Assess renal function prior to initiation of AVGEMSI and periodically during treatment. Consider the diagnosis of HUS in patients who develop anemia with evidence of microangiopathic hemolysis; increased bilirubin or LDH; reticulocytosis; severe thrombocytopenia; or evidence of renal failure (increased serum creatinine or BUN). Permanently discontinue AVGEMSI in patients with HUS or severe renal impairment. Renal failure may not be reversible even with the discontinuation of therapy.

Hepatic Toxicity: Drug-induced liver injury, including liver failure and death, has been reported in patients receiving gemcitabine alone or with other potentially hepatotoxic drugs. Administration of gemcitabine in patients with concurrent liver metastases or a pre-existing medical history of hepatitis, alcoholism, or liver cirrhosis can lead to exacerbation of the underlying hepatic insufficiency. Assess hepatic function prior to initiation of AVGEMSI and periodically during treatment. Permanently discontinue AVGEMSI in patients who develop severe hepatic toxicity.

Embryo-Fetal Toxicity: AVGEMSI can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with AVGEMSI and for 6 months after the final dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with AVGEMSI and for 3 months following the final dose.

Exacerbation of Radiation Therapy Toxicity: Gemcitabine is not recommended for use in combination with radiation therapy.

Concurrent (given together or ≤7 days apart)

Life-threatening mucositis, especially esophagitis and pneumonitis occurred in a trial in which gemcitabine was administered at a dose of 1000 mg/m^2 to patients with non-small cell lung cancer for up to 6 consecutive weeks concurrently with thoracic radiation.

Non-concurrent (given >7 days apart)

Excessive toxicity has not been observed when gemcitabine is administered more than 7 days before or after radiation. Radiation recall has been reported in patients who received gemcitabine after prior radiation.

Capillary Leak Syndrome (CLS): CLS with severe consequences has been reported in patients receiving gemcitabine as a single agent or in combination with other chemotherapeutic agents. Permanently discontinue AVGEMSI if CLS develops during therapy.

Posterior Reversible Encephalopathy Syndrome (PRES): PRES has been reported in patients receiving gemcitabine as a single agent or in combination with other chemotherapeutic agents. PRES can present with headache, seizure, lethargy, hypertension, confusion, blindness, and other visual and neurologic disturbances. Confirm the diagnosis of PRES with magnetic resonance imaging (MRI). Permanently discontinue AVGEMSI if PRES develops during therapy.

ADVERSE REACTIONS

The most common adverse reactions for the single agent (≥20%) are nausea/vomiting, anemia, increased aspartate aminotransferase (AST), increased alanine aminotransferase (ALT), neutropenia, increased alkaline phosphatase, proteinuria, fever, hematuria, rash, thrombocytopenia, dyspnea, and edema.

USE IN SPECIFIC POPULATIONS

Pregnancy: Advise pregnant women of the potential risk to a fetus with AVGEMSI.

Lactation: Advise women not to breastfeed during treatment with AVGEMSI.

Females and Males of Reproductive Potential: Advise females and males of reproductive potential to use effective contraception during treatment with AVGEMSI.

OVERDOSAGE

There is no known antidote for overdoses of gemcitabine. Myelosuppression, paresthesias, and severe rash were the principal toxicities seen when a single dose as high as 5700 mg/m^2 was administered by intravenous infusion over 30 minutes every 2 weeks to several patients in a dose-escalation study. In the event of suspected overdose, monitor with appropriate blood counts and provide supportive therapy, as necessary.

To report SUSPECTED ADVERSE REACTIONS, contact Avyxa Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information of AVGEMSI.

Notes

References:

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