

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.

Please see Important Safety Information on pages 3 and 15-16 and full [Prescribing Information](#) for AVGEMSI™.

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



Unique J-Code Coming
January 1, 2026

Please see Important Safety Information on pages 3 and 15-16
and full [Prescribing Information](#) for AVGEMSI™.



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](#)



Online

Click on the link below
to begin your online
enrollment

[ENROLL NOW](#)



Fax

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

[DOWNLOAD NOW](#)

OR

OR

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

Please see Important Safety Information on pages 3 and 15-16
and full [Prescribing Information](#) for AVGEMSITM.

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.

NDCs¹

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, it is vital to include the following information when billing:

- Name of Drug
- Strength and Dosage
- National Drug Code (NDC)
- Pricing for the product, if available³
- Recommended to also attach invoice and clinical notes

J-Code Billing Unit Conversion

One milligram of AVGEMSI™ equals one (1) J-Code billing unit. When billing for quantities greater than one milligram, indicate the total amount used as a multiple of billing units on the claim form.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/m² intravenously over 30 minutes.⁶

An individual with a body surface area of 1.9 m² receives 1.9 g of AVGEMSI™ over 30 minutes. In this example, the patient received 1,900 billed J-Code units of AVGEMSI™.

Please see Important Safety Information on pages 3 and 15-16
and full [Prescribing Information](#) for AVGEMSI™.

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

CPT Code	Description	Place of Service (POS) ¹¹
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)On-Campus Outpatient Hospital (22)
96417	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug), up to 1 hour ¹⁰	

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.

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™¹².

Revenue Codes

Claim Item	Revenue Code	Description	Place of Service (POS)
AVGEMSI™	0636	Drugs Requiring Detailed Coding ¹³	<ul style="list-style-type: none">Off-Campus Outpatient Hospital (19)
Drug Administration	0335	Chemotherapy Administration – IV ¹⁴	<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.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.

Please see Important Safety Information on pages 3 and 15-16 and full [Prescribing Information](#) for AVGEMSI™.

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

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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

Please see Important Safety Information on pages 3 and 15-16
and full [Prescribing Information](#) for AVGEMS!™.

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

Please see Important Safety Information on pages 3 and 15-16
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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 AVGEMSIT™ 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 42

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50. PAYER NAME	51. HEALTH PLAN ID	52. HCPCS CODE	53. NPPS CODE	54. PRIOR PAYMENTS	55. EST. AMOUNT DUE	56. NPI	57. OTHER PRV ID	58. INSURED'S NAME	59. P. REL	60. INSURED'S UNIQUE ID	61. GROUP NAME	62. INSURANCE GROUP NO.	63. TREATMENT AUTHORIZATION CODES	64. DOCUMENT CONTROL NUMBER	65. EMPLOYER NAME	66	67	68	69. ADMIT DX	70. PATIENT REASON DX	71. PPS CODE	72. ECI	73	74. PRINCIPAL PROCEDURE CODE	75. OTHER PROCEDURE CODE	76. ATTENDING NPI	77. OPERATING NPI	78. OTHER NPI	79. OTHER NPI	80. REMARKS	81. C2	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	345	346	347	348	349	350	351	352	353	354	355	356	357	358	359	360	361	362	363	364	365	366	367	368	369	370	371	372	373	374	375	376	377	378	379	380	381	382	383	384	385	386	387	388	389	390	391	392	393	394	395	396	397	398	399	400	401	402	403	404	405	406	407	408	409	410	411	412	413	414	415	416	417	418	419	420	421	422	423	424	425	426	427	428	429	430	431	432	433	434	435	436	437	438	439	440	441	442	443	444	445	446	447	448	449	450	451	452	453	454	455	456	457	458	459	460	461	462	463	464	465	466	467	468	469	470	471	472	473	474	475	476	477	478	479	480	481	482	483	484	485	486	487	488	489	490	491	492	493	494	495	496	497	498	499	500	501	502	503	504	505	506	507	508	509	510	511	512	513	514	515	516	517	518	519	520	521	522	523	524	525	526	527	528	529	530	531	532	533	534	535	536	537	538	539	540	541	542	543	544	545	546	547	548	549	550	551	552	553	554	555	556	557	558	559	560	561	562	563	564	565	566	567	568	569	570	571	572	573	574	575	576	577	578	579	580	581	582	583	584	585	586	587	588	589	590	591	592	593	594	595	596	597	598	599	600	601	602	603	604	605	606	607	608	609	610	611	612	613	614	615	616	617	618	619	620	621	622	623	624	625	626	627	628	629	630	631	632	633	634	635	636	637	638	639	640	641	642	643	644	645	646	647	648	649	650	651	652	653	654	655	656	657	658	659	660	661	662	663	664	665	666	667	668	669	670	671	672	673	674	675	676	677	678	679	680	681	682	683	684	685	686	687	688	689	690	691	692	693	694	695	696	697	698	699	700	701	702	703	704	705	706	707	708	709	710	711	712	713	714	715	716	717	718	719	720	721	722	723	724	725	726	727	728	729	730	731	732	733	734	735	736	737	738	739	740	741	742	743	744	745	746	747	748	749	750	751	752	753	754	755	756	757	758	759	760	761	762	763	764	765	766	767	768	769	770	771	772	773	774	775	776	777	778	779	780	781	782	783	784	785	786	787	788	789	790	791	792	793	794	795	796	797	798	799	800	801	802	803	804	805	806	807	808	809	810	811	812	813	814	815	816	817	818	819	820	821	822	823	824	825	826	827	828	829	830	831	832	833	834	835	836	837	838	839	840	841	842	843	844	845	846	847	848	849	850	851	852	853	854	855	856	857	858	859	860	861	862	863	864	865	866	867	868	869	870	871	872	873	874	875	876	877	878	879	880	881	882	883	884	885	886	887	888	889	890	891	892	893	894	895	896	897	898	899	900	901	902	903	904	905	906	907	908	909	910	911	912	913	914	915	916	917	918	919	920	921	922	923	924	925	926	927	928	929	930	931	932	933	934	935	936	937	938	939	940	941	942	943	944	945	946	947	948	949	950	951	952	953	954	955	956	957	958	959	960	961	962	963	964	965	966	967	968	969	970	971	972	973	974	975	976	977	978	979	980	981	982	983	984	985	986	987	988	989	990	991	992	993	994	995	996	997	998	999	1000

Please see Important Safety Information on pages 3 and 15-16 and full [Prescribing Information](#) for AVGEMSIT™.

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****FL 63****FL 67A-Q**

1	2	3a PAT CNT #	4 TYPE OF BILL				
		b. MED REC #					
		5 FED. TAX NO.	6 STATEMENT COVERS PERIOD FROM 7				
8 PATIENT NAME		9 PATIENT ADDRESS	a				
10 BIRTHDATE	11 SEX	12 DATE ADMISSION 13 HR 14 TYPE 15 SRS	16 DHR 17 STAT 18 19 20 21 22 23 24 25 26 27 28 29 ACCT 30 STATE				
31 OCCURRENCE DATE CODE	32 OCCURRENCE DATE CODE	33 OCCURRENCE DATE CODE	34 OCCURRENCE DATE CODE	35 OCCURRENCE SPAN FROM	36 OCCURRENCE SPAN FROM	37	
b				THROUGH	THROUGH		
38				39 CODE VALUE CODES AMOUNT	40 CODE VALUE CODES AMOUNT	41 CODE VALUE CODES AMOUNT	
a				b			
c				c			
42 REV CO.	43 DESCRIPTION	44 HCPCS / RATE / HRS	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
1							1
2							2
3							3
4							4
5							5
6							6
7							7
8							8
9							9
10							10
11							11
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13							13
14							14
15							15
16							16
17							17
18							18
19							19
20							20
21							21
22							22
23	PAGE ____ OF ____	CREATION DATE	TOTALS ➡				
50 PAYER NAME	51 HEALTH PLAN ID	52 REC. INFO	53 REC. INFO	54 PRIOR PAYMENTS	55 EST. AMOUNT DUE	56 NPI	
A						57	A
B						OTHER	B
C						PRV ID	C
58 INSURED'S NAME	59 PREL	60 INSURED'S UNIQUE ID	61 GROUP NAME	62 INSURANCE GROUP NO.			
A							A
B							B
C							C
63 TREATMENT AUTHORIZATION CODES	64 DOCUMENT CONTROL NUMBER	65 EMPLOYER NAME					
A							A
B							B
C							C
66 C50.111	A	B	C	D	E	F	G
67 DX							68
68 ADMIT DX	69 PATIENT REASON DX	70 OTHER PROCEDURE CODE	71 OTHER PROCEDURE CODE	72 EDI	73		
74 a. PRINCIPAL PROCEDURE DATE	b. OTHER PROCEDURE DATE	c. OTHER PROCEDURE DATE	d. OTHER PROCEDURE DATE	e. OTHER PROCEDURE DATE	f. OTHER PROCEDURE DATE	76 ATTENDING NPI	77 OPERATING NPI
70						LAST	LAST
71						FIRST	FIRST
72						LAST	LAST
73						FIRST	FIRST
78 OTHER	NPI	79 OTHER	NPI	80 REMARKS	81 CCR	82 OTHER	83 OTHER
a		b			a		
b		c			b		
c		d			c		
d					d		
84 APPROVED OMB NO. 0938-0997	NUBC™ National Uniform Bill of Costs	THE CERTIFICATIONS ON THE REVERSE APPLY TO THIS BILL AND ARE MADE A PART HEREOF.					

[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. Palmettoga.com. Palmetto GBA, Accessed April 3, 2023. [\\$File/EDI_837I_v5010A2_crosswalk.pdf](https://dominoapps.palmettoga.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf)

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Please see Important Safety Information on pages 3 and 15-16
and full [Prescribing Information](#) for AVGEMS™.

Sample Claim Form CMS-1500

Box 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.



HEALTH INSURANCE CLAIM FORM

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

PICA										PICA	
1. MEDICARE	MEDICAID	TRICARE	CHAMPVA	GROUP HEALTH PLAN (/D#)	FECA BLKLNG (/D#)	OTHER (/D#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1)				
<input type="checkbox"/> Medicare#	<input type="checkbox"/> Medicaid#	<input type="checkbox"/> TRICARE	<input type="checkbox"/> CHAMPVA	<input type="checkbox"/> Group Health Plan (/D#)	<input type="checkbox"/> FECA BLKLNG (/D#)	<input type="checkbox"/> Other (/D#)					
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) CITY <input type="checkbox"/> STATE							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 <input type="checkbox"/> STATE	
ZIP CODE <input type="checkbox"/>		TELEPHONE (Include Area Code) <input type="checkbox"/>					ZIP CODE <input type="checkbox"/>		TELEPHONE (Include Area Code) <input type="checkbox"/>		
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)							10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO				11. INSURED'S POLICY GROUP OR FECA NUMBER
b. RESERVED FOR NUCC USE							b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> PLACE (State)				a. INSURED'S DATE OF BIRTH MM DD YY M <input type="checkbox"/> F <input type="checkbox"/>
c. RESERVED FOR NUCC USE							c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO				b. OTHER CLAIM ID (Designated by NUCC)
d. INSURANCE PLAN NAME OR PROGRAM NAME							10d. CLAIM CODES (Designated by NUCC)				c. INSURANCE PLAN NAME OR PROGRAM NAME
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 as 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.				d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>
SIGNED <input type="checkbox"/> DATE <input type="checkbox"/>							SIGNED <input type="checkbox"/>				
14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY <input type="checkbox"/> QUAL							15. OTHER DATE MM DD YY <input type="checkbox"/> QUAL				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. <input type="checkbox"/> 17b. <input type="checkbox"/> NPI							18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY				20. OUTSIDE LAB? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> \$ CHARGES
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)							21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY: Relate A-L to service line below (24E) ICD Ind. <input type="checkbox"/>				22. RESUBMISSION CODE <input type="checkbox"/> ORIGINAL REF. NO. <input type="checkbox"/>
A. <input type="checkbox"/> B. <input type="checkbox"/> C. <input type="checkbox"/> D. <input type="checkbox"/> E. <input type="checkbox"/> F. <input type="checkbox"/> G. <input type="checkbox"/> H. <input type="checkbox"/> I. <input type="checkbox"/> J. <input type="checkbox"/> K. <input type="checkbox"/> L. <input type="checkbox"/>							D. PROCEDURES, SERVICES, OR SUPPLIES (Eg: Unusual Circumstances) CPT/HCPCS <input type="checkbox"/> MODIFIER				23. PRIOR AUTHORIZATION NUMBER <input type="checkbox"/> Box 23
24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY							E. DIAGNOSIS POINTER \$ CHARGES				F. G. H. I. J. RENDERING PROVIDER ID. #
1. <input type="checkbox"/> 2. <input type="checkbox"/> 3. <input type="checkbox"/> 4. <input type="checkbox"/> 5. <input type="checkbox"/> 6. <input type="checkbox"/>							2. <input type="checkbox"/> 3. <input type="checkbox"/> 4. <input type="checkbox"/> 5. <input type="checkbox"/> 6. <input type="checkbox"/>				1. <input type="checkbox"/> NPI 2. <input type="checkbox"/> NPI 3. <input type="checkbox"/> NPI 4. <input type="checkbox"/> NPI 5. <input type="checkbox"/> NPI 6. <input type="checkbox"/> NPI
25. FEDERAL TAX I.D. NUMBER SSN EIN <input type="checkbox"/>							26. PATIENT'S ACCOUNT NO. <input type="checkbox"/> 27. ACCEPT & ASSIGNMENT? (For Govt. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>				28. TOTAL CHARGE <input type="checkbox"/> \$ <input type="checkbox"/> 29. AMOUNT PAID <input type="checkbox"/> \$ <input type="checkbox"/> 30. Paid for NUCC Use <input type="checkbox"/>
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 a. <input type="checkbox"/> NPI b. <input type="checkbox"/>				33. BILLING PROVIDER INFO & PH# <input type="checkbox"/> () a. <input type="checkbox"/> NPI b. <input type="checkbox"/>
NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB 0938-1197 FORM 1500 (02-12)											

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

Box 23

(Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.

Box 24D

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

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

Box 21

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

Box 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.

Box 24D

Box 24E

Box 23

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

Box 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 quantity and, last, the unit measurement code.

Box 24G

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

Enter the number of J-Code service units for each item.

Box 24A-B



HEALTH INSURANCE CLAIM FORM

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

1. MEDICARE [Medicare#]		MEDICAID [Medicaid#]		TRICARE [TRICARE#]		CHAMPVA [Champva#]		GROUP HEALTH PLAN [Group#]		FECA [FECA#]		BU/UNG [BU/UNG#]		OTHER [Other#]		a. INSURED'S I.D. NUMBER (For Program in Item 1)		PICA [PICA#]																	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)												3. PATIENT'S BIRTH DATE MM DD YY		SEX M [] F []		4. INSURED'S NAME (Last Name, First Name, Middle Initial)																			
5. PATIENT'S ADDRESS (No., Street)												6. PATIENT RELATIONSHIP TO INSURED Self [] Spouse [] Child [] Other []												7. INSURED'S ADDRESS (No., Street)											
CITY						STATE						CITY						STATE																	
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: a. EMPLOYMENT? (Current or Previous) [] YES [] NO												11. INSURED'S POLICY GROUP OR FECA NUMBER											
b. RESERVED FOR NUCC USE												b. AUTO ACCIDENT? [] YES [] NO PLACE (State)												a. INSURED'S DATE OF BIRTH MM DD YY M [] F []											
c. RESERVED FOR NUCC USE												c. OTHER ACCIDENT? [] YES [] NO												b. OTHER CLAIM ID (Designated by NUCC)											
d. INSURANCE PLAN NAME OR PROGRAM NAME												d. IS THERE ANOTHER HEALTH BENEFIT PLAN? [] YES [] NO // if yes, complete items 9, 9a, and 9d.												c. INSURANCE PLAN NAME OR PROGRAM NAME											
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.												14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (MM/YY) QUAL											
15. OTHER DATE (MM/YY) QUAL												16. DATE(S) PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY																							
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. [] 17b. NPI []												18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY																							
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) A. [] B. [] C. [] D. [] E. [] F. [] G. [] H. [] I. [] J. [] K. [] L. []												20. OUTSIDE LAB? \$ CHARGES [] YES [] NO																							
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. []												22. RESUBMISSION CODE ORIGINAL REF. NO.																							
24. a. DATE(S) OF SERVICE From MM DD YY To MM DD YY b. PLACE OF SERVICE EMG c. PROCEDURES, SERVICES, OR SUPPLIES CPT/HCPCS d. MODIFIER e. DIAGNOSIS PONTER												25. FEDERAL TAX I.D. NUMBER SSN EIN [] 26. PATIENT'S ACCOUNT NO. [] 27. ACCEPT ASSIGNMENT? For govt claims, see back [] YES [] NO												28. TOTAL CHARGE \$ [] 29. AMOUNT PAID \$ [] 30. Rsd 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 hereof.)												32. SERVICE FACILITY LOCATION INFORMATION a. NPI [] b. []												33. BILLING PROVIDER INFO & PH# () a. NPI [] b. []											
SIGNED [] DATE []												PLEASE PRINT OR TYPE												APPROVED OMB 0938-1197 FORM 1500 (02-12)											

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

[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. Palmettoga.com. Palmetto GBA, Accessed April 3, 2023. [\\$File/EDI_837I_v5010A2_crosswalk.pdf](https://dominoapps.palmettoga.com/palmetto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf)

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and full **Prescribing Information** for AVGEMS™.

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/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

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