INFUGEM™
Billing and Coding Guide

INDICATIONS AND USAGE

INFUGEM (gemcitabine hydrochloride in 0.9% sodium chloride injection) is a nucleoside metabolic inhibitor indicated for:

Ovarian Cancer: in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

Breast Cancer: 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.

Non-Small Cell Lung Cancer: in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information on pages 22-23 and accompanying Full Prescribing Information.

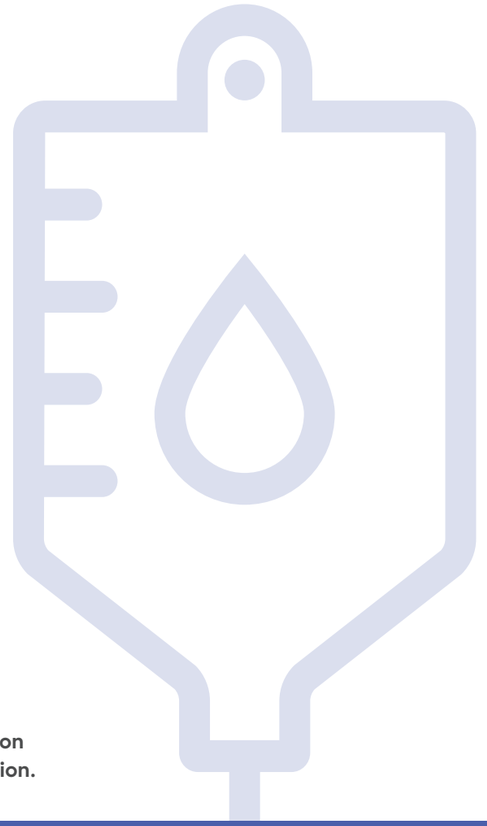
INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Product Description

INFUGEM™ (gemcitabine hydrochloride in 0.9% sodium chloride injection), 10 mg/mL for intravenous (IV) use in a ready-to-infuse (RTI) bag is a nucleoside metabolic inhibitor.

INFUGEM™ utilizes a novel technology that enables cytotoxic oncology products to be premixed in a sterile setting and to be supplied to prescribers in RTI infusion bags. Through dose banding, standardized doses of IV cytotoxic drugs are used for ranges of doses calculated for individual patients.



Please see Indications and Important Safety Information on pages 22-23 and accompanying Full Prescribing Information.

Indications

The FDA-Approved Indications for INFUGEM™ Are[1]:

- 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 (NSCLC)**
- As a single agent for the treatment of **pancreatic cancer**

Advanced ovarian cancer

Ovarian cancer is the second most common cancer of the reproductive organs among women in the United States. In its advanced stage, ovarian cancer may spread beyond the reproductive system and pelvis to other organs, such as the liver, lungs, brain, and/or skin. There are several different types of cancer that can develop in the ovary; epithelial ovarian cancer (EOC) is the most common.[2] A representative list of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes can be found on page 16.

Metastatic breast cancer

Breast cancer is the most common cancer diagnosed in women in the United States after skin cancer. In its metastatic form, the disease may spread beyond the breast to another part of the body, most commonly the liver, brain, bones, or lungs.[3] A representative list of ICD-10-CM diagnosis codes can be found on page 17.

Non-small cell lung cancer

NSCLC is the most common form of lung cancer; 80% to 85% of those with lung cancer have NSCLC. The most common subtypes of NSCLC are squamous cell (epidermoid) carcinoma – often linked to a history of smoking – and large cell (undifferentiated) carcinoma.[4] A representative list of ICD-10-CM diagnosis codes can be found on page 18.

Pancreatic cancer

Pancreatic cancer begins in the tissues of the pancreas and typically spreads rapidly to nearby organs. There are 2 types of pancreatic cancer: that of the exocrine gland and that of the endocrine gland. The vast majority (95%) of pancreatic cancers begin in the exocrine (enzyme-producing) cells of the pancreas.[5] A representative list of ICD-10-CM diagnosis codes can be found on page 19.

Healthcare providers are encouraged to contact individual payers to confirm their coverage policies for INFUGEM™. Payment cannot be guaranteed.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Helping Patients Secure Their Prescribed Therapy

This guide provides useful information and resources that are designed to help you submit claims to request payment for patients who have been prescribed INFUGEM™. Here, you will find information about using codes that may be considered for use when submitting claims, including National Drug Code (NDC) and Healthcare Common Procedure Coding System (HCPCS) codes, and administrative procedures for INFUGEM™.

INFUGEM™ Is Available in the Hospital Inpatient, Outpatient, or Physician Office Setting

The following chart provides a summary of the coding requirements necessary based on the various healthcare provider settings. The appropriate dosage amounts and NDC codes are available on pages 20 to 21.

Filling out the UB-04

The CMS-1450 claim form, also known as the UB-04, is the standard claim form for billing multiple third-party payers. It is prescribed by the Centers for Medicare & Medicaid Services (CMS) for the Medicare and Medicaid programs for hospital claims, including hospital outpatient departments.

See page 12 for how to complete the UB-04.

Filling out the CMS-1500

The CMS-1500 claim form is the standard claim form to bill government and private insurers. The sample provided in this booklet is intended to assist you with completing the form for billing INFUGEM™. Be sure to enter the appropriate ICD-10-CM code for the patient's diagnosis or condition.

See page 14 for how to complete the CMS-1500.

Coding Summary

	Hospital Inpatient	Hospital Outpatient	Physician Office
NDC Code*	See INFUGEM™ NDC Code Selection Guide on pages 20-21 for full list of all applicable NDC codes	See INFUGEM™ NDC Code Selection Guide on pages 20-21 for full list of all applicable NDC codes	See INFUGEM™ NDC Code Selection Guide on pages 20-21 for full list of all applicable NDC codes
Administration Procedure	**3E04305** (Introduction of other antineoplastic into central vein, percutaneous approach)	**CPT 96413** (Chemotherapy administration, intravenous infusion technique; up to 1 hour)	**CPT 96413** (Chemotherapy administration, intravenous infusion technique; up to 1 hour)
		CPT 96415 (Chemotherapy administration, intravenous infusion technique; each additional hour)	**CPT 96415** (Chemotherapy administration, intravenous infusion technique; each additional hour)
	3E03305 (Introduction of other antineoplastic into peripheral vein, percutaneous approach)	**CPT 96416** (Chemotherapy administration, intravenous infusion; initiation of prolonged chemotherapy infusion [more than 8 hours] requiring use of portable or implantable pump)	**CPT 96416** (Chemotherapy administration, intravenous infusion; initiation of prolonged chemotherapy infusion [more than 8 hours] requiring use of portable or implantable pump)
		CPT 96417 (Chemotherapy administration, intravenous infusion technique; each additional sequential infusion [different substance/drug] up to 1 hour)	**CPT 96417** (Chemotherapy administration, intravenous infusion technique; each additional sequential infusion [different substance/drug] up to 1 hour)
HCPCS Code	**J9198** (Injection, INFUGEM™, 100 mg)	**J9198** (Injection, INFUGEM™, 100 mg)	**J9198** (Injection, INFUGEM™, 100 mg)
Revenue Code	**025X** (General pharmacy)	**025X** (General pharmacy)	**Not applicable**
	0636 (Drugs requiring detailed coding)	**0636** (Drugs requiring detailed coding)	

Note: Utilization of miscellaneous codes is expected until a permanent code is assigned.
CPT=Current Procedural Terminology.
*The appropriate dosage amount and subsequent NDC code are based on the patient's body surface area (BSA) range, measured in squared meters. See the INFUGEM™ NDC Code Selection Guide on pages 20-21.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Billing for INFUGEM™ in the Hospital Inpatient Setting

Claims Processing

Medicare does not reimburse separately for INFUGEM™ when administered in the inpatient setting of care. Rather, INFUGEM™ is reimbursed through the Medicare Severity Diagnosis Related Groups (MS-DRGs) system.

Private insurers and state Medicaid agency reimbursement policies vary but typically will not provide a separate reimbursement for INFUGEM™ administered in the inpatient setting. It is important to code to the highest level of specificity possible based on the complexity of the patient's case, including secondary codes and relevant procedure codes as appropriate to ensure assignment to the correct MS-DRG.

The Diagnosis Related Groups (DRGs) system is the prospective payment system Medicare uses to reimburse hospitals for inpatient services. Each inpatient stay is assigned to a specific group based on clinical and resource similarities for its ICD-10-CM diagnosis and International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) procedure codes. Only 1 DRG is assigned to each inpatient case, regardless of the number of diagnosis and procedure codes. DRGs are further impacted by secondary diagnoses meeting CMS criteria for complications/comorbidities.

Hospitals must report their charges for INFUGEM™ under the appropriate revenue code based on specific payer requirements on inpatient claims.

Hospital Inpatient Coding Summary

NDC Code*	**62756-073-60:** 1200 mg in 120 mL	**62756-438-60:** 1700 mg in 170 mL
	62756-008-60: 1300 mg in 130 mL	**62756-533-60:** 1800 mg in 180 mL
	62756-102-60: 1400 mg in 140 mL	**62756-614-60:** 1900 mg in 190 mL
	62756-219-60: 1500 mg in 150 mL	**62756-746-60:** 2000 mg in 200 mL
	62756-321-60: 1600 mg in 160 mL	**62756-974-60:** 2200 mg in 220 mL
Administration Procedure	**3E04305** (Introduction of other antineoplastic into central vein, percutaneous approach)	
	3E03305 (Introduction of other antineoplastic into peripheral vein, percutaneous approach)	
HCPCS Code	**J9198** (Injection, INFUGEM™, 100 mg)	
Revenue Code	**025X** (General pharmacy)	
	0636 (Drugs requiring detailed coding)	

Have a billing and coding question?

Call a certified coding specialist at 1-877-INFUGEM (1-877-463-8436), Monday to Friday, 8:30 AM to 6:00 PM EST

*The appropriate dosage amount and subsequent NDC code are based on the patient's BSA range, measured in squared meters. See the INFUGEM™ NDC Code Selection Guide on pages 20 and 21.

Effective January 1, 2017, CMS requires providers to report discarded amounts of products on a separate claim line item by attaching the JW modifier to the HCPCS code to describe wastage.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Billing for INFUGEM™ in the Hospital Outpatient Setting

Claims Processing

Claims will be processed through correct reporting and the use of appropriate codes (see sample outpatient Medicare claim form on page 13).

The billable amount for INFUGEM™ will vary based on the dosage administered. The billable amount will be made based on the number of infusion bags used. Please confirm specific billing requirements, including wastage and NDC code, with each individual payer. Please consult specific payer policies or contact the payer directly to determine billing requirements and payment.

HCPCS Level II (Alphanumeric) INFUGEM™ Drug Reporting

CMS guidelines state that injectable drugs that ordinarily cannot be self-administered, such as INFUGEM™, must be reported using a unique J-code. The J-code for INFUGEM™ is J9198.

The INFUGEM™ administration procedure may be reported using CPT codes 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug) and 96415 (Chemotherapy administration, intravenous infusion technique; each additional hour). The administration of INFUGEM™ typically lasts approximately 30 minutes.

Hospitals must report their charges for INFUGEM™ under the appropriate revenue code based on specific payer requirements on inpatient claims.

Hospital Outpatient Coding Summary

NDC Code*	**62756-073-60:** 1200 mg in 120 mL	**62756-438-60:** 1700 mg in 170 mL
	62756-008-60: 1300 mg in 130 mL	**62756-533-60:** 1800 mg in 180 mL
	62756-102-60: 1400 mg in 140 mL	**62756-614-60:** 1900 mg in 190 mL
	62756-219-60: 1500 mg in 150 mL	**62756-746-60:** 2000 mg in 200 mL
	62756-321-60: 1600 mg in 160 mL	**62756-974-60:** 2200 mg in 220 mL
Administration Procedure	**CPT 96413** (Chemotherapy administration, intravenous infusion technique; up to 1 hour)	
	CPT 96415 (Chemotherapy administration, intravenous infusion technique; each additional hour)	
	CPT 96416 (Chemotherapy administration, intravenous infusion; initiation of prolonged chemotherapy infusion [more than 8 hours] requiring use of portable or implantable pump)	
	CPT 96417 (Chemotherapy administration, intravenous infusion technique; each additional sequential infusion [different substance/drug] up to 1 hour)	
HCPCS Code	**J9198** (Injection, INFUGEM™, 100 mg)	
Revenue Code	**025X** (General pharmacy)	
	0335 (Chemotherapy administration-IV)	
	0636 (Drugs requiring detailed coding)	

Have a billing and coding question?

Call a certified coding specialist at 1-877-INFUGEM (1-877-463-8436), Monday to Friday, 8:30 AM to 6:00 PM EST

*The appropriate dosage amount and subsequent NDC code are based on the patient's BSA range, measured in squared meters. See the INFUGEM™ NDC Code Selection Guide on pages 20 and 21.

Effective January 1, 2017, CMS requires providers to report discarded amounts of products on a separate claim line item by attaching the JW modifier to the HCPCS code to describe wastage.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Billing for INFUGEM™ in the Physician Office Setting

Claims Processing

Claims will be processed through correct reporting and the use of appropriate codes (see sample physician office claim form on page 15).

The billable amount for INFUGEM™ will vary based on the dosage administered. The billable amount will be made based on the number of infusion bags used. Please confirm specific billing requirements, including wastage and NDC code, with each individual payer. Please consult specific payer policies or contact the payer directly to determine billing requirements and payment.

HCPCS Level II (Alphanumeric) INFUGEM™ Drug Reporting

CMS guidelines state that injectable drugs that ordinarily cannot be self-administered, such as INFUGEM™, must be reported using a unique J-code. The J-code for INFUGEM™ is J9198.

The INFUGEM™ administration procedure must be reported using CPT codes 96413 (Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug); 96415 (Chemotherapy administration, intravenous infusion technique; each additional hour); 96416 (Chemotherapy administration, intravenous infusion; initiation of prolonged chemotherapy infusion [more than 8 hours] requiring use of portable or implantable pump); and 96417 (Chemotherapy administration, intravenous infusion technique; each additional sequential infusion [different substance/drug] up to 1 hour). The administration of INFUGEM™ typically lasts approximately 30 minutes.

Physician Office Coding Summary

NDC Code*	**62756-073-60:** 1200 mg in 120 mL	**62756-438-60:** 1700 mg in 170 mL
	62756-008-60: 1300 mg in 130 mL	**62756-533-60:** 1800 mg in 180 mL
	62756-102-60: 1400 mg in 140 mL	**62756-614-60:** 1900 mg in 190 mL
	62756-219-60: 1500 mg in 150 mL	**62756-746-60:** 2000 mg in 200 mL
	62756-321-60: 1600 mg in 160 mL	**62756-974-60:** 2200 mg in 220 mL
Administration Procedure	**CPT 96413** (Chemotherapy administration, intravenous infusion technique; up to 1 hour)	
	CPT 96415 (Chemotherapy administration, intravenous infusion technique; each additional hour)	
	CPT 96416 (Chemotherapy administration, intravenous infusion; initiation of prolonged chemotherapy infusion [more than 8 hours] requiring use of portable or implantable pump)	
	CPT 96417 (Chemotherapy administration, intravenous infusion technique; each additional sequential infusion [different substance/drug] up to 1 hour)	
HCPCS Code	**J9198** (Injection, INFUGEM™, 100 mg)	
Revenue Code	**Not applicable**	

Have a billing and coding question?

Call a certified coding specialist at 1-877-INFUGEM (1-877-463-8436), Monday to Friday, 8:30 AM to 6:00 PM EST

*The appropriate dosage amount and subsequent NDC code are based on the patient's BSA range, measured in squared meters. See the INFUGEM™ NDC Code Selection Guide on pages 20 and 21.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Sample Hospital Outpatient and Medicare Claim Form

Claims Processing

A sample CMS-1450 claim form is provided on the right.

The CMS-1450 claim form, also known as the UB-04, is a uniform institutional healthcare provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for hospital claims, including hospital outpatient departments. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1450 items and other CMS manuals, please visit https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/Manuals/.

The information contained in the following example claim form is based on guidance from CMS manuals. It is intended to be a guide for claim submission and is not intended to assist healthcare providers in obtaining reimbursement for any specific claim. The information should not be construed as legal advice, nor is it advice about how to code, complete, bill, or submit any particular claim for payment. Therefore, it is important to check with the payer directly to confirm coverage for individual patients.

1 Field 42: Revenue Code

Hospitals should report their charges for INFUGEM™ (gemcitabine in a 0.9% sodium chloride injection), 10 mg/mL under the appropriate revenue code based on specific payer requirements on submitted claims. Common revenue codes include:

- 025X: General pharmacy
- 0335: Chemotherapy administration-IV
- 0636: Drugs requiring detailed coding

2 Field 43: Description

Hospitals should enter the corresponding description for the appropriate revenue code.

3 Field 44: Product and Procedure Coding

Drug: J9198

Drug administration: CPT 96413, CPT 96415, CPT 96416, CPT 96417

4 Field 46: Units

Report the appropriate unit of service. Hospitals should bill for INFUGEM™ on a per-infusion bag basis.

5 Field 66 (A-Q): Principal Diagnosis Code(s)

Enter appropriate ICD-10-CM diagnosis code(s) as detailed above. ICD-10-CM External Cause of Morbidity codes may also be listed here if appropriate but should not be listed as the primary diagnosis.

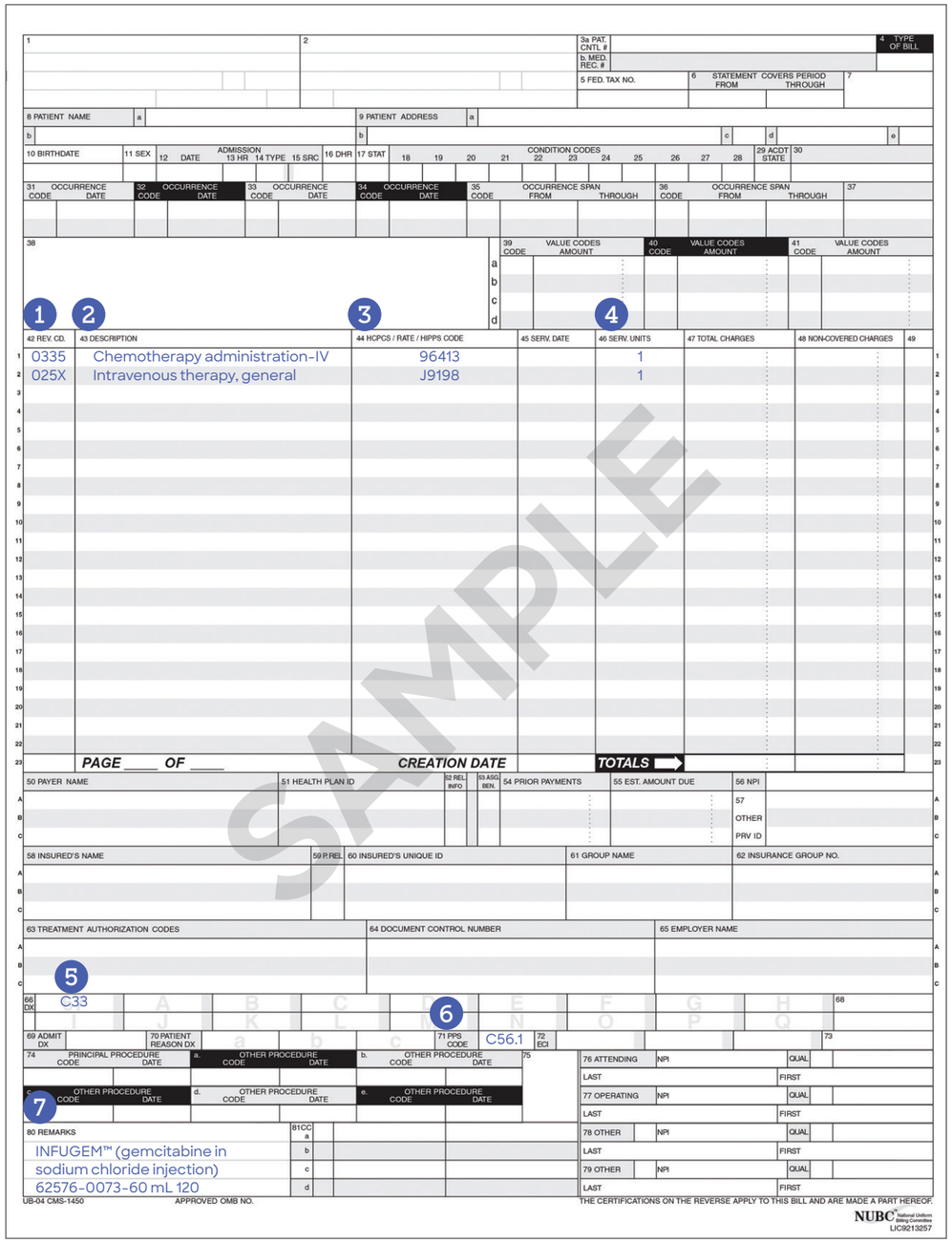
6 Field 71: Prospective Payment System (PPS) Code(s)

Enter the corresponding 3-digit DRG if applicable. Note: Only use if patient is admitted as an inpatient.

7 Field 80: Remarks

Enter drug-identifying information as required by the payer. There are 4 lines, with 21 characters on line 1 and 26 characters each on lines 2-4, but a maximum of 80 characters total in electronic data interchange (EDI) format.

- Line 1: INFUGEM™ (gemcitabine in a 0.9% sodium chloride injection), 10 mg/mL
- Line 2: NDC code and basis of measurement



INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Sample Physician Office Claim Form

Medicare Claim Form

A sample CMS-1500 claim form is provided on the right.

The CMS-1500 claim form is a uniform institutional healthcare provider bill suitable for use in billing multiple third-party payers. It is the basic form prescribed by CMS for the Medicare and Medicaid programs for claims in the physician office setting. Because it serves many payers, a particular payer may not need some data elements. For detailed guidance on completing the CMS-1500 items and other CMS manuals, please visit https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/Manuals/.

The information contained in the following example claim form is based on guidance from CMS manuals. It is intended to be a guide for claim submission and is not intended to assist healthcare providers in obtaining reimbursement for any specific claim. The information should not be construed as legal advice, nor is it advice about how to code, complete, bill, or submit any particular claim for payment. Therefore, it is important to check with the payer directly to confirm coverage for individual patients.

1. **Field 19: Additional Claim Information**
   List drug name, dosage, route of administration, and NDC code.
2. **Field 21: Diagnosis Code**
   Enter ICD-10-CM diagnosis code.
3. **Field 24 (D): Procedure Code**
   Enter the appropriate CPT code for the administration procedure of INFUGEM™ (gemcitabine in a 0.9% sodium chloride injection), 10 mg/mL (CPT 96413, CPT 96415, CPT 96416, CPT 96417).
4. **Field 24 (D): Product Code**
   Enter the appropriate HCPCS code to denote the infusion of INFUGEM™ (J9198).

   Note: State Medicaid agencies, secondaries, and some private payers may require healthcare providers to report the NDC code in addition to the HCPCS code; however, the NDC code is not required for Medicare claims.
5. **Field 24 (G): Units Administration**
   Enter the appropriate number of mL used.

HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (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 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

8. RESERVED FOR NUCC USE

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:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

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 NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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.

SIGNED DATE

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

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

1 62576-0073-60 mL 120

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

2 A. C33 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1				3 96413						NPI	
2				4 J9198				5 120		NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

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. Rsvd 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.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

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

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Common Diagnosis Codes Associated With INFUGEM™ Administration

Representative Ovarian Cancer ICD-10-CM Diagnosis Codes

ICD-10-CM Code	Description
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum

Representative Breast Cancer ICD-10-CM Diagnosis Codes

ICD-10-CM Code (Right Breast)	ICD-10-CM Code (Left Breast)	Description
C50.011	C50.012	Malignant neoplasm of nipple and areola, female
C50.021	C50.022	Malignant neoplasm of nipple and areola, male
C50.111	C50.112	Malignant neoplasm of central portion, female
C50.121	C50.122	Malignant neoplasm of central portion, male
C50.211	C50.212	Malignant neoplasm of upper-inner quadrant, female
C50.221	C50.222	Malignant neoplasm of upper-inner quadrant, male
C50.311	C50.312	Malignant neoplasm of lower-inner quadrant, female
C50.321	C50.322	Malignant neoplasm of lower-inner quadrant, male
C50.411	C50.412	Malignant neoplasm of upper-outer quadrant, female
C50.421	C50.422	Malignant neoplasm of upper-outer quadrant, male
C50.511	C50.512	Malignant neoplasm of lower-outer quadrant, female
C50.521	C50.522	Malignant neoplasm of lower-outer quadrant, male
C50.611	C50.612	Malignant neoplasm of axillary tail, female
C50.621	C50.622	Malignant neoplasm of axillary tail, male
C50.811	C50.812	Malignant neoplasm of overlapping sites, female
C50.821	C50.822	Malignant neoplasm of overlapping sites, male
C50.911	C50.912	Malignant neoplasm of unspecified site, female
C50.921	C50.922	Malignant neoplasm of unspecified site, male

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Common Diagnosis Codes Associated With INFUGEM™ Administration (cont'd)

Representative NSCLC ICD-10-CM Diagnosis Codes

ICD-10-CM Code	Description
C33	Malignant neoplasm of trachea
C34.00-C34.02	Malignant neoplasm of bronchus and lung; main bronchus
C34.10-C34.12	Malignant neoplasm of bronchus and lung; upper lobe
C34.2	Malignant neoplasm of bronchus and lung; middle lobe
C34.30-C34.32	Malignant neoplasm of bronchus and lung; lower lobe
C34.80-C34.82	Malignant neoplasm of overlapping sites of unspecified; unspecified part
C34.90-C34.92	Malignant neoplasm of bronchus and lung; unspecified part

Representative Pancreatic Cancer ICD-10-CM Diagnosis Codes

ICD-10-CM Code	Description
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail 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 pancreas
D13.6	Benign neoplasm of pancreas
D13.7	Benign neoplasm of endocrine pancreas

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

INFUGEM™ NDC Code Selection Guide

INFUGEM™ Infusion Bag(s) Selection

1000 mg/m² in NSCLC, Ovarian Cancer, and Pancreatic Cancer[1]

BSA Range (m²)	INFUGEM™ Infusion Bag(s)	NDC Code
1.16 to 1.25	1200 mg	62756-0073-60
1.26 to 1.35	1300 mg	62756-0008-60
1.36 to 1.45	1400 mg	62756-0102-60
1.46 to 1.55	1500 mg	62756-0219-60
1.56 to 1.65	1600 mg	62756-0321-60
1.66 to 1.75	1700 mg	62756-0438-60
1.76 to 1.85	1800 mg	62756-0533-60
1.86 to 1.95	1900 mg	62756-0614-60
1.96 to 2.10	2000 mg	62756-0746-60
2.11 to 2.30	2200 mg	62756-0974-60
2.31 to 2.45	2400 mg (1200 mg and 1200 mg)*	(62756-0073-60 x2)
2.46 to 2.55	2500 mg (1200 mg and 1300 mg)*	(62756-0073-60, 62756-0008-60)
2.56 to 2.64	2600 mg (1300 mg and 1300 mg)*	(62756-0008-60 x2)*

1250 mg/m² in Breast Cancer and NSCLC[1]

BSA Range (m²)	INFUGEM™ Infusion Bag(s)	NDC Code
1.16 to 1.24	1500 mg	62756-0219-60
1.25 to 1.32	1600 mg	62756-0321-60
1.33 to 1.40	1700 mg	62756-0438-60
1.41 to 1.47	1800 mg	62756-0533-60
1.48 to 1.56	1900 mg	62756-0614-60
1.57 to 1.68	2000 mg	62756-0746-60
1.69 to 1.84	2200 mg	62756-0974-60
1.85 to 1.96	2400 mg (1200 mg and 1200 mg)	(62756-0073-60 x2)*
1.97 to 2.04	2500 mg (1300 mg and 1200 mg)	(62756-0073-60, 62756-0008-60)*
2.05 to 2.12	2600 mg (1300 mg and 1300 mg)*	(62756-0008-60 x2)*
2.13 to 2.20	2700 mg (1200 mg and 1500 mg)*	(62756-0073-60, 62756-0219-60)*
2.21 to 2.28	2800 mg (1400 mg and 1400 mg)*	(62756-0102-60 x2)*
2.29 to 2.36	2900 mg (1200 mg and 1700 mg)*	(62756-0073-60, 62756-0438-60)*
2.37 to 2.44	3000 mg (1500 mg and 1500 mg)*	(62756-0219-60 x2)*
2.45 to 2.52	3100 mg (1200 mg and 1900 mg)*	(62756-0073-60, 62756-0614-60)*
2.53 to 2.60	3200 mg (1600 mg and 1600 mg)*	(62756-0321-60 x2)*
2.61 to 2.64	3300 mg (1600 mg and 1700 mg)*	(62756-0321-60, 62756-0438-60)*

*Suggested combination. Other possible combinations may be used to reach the appropriate dose.

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION

Indications, Usage, and Important Safety Information

INDICATIONS AND USAGE

INFUGEM (gemcitabine hydrochloride in 0.9% sodium chloride injection) is a nucleoside metabolic inhibitor indicated for:

Ovarian Cancer: in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

Breast Cancer: 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.

Non-Small Cell Lung Cancer: in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.

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

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INFUGEM 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.

Myelosuppression: Myelosuppression manifested by neutropenia, thrombocytopenia, and anemia occurs with INFUGEM as a single agent. The risks are increased when INFUGEM is combined with other cytotoxic drugs. Monitor patients receiving INFUGEM prior to each dose with a complete blood count (CBC), including differential and platelet count, and modify the dosage as recommended.

Pulmonary Toxicity and Respiratory Failure: Permanently discontinue INFUGEM in patients who develop unexplained dyspnea, with or without bronchospasm, or have any evidence of pulmonary toxicity.

Hemolytic Uremic Syndrome: Hemolytic uremic syndrome (HUS), including fatalities from renal failure or the requirement for dialysis, can occur in patients treated with INFUGEM. 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 INFUGEM and periodically during treatment. Permanently discontinue INFUGEM in patients with HUS or severe renal impairment. Renal failure may not be reversible even with discontinuation of therapy.

Hepatic Toxicity: Drug-induced liver injury, including liver failure and death, has been reported in patients receiving gemcitabine alone or in combination with other potentially hepatotoxic drugs. Assess hepatic function prior to initiation of INFUGEM and periodically during treatment. Permanently discontinue INFUGEM in patients that develop severe liver injury.

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

Please see Indications and additional Important Safety Information on the cover and accompanying Full Prescribing Information.

Exacerbation of Radiation Therapy Toxicity: INFUGEM is not recommended for use in combination with radiation therapy, either concurrently 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.

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 receive gemcitabine after prior radiation.

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

ADVERSE REACTIONS

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

USE IN SPECIFIC POPULATIONS

Due to the potential for serious adverse reactions in nursing infants from INFUGEM, women should not breastfeed during treatment with INFUGEM and for at least one week after the last dose.

The safety and effectiveness of INFUGEM have not been established in pediatric patients.

You are encouraged to report all side effects or Adverse Drug Events (ADEs) of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088. You are also encouraged to report side effects or ADEs to our Drug Safety Department at 1-800-406-7984 or drug.safetyUSA@sunpharma.com (preferred) with as much information as available.

References

1. INFUGEM™ [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc; 2020.
2. Chen L, Berek JS. Patient education: ovarian cancer diagnosis and staging (beyond the basics). https://www.uptodate.com/contents/ovarian-cancer-diagnosis-and-staging-beyond-the-basics#H1. UpToDate website. Accessed February 11, 2019.
3. Esserman LJ, Joe BN. Clinical features, diagnosis, and staging of newly diagnosed breast cancer. UpToDate website. https://www.uptodate.com/contents/clinical-features-diagnosis-and-staging-of-newly-diagnosed-breast-cancer?search=clinical-features-diagnosis-and-staging-of-newly-diagnosedbreast-cancer&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed February 11, 2019.
4. American Cancer Society. What is non-small cell lung cancer? https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html. Accessed February 11, 2019.
5. American Cancer Society. What is pancreatic cancer? https://www.cancer.org/cancer/pancreatic-cancer/about/what-is-pancreatic-cancer.html. Accessed February 11, 2019.
6. Center for Medicare and Medicaid Services. Medicare Claims Processing Manual, Chapter 17.
7. Center for Medicare and Medicaid Services. Medicare Claims Processing Manual, Chapter 25.
8. Center for Medicare and Medicaid Services. Medicare Claims Processing Manual, Chapter 26.

Stay connected at www.INFUGEM.com

If you need assistance with a particular payer or additional information about coding, billing, and coverage of INFUGEM™, please call 1-877-INFUGEM (1-877-463-8436).

SUN PHARMA

PM-US-INF-0208 05/2020

INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION