Mass General Brigham
Health Plan

Systemic Chemotherapy:
Infugem (gemcitabine)
Marqibo (vincristine liposome)
Onivyde® (irinotecan liposome)
Pemfexy (pemetrexed)
Vyxeos (daunorubicine/cytarabine)
Effective 07/31/2023

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

No PA	Drugs that require PA
Adrucil® # (fluorouracil injection) Alimta® # (pemetrexed) MB Camptosar® # (irinotecan) MB cytarabine MB daunorubicin MB Etopophos® (etoposide phosphate) MB etoposide injection MB fluorouracil injection MB gemcitabine vial MB leucovorin oxaliplatin MB pemetrexed MB Xeloda® # (capecitabine) vincristine MB	Infugem® (gemcitabine) MB Marqibo® (vincristine liposome) MB Onivyde® (irinotecan liposome) MB Pemfexy® (pemetrexed) MB Vyxeos® (daunorubicin/cytarabine) MB

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through the retail pharmacy.

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

Marqibo® (vincristine liposome)

1. Diagnosis of Philadelphia chromosome-negative acute lymphoblastic leukemia
2. Prescriber is a hematologist or oncologist
3. Appropriate dosing
4. Member ≥18 years of age
5. Medical records documenting a trial with **TWO** previous chemotherapy regimens (see appendix for examples)

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. Requested agent will be used in combination with fluorouracil and leucovorin
6. Physician attestation of inadequate response or adverse reaction to ONE or contraindication to BOTH of the following: gemcitabine- and fluoropyrimidine-based chemotherapy regimen (see appendix for gemcitabine- and fluoropyrimidine-based chemotherapy regimens)

Pemfexy® (pemetrexed)

1. Diagnosis of malignant pleural mesothelioma or 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

Appendix
Examples of Chemotherapy Regimens (not all inclusive) for the Treatment of Acute Lymphoblastic Leukemia
- **CALGB 8811 Larson regimen:** daunorubicin, vincristine, prednisone, pegaspargase, and cyclophosphamide
- **Linker 4-drug regimen:** daunorubicin, vincristine, prednisone, and pegaspargase
- **Hyper-CVAD +/- rituximab:** hyper-fractionated cyclophosphamide, vincristine, doxorubicin, and dexamethasone, alternating with high-dose methotrexate and cytarabine; with or without rituximab for CD20-positive disease
- **MRC UKALLXII/ECOG2993 regimen:** daunorubicin, vincristine, prednisone, and pegaspargase (induction phase 1) and cyclophosphamide and 6-mercaptopurine (induction phase 2)
- **GRAALL-2005 regimen:** daunorubicin, vincristine, prednisone, pegaspargase, and cyclophosphamide with rituximab for CD20-positive disease
- **COG AALL0434 regimen with nelarabine (for T-ALL):** daunorubicin, vincristine, prednisone, pegaspargase, with nelarabine added to the consolidation regimen
- **COG AALL0232 regimen:** daunorubicin, vincristine, prednisone, and pegaspargase (patients aged ≤21 years)
- **PETHEMA ALL-96 regimen:** daunorubicin, vincristine, prednisone, pegaspargase, and cyclophosphamide (patients aged < 30 years)
- **CALGB 10403 regimen:** daunorubicin, vincristine, prednisone, and pegaspargase
- **DFCI ALL regimen based on DFCI Protocol 00-01:** doxorubicin, vincristine, prednisone, high-dose methotrexate, and pegaspargase
- **USC/MSKCC ALL regimen based on CCG-1882 regimen:** daunorubicin, vincristine, prednisone, and methotrexate with augmented pegaspargase (patients aged <60 years)
- **Blinatumomab** (for B-ALL) (category 1)
- **Inotuzumab ozogamicin** (for B-ALL) (category 1)
- Clofarabine
- **Clofarabine-containing regimens**
- **Fludarabine-based regimens**
- **Cytarabine-containing regimens**
- Alkylator combination regimens
- **Nelarabine** (for T-ALL)
- **Nelarabine, etoposide, cyclophosphamide** (young and fit patients)
- **MOpAD regimen:** methotrexate, vincristine, pegaspargase, dexamethasone; with rituximab for CD20-positive disease
- **Tisagenlecleucel** (for B-ALL) (patients <26 years and with refractory disease or ≥2 relapses)
- **Brexucabtagene** (for B-ALL)
- Bortezomib + chemotherapy
- **Daratumumab** (category 2B)
- **HiDAC:** high-dose cytarabine

- Mitoxantrone, etoposide, and cytarabine
- **Venetoclax + chemotherapy** (e.g., decitaibine, hyperCVAD, nelarabine, mini-hyper CVD) (Category 2B)

Gemcitabine- and Fluoropyrimidine-based Chemotherapy Regimens (not all inclusive)
Per NCCN guidelines for pancreatic adenocarcinoma, the following is a list of gemcitabine- and fluoropyrimidine-based first-line options for locally advanced/unresectable and metastatic pancreatic adenocarcinoma:

- FOLFIRINOX
- Modified FOLFIRINOX
- Gemcitabine + albumin-bound paclitaxel
- Gemcitabine + erlotinib
- Gemcitabine + capecitabine
- Gemcitabine + cisplatin (only for known BRCA 1/2 or APLB2 mutations)
- Gemcitabine
- Capecitabine (category 2B)
- Continuous infusion 5-FU (category 2B)
- Fixed-dose-rate gemcitabine, docetaxel, capecitabine (GTX regimen) (category 2B)
- Fluoropyrimidine + oxaliplatin (5-FU + leucovorin + oxaliplatin [OFF] or CapeOX) (Category 2b)

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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.