

INFUGEM Support™

Frequently Asked Questions

Please see the potential questions you may receive from healthcare providers.

General Information



What is the FDA-approved indication for INFUGEM™ (gemcitabine hydrochloride in 0.9% sodium chloride injection), 10 mg/mL?¹

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.



Does INFUGEM™ require refrigeration?²

No. INFUGEM™ does not require refrigeration.

Unopened infusion bags of INFUGEM™ are stable until the expiration date indicated on the package when stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [see USP Controlled Room Temperature].¹



When was INFUGEM™ approved by the FDA?

INFUGEM™ was approved by the FDA on July 18, 2018.



Who manufactures INFUGEM™?

INFUGEM™ is manufactured by Sun Pharmaceutical Industries Ltd.

General Information (cont'd)

What is INFUGEM Support™?

INFUGEM Support™ is a patient access and reimbursement support program. Our hours of operation are Monday to Friday, 8:30 AM to 6:00 PM EST.

Who is The Pinnacle Health Group?

INFUGEM Support™ is a patient access program to support healthcare providers with reimbursement. Sun Pharma is partnering with The Pinnacle Health Group to provide services that include a hotline to answer potential questions and case management support.

What services are available through INFUGEM Support™?

INFUGEM Support™ is accessible by phone to answer any questions you may have about billing and coding, the enrollment process, and benefit verification (BV) based on site of care.

Where can the forms needed to begin the enrollment process be found?

Forms can be found at www.INFUGEM.com. These include:

- INFUGEM Support™ Enrollment Form
- Prior Authorization Checklist
- Sample Letter of Medical Necessity
- Sample Letter of Appeal
- Business Associate Agreement

How are the forms submitted?

You can submit completed forms by:

Email: BV@thepinnaclehealthgroup.com

Fax: 1-215-369-9198

Will a field representative be assigned to our practice?

Your representative will notify you if information on a submitted INFUGEM Support™ Enrollment Form is complete.

General Information (cont'd)

Is there someone I can call with reimbursement questions?

Yes, INFUGEM Support™ offers a hotline service for reimbursement questions. You can call 1-877-INFUGEM (1-877-463-8436), Monday to Friday, 8:30 AM to 6:00 PM EST.

Enrollment

How long does it take to hear back about a BV after the submission of an INFUGEM Support™ Enrollment Form?

If you request a BV,* INFUGEM Support™ will contact you by email within 24 to 48 hours upon receipt of all required information. The BV is usually completed up to 3 days from the date of the request.

What are the next steps once the BV is approved?

INFUGEM Support™ will communicate your patient's insurance plan restrictions and limitations regarding the cost and administration of INFUGEM™ (gemcitabine hydrochloride in 0.9% sodium chloride injection), 10 mg/mL.

- Your practice will be notified of important plan information regarding any deductibles, copays, or payments
- With approval, you will be provided with a verification of benefits (VOB) authorization number, which will be updated on the VOB Form

What happens if a prior authorization (PA) is required?

INFUGEM Support™ is available to help you with the appeals and denials process and will also confirm if you would like to appeal the denial.

The INFUGEM Support™ Enrollment Form is a dual-use form. Simply check the appropriate boxes on the form and attach supporting documentation:

- A copy of the Remittance Advice; indicate the code(s) or service(s) being appealed
- Medical documentation related to the appeal (medical records, operative report, etc)
- A copy of the claim form submitted to insurance
- Any additional documentation that will assist in the review

*Verification of benefits is not a guarantee of payment and does not take the place of written policy information.

Enrollment (cont'd)

Q How long does it take to complete a PA through INFUGEM Support™?

Timing for PA is 5 to 10 business days after the PA is received. Health plans typically take 5 to 7 days to determine an approval.

Q Why would my patient's insurance not cover INFUGEM™?

There are several reasons why INFUGEM™ may be denied, including documentation errors, failure to obtain necessary documents, or if the health plan determines treatment is not covered.

Q What do I do if I want to appeal the health plan's decision?

INFUGEM Support™ will walk you through appeals process.

- The Pinnacle Health Group will reach out to your field representative. You may also receive a visit from your representative
- Sample letters (eg, Letter of Appeal and Letter of Medical Necessity) are provided in the Office Kit, Access Guide, and online at www.INFUGEM.com to assist you with this process
- Your field representative can help guide you through the necessary documentation needed to properly appeal the denial from the health plan

Billing and Coding

Q Does INFUGEM™ (gemcitabine hydrochloride in 0.9% sodium chloride injection), 10 mg/mL have a unique J-code?

Yes. The unique J-code for INFUGEM™ is J9198.

Would you like to be transferred to a certified coding specialist?

Q Is INFUGEM™ covered under medical benefit and by Medicare Part B?

Yes.

Medical Information: Reporting Adverse Events or Product Quality Issues

Q If I need to report a potential adverse event, who do I speak with?

You will have to speak to our Drug Safety Department at Sun Pharma to report a potential adverse event (PAE). In case we get disconnected, the number is 1-800-406-7984.

Q If I have a product quality issue, who do I speak with?

I can transfer you to our Product Quality Complaint Department, where you can be further assisted with your issues. In case we get disconnected, the number is 1-800-818-4555, option 4.

Q If I have a medical/clinical question (eg, safety, efficacy, dosing, storage, preparation, or administration), who do I speak with?

I can transfer you to our Medical Information Department, where you can be further assisted with your question. In case we get disconnected, the number is 1-800-818-4555, option 5.

References: 1. INFUGEM™ [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; 2020.
2. Data on file. Sun Pharmaceutical Industries, Inc.



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INFUGEM™
GEMCITABINE IN SODIUM CHLORIDE INJECTION