

Gemcitabine Hydrochloride (Gemzar®)	
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Revised	Original Committee Approval: 12/3/08
	Last Committee Approval: 12/3/08
	Last Review: October 2008

Background

Gemcitabine Hydrochloride ((Gemzar®, made by Eli Lilly and Company) is a pyrimidine analogue of the antimetabolite nucleoside deoxycytidine. It is an infusible drug with antineoplastic activity. It interferes with DNA synthesis by inhibition of DNA polymerase and ribonucleotide reductase, specific for the S-phase of the cell cycle. Gemcitabine thus primarily kills cells undergoing DNA synthesis.

The U.S. Food and Drug Administration initially approved gemcitabine in May 2004 in combination with paclitaxel for the first-line treatment of patients with metastatic breast cancer. These patients had either failed previous courses of anthracycline (e.g., doxorubicin)-containing adjuvant (post-operative) chemotherapy or had clinical contraindications to anthracyclines. The FDA then approved gemcitabine in combination with carboplatin for the treatment of patients with advanced ovarian cancer that has relapsed at least six months after completion of platinum-based therapy. Subsequent to this, gemcitabine has received FDA approval and National Comprehensive Cancer Network (NCCN) recommendations for the other indications as specified below.

Indications/Criteria

Gemcitabine is considered medically necessary for the following indications:

Breast cancer

As first-line therapy, in combination with paclitaxel, for metastatic breast cancer after failure of prior anthracycline-containing adjuvant (post-operative) chemotherapy (unless anthracyclines were previously clinically contraindicated).

Non-small cell lung cancer (NSCLC)

As first-line therapy, in combination with cisplatin, for inoperable, locally advanced (stage IIIA or IIIB), or metastatic (stage IV) disease.

Ovarian cancer

As combination therapy with carboplatin for advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy.

Pancreatic cancer

- As first-line therapy for locally advanced (nonresectable stage II or stage III) or metastatic (stage IV) adenocarcinoma of the pancreas.
- For advanced adenocarcinoma of the pancreas previously treated with 5-fluorouracil (5-FU).
- In combination therapy with capecitabine or erlotinib in the adjuvant setting and in the management of locally advanced unresectable and metastatic disease.

Diffuse Large B-Cell Lymphoma

- The GDP regimen (with dexamethasone, cisplatin +/- rituximab) as a second-line therapy option.

Gemcitabine is considered experimental and investigational for the following conditions:

- Bladder cancer
- Biliary cancer
- Squamous cell carcinoma of the head and neck
- Relapsed testicular cancer
- Acute leukemia

Special Considerations

Hematologic effects

Like many other cytotoxic antineoplastic drugs, Gemcitabine can suppress bone marrow function as manifested by leukopenia, thrombocytopenia, or anemia. Myelosuppression generally is the dose-limiting toxicity. Patients require monitoring for myelosuppression during therapy. Dosage adjustment may be necessary, based on the degree of hematologic toxicity demonstrated.

Hepatotoxicity

Gemcitabine has been associated with significant hepatotoxicity. Caution is advised in treating patients with impaired hepatic function (e.g., history of cirrhosis, hepatitis, or alcoholism) or in patients with hepatic metastases.

Limitations/Exclusions

Healthy Options:	None; pre-authorization required.
Basic Health Plan:	None; pre-authorization required.
GAU:	None; pre-authorization required.
Medicare Advantage:	None; pre-authorization required.

Required Review and Approvals

Infusions require prior authorization by the CHP Medical Director or his/her designee. Each authorization period will be for six months.

All requests for this IV medication also require referral to CHP Case Management.

References

National Cancer Institute (www.cancer.gov)

Federal Drug Administration (www.fda.gov)

Facts and Comparisons 4.0 (<http://online.factsandcomparisons.com>)

National Comprehensive Cancer Network, Clinical Practice Guidelines in Oncology™
(www.nccn.org)

UpToDate Online 16.2 (www.uptodate.com)

Hayes, Inc. Online (www.hayesinc.com)