Mass General Brigham
Health Plan

Systemic Chemotherapy
Infugem (gemcitabine)
Onivyde (irinotecan liposome)
Pemfexy (pemetrexed)
Vyxeos (daunorubicine/cytarabine)
Effective 09/01/2025

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview

Infugem (gemcitabine in sodium chloride injection) is a nucleoside metabolic inhibitor indicated:

- in combination with carboplatin, for the treatment of advanced ovarian cancer that has relapsed at least six months after completion of platinum-based therapy
- in combination with paclitaxel, for first-line treatment of metastatic breast cancer (mBC) after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were clinically contraindicated
- in combination with cisplatin for the treatment of NSCLC
- as a single agent as first-line treatment for patients with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) pancreatic cancer.

It is the first chemotherapy product that comes in a premixed, ready-to-infuse formulation.

Pemfexy (pemetrexed) is a folate analog metabolic inhibitor designed to block DNA replication and cell division. It is indicated:

- in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of patients with metastatic non-squamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations.
- in combination with cisplatin for the initial treatment of patients with locally advanced or metastatic, non-squamous NSCLC.
- as a single agent for the maintenance treatment of patients with locally advanced or metastatic non-squamous NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
- as a single agent for the treatment of patients with recurrent, metastatic non-squamous NSCLC after prior chemotherapy.

Onivyde (irinotecan liposome) is indicated in combination with fluorouracil and leucovorin for the treatment of patients with metastatic adenocarcinoma of the pancreas after disease progression following gemcitabine-based therapy, and was more recently approved in combination with oxaliplatin, fluorouracil and leucovorin, for the first-line treatment of adult patients with metastatic pancreatic adenocarcinoma.

Vyxeos (daunorubicin/cytarabine liposome) is a liposomal combination of daunorubicin, an anthracycline topoisomerase inhibitor, and cytarabine, a nucleoside metabolic inhibitor, in a 1:5 molar ratio that is indicated for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in pediatric patients one year and older.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Infugem (gemcitabine)
1. Diagnosis of breast cancer, non-small cell lung cancer, ovarian cancer, or pancreatic cancer
2. Prescriber is a hematologist or oncologist
3. Member ≥18 years of age
4. Appropriate dosing
5. Physician attestation of inadequate response, adverse reaction or contraindication to a gemcitabine product available without prior authorization

Onivyde (irinotecan liposome)
1. Diagnosis of metastatic adenocarcinoma of the pancreas
2. Prescriber is a hematologist or oncologist
3. Appropriate dosing
4. Member ≥18 years of age
5. **ONE** of the following:
    a. Requested agent will be used in combination with fluorouracil and leucovorin
    b. **BOTH** of the following:
        i. Requested agent will be used in combination with fluorouracil and leucovorin
        ii. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following (see appendix for gemcitabine- and fluoropyrimidine-based chemotherapy regimens):
            1. gemcitabine-based chemotherapy regimen
            2. fluoropyrimidine-based chemotherapy regimen

Pemfexy (pemetrexed)
1. Diagnosis of malignant pleural mesothelioma or non-small cell lung cancer (NSCLC)
2. Prescriber is a hematologist or oncologist
3. Appropriate dosing
4. Physician attestation of inadequate response, adverse reaction, or contraindication to a pemetrexed product available without prior authorization

Vyxeos (daunorubicin/cytarabine)

1. Diagnosis of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) or MDS/CMML
2. Prescriber is a hematologist or oncologist
3. Appropriate dosing
4. Member ≥1 year of age
5. Physician attestation of inadequate response, adverse reaction or contraindication to use of separate daunorubicin and cytarabine chemotherapy agents

Continuation of Therapy

Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals will be granted 3 months
2. Reauthorizations will be granted for 6 months

References

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Review History

02/08/2023 - Reviewed and created for Feb P&T; Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Effective 4/1/23.
04/12/23 – Reviewed and updated for Apr P&T. Added Alimta and pemetrexed to Overview table under no PA. No clinical changes. Effective 5/1/23.
05/10/23 – Reviewed and updated for P&T. Vyxeos was added to MB management for consistency with the rest of the class. Effective 6/5/23
06/14/23 – Reviewed and updated for P&T. Etopophos (etoposide phosphate) will be managed under MB no PA. Effective 7/31/23.
09/11/24 – Reviewed and updated for P&T. Removed Marqibo due to no longer FDA approved and obsolete. Added expanded indication for Onivyde as a first-line treatment option in combination with oxaliplatin, fluorouracil and leucovorin for adults with metastatic pancreatic adenocarcinoma. Effective 10/1/24.
07/09/25 – Reviewed and updated for P&T. Removed appendix as this info can be found on NCCN. Updated the Overview section to include indications of impacted drugs. Effective 9/1/25