

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.



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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



Effective 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 support
- Claims support
- Referrals to 501(c)(3) foundations
- Free product assistance
- Bridge supply
- Product replacement
- Copay assistance

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

To enroll, please choose one of the following options.

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



CALL NOW

Click on the link
below to begin
online enrollment



ENROLL
NOW

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



DOWNLOAD
NOW

Commercially eligible
patients prescribed an
AVYXA product may pay
as little as

\$0 per dose*

AVYXASSIST™		ELIGIBLE PATIENTS MAY PAY AS LITTLE AS \$0
BIN	025706	
PCN	IFX	
GROUP #	00000000	
MEMBER #	0000000000	
<small>Patients with questions, please call 866-939-8927</small>		

Our dedicated AVYXASSIST Patient Access Specialists work collaboratively with you to explore tailored affordability solutions. AVYXA aims to facilitate financial accessibility for eligible patients in need.



ENROLL
NOW

Copay Program Details for Eligible Patients

In some cases, the patient out-of-pocket cost for their AVYXA product could be as low as \$0.*

- Up to \$25,000 **per product** in annual benefits

*Please visit avyxassist.com/copay-assistance-program to see full Terms and Conditions.

Additional Assistance

Patients without insurance or who do not qualify for copay assistance through AVYXASSIST may qualify for free product assistance. Call an AVYXASSIST Patient Access Specialist to learn more.

Call 866-939-8927 or Fax 833-852-3420 | Monday through Friday, 8:00 AM to 8:00 PM ET

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

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

Nearly all drugs in the United States are assigned a unique National Drug Code (NDC), which identifies all currently manufactured drugs and is maintained by the U.S. Food and Drug Administration (FDA). NDCs are sometimes packaged with fewer than 11 digits—some have fewer than 10. However, for billing purposes, the NDC must be reported in the 11-digit 5-4-2 format, as shown above.

HCPCS Code

HCPCS Level II codes are used to identify most drugs and biologics administered in the office².

AVGEMSI™ Unique J-Code	Description
J9184	Injection, gemcitabine hydrochloride (avyxa), 200 mg

Note: While there are several HCPCS codes associated with gemcitabine products, **AVGEMSI** is assigned a unique HCPCS code (**J9184**). Please ensure the HCPCS code used matches the specific product purchased and administered.

J-Code Billing Unit Conversion

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 fluorouracil³.

The recommended dosage of AVGEMSI is 1,000 mg/m² intravenously over 30 minutes⁴. An individual with a body surface area of 1.9 m² receives 1900 mg of AVGEMSI™ in over 30 minutes. The service unit for J9184 is 200mg. Service units must be rounded to whole numbers. In this example, 2000mg is billed as 10 units.

CPT Drug Administration Codes

CPT codes are used to bill drug administration services in the physician's office and other outpatient settings.⁵ 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.⁶ Please schedule patients to ensure minimal disposal. 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™.⁷

CPT Code	Description	Place of Service (POS) ⁸
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance drug ⁹	<ul style="list-style-type: none"> Physician Office (11) Off-Campus Outpatient Hospital (19)
96417	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug), up to 1 hour ¹⁰	<ul style="list-style-type: none"> On-Campus Outpatient Hospital (22)

CPT codes, descriptions, and other data only are copyright 2022 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Revenue Codes

Claim Item	Revenue Code	Description	Place of Service (POS)
AVGEMSI™	0636	Drugs Requiring Detailed Coding ¹¹	<ul style="list-style-type: none"> Off-Campus Outpatient Hospital (19)
Drug Administration	0335	Chemotherapy Administration – IV ¹²	<ul style="list-style-type: none"> On-Campus Outpatient Hospital (22)

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.¹³

Please use the code for the cancer that is being treated with AVGEMSI. Denials can be avoided if the most specific code is used for the AVGEMSI indication treated at each encounter. We have listed specific codes below.

International Classification of Disease, 10th Edition, Clinical Modification Codes for AVGEMSI™	
Indication	ICD-10-CM Codes
Ovarian Cancer ¹⁴	C56.1, C65.2, C56.3, C56.9
Breast Cancer ¹⁵	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 ¹⁶	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 ¹⁷	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 in the FL descriptor.

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 42

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. The NDC Unit of Measurement for AVGEMSI is ML.

FL 44

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

Enter the appropriate HCPCS code: **J9184, Injection, gemcitabine hydrochloride (avyxa), 200 mg.**

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

1		2		3a PAT CONTL #		4 TYPE OF BILL	
5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH			
8 PATIENT NAME		9 PATIENT ADDRESS					
10 BIRTHDATE	11 SEX	12 DATE	ADMISSION 13 HR	14 TYPE	15 SRC	16 DHR	17 STAT
18		19		20		21	
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26		27		28		29 ACCT STATE	
30		31 OCCURRENCE DATE		32 OCCURRENCE DATE		33 OCCURRENCE DATE	
34		35 CODE		36 OCCURRENCE SPAN FROM		37 THROUGH	
38		39 VALUE CODES AMOUNT		40 VALUE CODES AMOUNT		41 VALUE CODES AMOUNT	
42 REV CD		43 DESCRIPTION		44 HCPCS / RATE / HPPS CODE		45 SERV DATE	
46		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49	
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54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI		57 OTHER PRV ID	
58 INSURED'S NAME		59 PREL		60 INSURED'S UNIQUE ID		61 GROUP NAME	
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10		11		12		13	
14		15		16		17	
18		19		20		21	
22		23		24		25	
26		27		28		29	
30		31		32		33	
34		35		36		37	
38		39		40		41	
42		43		44		45	
46		47		48		49	
50		51		52		53	
54		55		56		57	
58		59		60		61	
62		63		64		65	
66		67		68		69	
70		71		72		73	
74		75		76		77	
78		79		80		81	
82		83		84		85	
86		87					

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**

The image shows a CMS-1450 claim form with several red callouts pointing to specific fields:

- FL 45** points to field 46 (SERV UNITS).
- FL 46** points to field 39 (VALUE CODES AMT).
- FL 63** points to field 63 (TREATMENT AUTHORIZATION CODES).
- FL 67A-Q** points to field 80 (REMARKS).

Other visible fields include: 1-4 (PATIENT INFO), 5-8 (PATIENT ADDRESS), 9-10 (BIRTHDATE), 11-17 (ADMISSION), 18-21 (CONDITION CODES), 22-28 (STATE), 29-37 (OCCURRENCE CODES), 38 (TOTAL CHARGES), 39-41 (VALUE CODES AMT), 42-43 (REV CD), 44 (HCPCS / RATE / HR), 45 (SERV DATE), 46 (SERV UNITS), 47 (TOTAL CHARGES), 48 (NON-COVERED CHARGES), 49 (OTHER PRV ID), 50-53 (PAYER NAME), 54 (HEALTH PLAN ID), 55 (EST. AMOUNT DUE), 56 (NPI), 57 (INSURER'S NAME), 58 (INSURER'S UNIQUE ID), 59 (GROUP NAME), 60 (INSURANCE GROUP NO.), 61 (EMPLOYER NAME), 62 (DOCUMENT CONTROL NUMBER), 63 (TREATMENT AUTHORIZATION CODES), 64 (C50.111), 65 (PPS CODE), 66 (ATTENDING), 67 (OPERATING), 68 (OTHER), 69 (OTHER), 70 (OTHER), 71 (OTHER), 72 (OTHER), 73 (OTHER), 74 (PRINCIPAL PROCEDURE), 75 (OTHER PROCEDURE), 76 (OTHER PROCEDURE), 77 (OTHER PROCEDURE), 78 (OTHER PROCEDURE), 79 (OTHER PROCEDURE), 80 (REMARKS).

[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 the CMS-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](https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf)

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Sample Claim Form CMS-1500

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: J9184, Injection, gemcitabine hydrochloride (avyxa), 200 mg 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 21

Item 24D

Item 24E

Item 23

Item 24E

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

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



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

<input type="checkbox"/> PICA <input type="checkbox"/> PICA									
1. MEDICARE <input type="checkbox"/> (Medicare#)	MEDICAID <input type="checkbox"/> (Medicaid#)	TRICARE <input type="checkbox"/> (TRICARE#)	CHAMPVA <input type="checkbox"/> (Member ID#)	GROUP HEALTH PLAN <input type="checkbox"/> (ID#)	EEOC/CLUB <input type="checkbox"/> (ID#)	OTHER <input type="checkbox"/> (ID#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1)		
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE MM DD YY		4. INSURED'S NAME (Last Name, First Name, Middle Initial)		5. PATIENT'S ADDRESS (No., Street)
6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>					7. INSURED'S ADDRESS (No., Street)		CITY	STATE	ZIP CODE
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State) _____ c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>		11. INSURED'S POLICY GROUP OR FECA NUMBER		13. INSURED'S DATE OF BIRTH MM DD YY
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.					14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (MM/DD/YY) QUAL		15. OTHER DATE MM DD YY		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)					17a. NPI		17b. NPI		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: Relate A-L to service line below (24E) (ICD Ind.)					20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/>		22. RESUBMISSION CODE		23. PRIOR AUTHORIZATION NUMBER
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY		D. PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS)		E. DIAGNOSIS POINTER		F. \$ CHARGES	G. DAYS OR UNITS	H. FEE#	I. ID. QUAL
25. FEDERAL TAX I.D. NUMBER		SSN/EIN	26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? (For Opt. Out) YES <input type="checkbox"/> NO <input type="checkbox"/>	28. TOTAL CHARGE \$	29. AMOUNT PAID \$	30. Paid for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof)					32. SERVICE FACILITY LOCATION INFORMATION				
SIGNED _____ DATE _____					a. NPI		b. NPI		33. BILLING PROVIDER INFO & PH# ()

CARRIER
PATIENT AND INSURED INFORMATION
PHYSICIAN OR SUPPLIER INFORMATION

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. The NDC Unit of Measurement for AVGEMSI™ is ML.

Item 24G

**(Electronic Claim Form = Loop
2400, SV104):**

Enter the number of service units for each item.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/82

PICA										PICA									
1. MEDICARE <input type="checkbox"/> (Medicare#) MEDICAID <input type="checkbox"/> (Medicaid#) TRICARE <input type="checkbox"/> (ID#/DOD#) CHAMPVA <input type="checkbox"/> (Member ID#) GROUP HEALTH PLAN <input type="checkbox"/> (ID#) FECA SEL (UNG) <input type="checkbox"/> (ID#) OTHER <input type="checkbox"/> (ID#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1)																		
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>			4. INSURED'S NAME (Last Name, First Name, Middle Initial)											
5. PATIENT'S ADDRESS (No., Street)					6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>			7. INSURED'S ADDRESS (No., Street)											
CITY		STATE			CITY		STATE			CITY		STATE							
ZIP CODE		TELEPHONE (Include Area Code)			ZIP CODE		TELEPHONE (Include Area Code)			ZIP CODE		TELEPHONE (Include Area Code)							
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO:			11. INSURED'S POLICY GROUP OR FECA NUMBER											
a. OTHER INSURED'S POLICY OR GROUP NUMBER					a. EMPLOYMENT? (Current or Previous) YES <input type="checkbox"/> NO <input type="checkbox"/>			a. INSURED'S DATE OF BIRTH MM DD YY SEX M <input type="checkbox"/> F <input type="checkbox"/>											
b. RESERVED FOR NUCC USE					b. AUTO ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)			b. OTHER CLAIM ID (Designated by NUCC)											
c. RESERVED FOR NUCC USE					c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/>			c. INSURANCE PLAN NAME OR PROGRAM NAME											
d. INSURANCE PLAN NAME OR PROGRAM NAME					10d. CLAIM CODES (Designated by NUCC)			d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> If yes, complete items 9, 9a, and 9d.											
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below.									
SIGNED _____ DATE _____					SIGNED _____														
14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY QUAL					15. OTHER DATE MM DD YY			16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY											
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE					17a. ICD Ind. _____			18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY											
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)					17b. NPI _____			20. OUTSIDE LAB? YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES _____											
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. Relate A-L to service line below (24B) ICD Ind. _____										22. RESUBMISSION CODE _____ ORIGINAL REF. NO. _____									
A _____		B _____		C _____		D _____		E _____		F _____		G _____		H _____		I _____		J _____	
K _____		L _____		M _____		N _____		O _____		P _____		Q _____		R _____		S _____		T _____	
U _____		V _____		W _____		X _____		Y _____		Z _____		AA _____		AB _____		AC _____		AD _____	
AE _____		AF _____		AG _____		AH _____		AI _____		AJ _____		AK _____		AL _____		AM _____		AN _____	
AO _____		AP _____		AQ _____		AR _____		AS _____		AT _____		AU _____		AV _____		AW _____		AX _____	
AY _____		AZ _____		BA _____		BB _____		BC _____		BD _____		BE _____		BF _____		BG _____		BH _____	
BI _____		BJ _____		BK _____		BL _____		BM _____		BN _____		BO _____		BP _____		BQ _____		BR _____	
BS _____		BT _____		BU _____		BV _____		BW _____		BX _____		BY _____		BZ _____		CA _____		CB _____	
CC _____		CD _____		CE _____		CF _____		CG _____		CH _____		CI _____		CJ _____		CK _____		CL _____	
CM _____		CN _____		CO _____		CP _____		CQ _____		CR _____		CS _____		CT _____		CU _____		CV _____	
CW _____		CX _____		CY _____		CZ _____		DA _____		DB _____		DC _____		DD _____		DE _____		DF _____	
DG _____		DH _____		DI _____		DJ _____		DK _____		DL _____		DM _____		DN _____		DO _____		DP _____	
DQ _____		DR _____		DS _____		DT _____		DU _____		DV _____		DW _____		DX _____		DY _____		DZ _____	
EA _____		EB _____		EC _____		ED _____		EE _____		EF _____		EG _____		EH _____		EI _____		EJ _____	
EK _____		EL _____		EM _____		EN _____		EO _____		EP _____		EQ _____		ER _____		ES _____		ET _____	
EU _____		EV _____		EW _____		EX _____		EY _____		EZ _____		FA _____		FB _____		FC _____		FD _____	
FE _____		FF _____		FG _____		FH _____		FI _____		FJ _____		FK _____		FL _____		FO _____		FP _____	
FQ _____		FR _____		FS _____		FT _____		FU _____		FV _____		FW _____		FX _____		FY _____		FZ _____	
GA _____		GB _____		GC _____		GD _____		GE _____		GF _____		GG _____		GH _____		GI _____		GJ _____	
GK _____		GL _____		GM _____		GN _____		GO _____		GP _____		GQ _____		GR _____		GS _____		GT _____	
GU _____		GV _____		GW _____		GX _____		GY _____		GZ _____		HA _____		HB _____		HC _____		HD _____	
HE _____		HF _____		HG _____		HH _____		HI _____		HJ _____		HK _____		HL _____		HO _____		HP _____	
HQ _____		HR _____		HS _____		HT _____		HU _____		HV _____		HW _____		HX _____		HY _____		HZ _____	
IA _____		IB _____		IC _____		ID _____		IE _____		IF _____		IG _____		IH _____		II _____		IJ _____	
IK _____		IL _____		IM _____		IN _____		IO _____		IP _____		IQ _____		IR _____		IS _____		IT _____	
IU _____		IV _____		IW _____		IX _____		IY _____		IZ _____		JA _____		JB _____		JC _____		JD _____	
JE _____		JF _____		JG _____		JH _____		JI _____		JJ _____		JK _____		JL _____		JO _____		JP _____	
JQ _____		JR _____		JS _____		JT _____		JU _____		JV _____		JW _____		JX _____		JY _____		JZ _____	
KA _____		KB _____		KC _____		KD _____		KE _____		KF _____		KG _____		KH _____		KI _____		KJ _____	
KK _____		KL _____		KM _____		KN _____		KO _____		KP _____		KQ _____		KR _____		KS _____		KT _____	
KU _____		KV _____		KW _____		KX _____		KY _____		KZ _____		LA _____		LB _____		LC _____		LD _____	
LE _____		LF _____		LG _____		LH _____		LI _____		LJ _____		LK _____		LL _____		LO _____		LP _____	
LQ _____		LR _____		LS _____		LT _____		LU _____		LV _____		LW _____		LX _____		LY _____		LZ _____	
MA _____		MB _____		MC _____		MD _____		ME _____		MF _____		MG _____		MH _____		MI _____		MJ _____	
MK _____		ML _____		MM _____		MN _____		MO _____		MP _____		MQ _____		MR _____		MS _____		MT _____	
MU _____		MV _____		MW _____		MX _____		MY _____		MZ _____		NA _____		NB _____		NC _____		ND _____	
NE _____		NF _____		NG _____		NH _____		NI _____		NJ _____		NK _____		NL _____		NO _____		NP _____	
NQ _____		NR _____		NS _____		NT _____		NU _____		NV _____		NW _____		NX _____		NY _____		NZ _____	
OA _____		OB _____		OC _____		OD _____		OE _____		OF _____		OG _____		OH _____		OI _____		OJ _____	
OK _____		OL _____		OM _____		ON _____		OO _____		OP _____		OQ _____		OR _____		OS _____		OT _____	
OU _____		OV _____		OW _____		OX _____		OY _____		OZ _____		PA _____		PB _____		PC _____		PD _____	
PE _____		PF _____		PG _____		PH _____		PI _____		PJ _____		PK _____		PL _____		PO _____		PP _____	
PQ _____		PR _____		PS _____		PT _____		PU _____		PV _____		PW _____		PX _____		PY _____		PZ _____	
QA _____		QB _____		QC _____		QD _____		QE _____		QF _____		QG _____		QH _____		QI _____		QJ _____	
QK _____		QL _____		QM _____		QN _____		QO _____		QP _____		QQ _____		QR _____		QS _____		QT _____	
QU _____		QV _____		QW _____		QX _____		QY _____		QZ _____		RA _____		RB _____		RC _____		RD _____	
RE _____		RF _____		RG _____		RH _____		RI _____		RJ _____		RK _____		RL _____		RO _____		RP _____	
RQ _____		RR _____		RS _____		RT _____		RU _____		RV _____		RW _____		RX _____		RY _____		RZ _____	
SA _____		SB _____		SC _____		SD _____		SE _____		SF _____		SG _____		SH _____		SI _____		SJ _____	
SK _____		SL _____		SM _____		SN _____		SO _____		SP _____		SQ _____		SR _____		SS _____		ST _____	
SU _____		SV _____		SW _____		SX _____		SY _____		SZ _____		TA _____		TB _____		TC _____		TD _____	
TE _____		TF _____		TG _____		TH _____		TI _____		TJ _____		TK _____		TL _____		TO _____		TP _____	
TQ _____		TR _____		TS _____		TT _____		TU _____		TV _____		TW _____		TX _____		TY _____		TZ _____	
UA _____		UB _____		UC _____		UD _____		UE _____		UF _____		UG _____		UH _____		UI _____		UJ _____	
UK _____		UL _____		UM _____		UN _____		UO _____		UP _____		UQ _____		UR _____		US _____		UT _____	
UU _____		UV _____		UW _____		UX _____		UY _____		UZ _____		VA _____		VB _____		VC _____		VD _____	
VE _____		VF _____		VG _____		VH _____		VI _____		VJ _____		VK _____		VL _____		VO _____		VP _____	
VQ _____		VR _____		VS _____		VT _____		VU _____		VV _____		VW _____		VX _____		VY _____		VZ _____	
WA _____		WB _____		WC _____		WD _____		WE _____		WF _____		WG _____		WH _____		WI _____		WJ _____	
WK _____		WL _____		WM _____		WN _____		WO _____		WP _____		WQ _____		WR _____		WS _____		WT _____	
WU _____		WV _____		WW _____		WX _____		WY _____		WZ _____		XA _____		XB _____		XC _____		XD _____	
XE _____		XF _____		XG _____		XH _____		XI _____		XJ _____		XK _____		XL _____		XO _____		XP _____	
XQ _____		XR _____		XS _____		XT _____		XU _____		XV _____		XW _____		XX _____		XY _____		XZ _____	
YA _____		YB _____		YC _____		YD _____		YE _____		YF _____		YG _____		YH _____		YI _____		YJ _____	
YK _____		YL _____		YM _____		YN _____		YO _____		YP _____		YQ _____		YR _____		YS _____		YT _____	
YU _____		YV _____		YW _____		YX _____		YY _____		YZ _____		ZA _____		ZB _____		ZC _____		ZD _____	
ZE _____		ZF _____		ZG _____		ZH _____		ZI _____		ZJ _____		ZK _____		ZL _____		ZO _____		ZP _____	
ZQ _____		ZR _____		ZS _____		ZT _____		ZU _____		ZV _____		ZW _____		ZX _____		ZY _____		ZZ _____	
25. FEDERAL TAX I.D. NUMBER SSN/EIN					26. PATIENT'S ACCOUNT NO.			27. ACCEPT ASSIGNMENT? YES <input type="checkbox"/> NO <input type="checkbox"/>		28. TOTAL CHARGE \$		29. AMOUNT PAID \$		30. Rsvd for NUCC Use					
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (Certify that the statements on the reverse apply to this bill and are made a part thereof.)					32. SERVICE FACILITY LOCATION INFORMATION					33. BILLING PROVIDER INFO & PH # ()									
SIGNED _____ DATE _____					a. NPI _____ b. _____					a. NPI _____ b. _____									

Item 24A-B

Item 24G

[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 the CMS-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](https://dominoapps.palmettogba.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf/$File/EDI_837I_v5010A2_crosswalk.pdf)

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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/m² 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 ($\geq 20\%$) 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/m² 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.

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