Mass General Brigham
Health Plan

Melanoma Agents
Braftovi® (encorafenib)
Cotellic® (cobimetinib)
Imlygic® (talimogene laherparepvec)
Kimmtrak®(tebentafusp-tebn)
Mekinist® (trametinib)
Mektovi® (binimetinib)
Tafinlar® (dabrafenib)
Zelboraf® (vemurafenib)
Effective 03/04/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications may have specialty designation and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
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	Imlygic and Kimmtrak are available through medical benefit only.		

Overview

No PA	Drugs that require PA
Alternatives vary by specific malignancy and may include systemic chemotherapy	Braftovi® (encorafenib) Cotellic® (cobimetinib) Imlygic® (talimogene laherparepvec) MB Kimmtrak®(tebentafusp-tebn) MB Mekinist® (trametinib) Mektovi® (binimetinib) Tafinlar® (dabrafenib) Zelboraf® (vemurafenib)

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy.

Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Braftovi® (encorafenib)

Unresectable or Metastatic Melanoma

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. Appropriate dosing (for 75 mg capsule, requested quantity is ≤ 6 units/day; for 50 mg capsules, requested quantity is ≤ 4 units/day)
4. Positive BRAF V600E or V600K mutation
5. Documentation that the requested agent will be used in combination with Mektovi® (binimetinib)

Metastatic colorectal cancer (CRC)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic colorectal cancer
2. Prescriber is an oncologist
3. Appropriate dosing (for 75 mg capsule and 50 mg capsule, requested quantity is ≤ 4 units/day)
4. Positive BRAF V600E mutation
5. Documentation that the requested agent will be used in combination with Erbitux® (cetuximab) or Vectibix® (panitumumab)
6. Inadequate response or adverse reaction to at least **ONE** of the following regimens or a contraindication to **ALL** of the following regimens:
    a. capecitabine/oxaliplatin (CAPEOX)
    b. leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin (FOLFOX)
    c. irinotecan-based therapy
    d. oxaliplatin-based therapy

Cotellic® (cobimetinib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. Requested quantity is ≤ 3 units/day
4. Positive BRAF V600E or V600K mutation
5. Documentation that the requested agent will be used in combination with Zelboraf® (vemurafenib)

Histiocytic neoplasms
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of histiocytic neoplasms
2. Prescriber is an oncologist
3. Member is ≥ 18 years of age
4. Requested quantity is ≤ 3 units/day

Low-grade or high-grade glioma *(off-label)*
Requests for members with a diagnosis of low-grade or high-grade gliomas may be approved if the following criteria are met:
1. Diagnosis of glioma
2. Prescriber is an oncologist
3. Positive BRAF V600E mutation
4. Appropriate dosing
5. Documentation that the requested agent will be administered with Zelboraf (vemurafenib) ≤ 960 mg every 12 hours

Imlygic®(talimogene laherparepvec)

Prescriber provides documentation of ALL of the following:

1. Diagnosis of unresectable melanoma
2. Prescriber is an oncologist
3. Requested quantity is ≤ 4 mL per treatment
4. Unresectable cutaneous, subcutaneous, or nodal lesions
5. Melanoma recurrent after initial surgery

Kimmtrak®(tebentafusp-tebn)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of unresectable or metastatic uveal melanoma
2. Member is positive for HLA-A*02:01 genotype
3. Prescriber is an oncologist
4. Appropriate dosing
5. **ONE** of the following:
    a. Member is refractory to radiation therapy
    b. Radiation therapy is not appropriate

Mekinist® (trametinib)

Unresectable or Metastatic Melanoma

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. **ONE** of the following:
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day
    b. For 2 mg tablets, requested quantity is ≤ 1 unit/day
4. Positive BRAF V600E or V600K mutation
5. **ONE** of the following:
    a. Documentation that the requested agent will be used in combination with Tafinlar® (dabrafenib)
    b. **ALL** of the following:
        i. Documentation that the requested agent will be used as a single agent (not in combination with Tafinlar® [dabrafenib])
        ii. No history of prior therapy with a BRAF inhibitor* (i.e. Tafinlar® [dabrafenib] or Zelboraf® [vemurafenib]) or in claims history or has not completed therapy with a BRAF inhibitor due to adverse drug event during such therapy noted on PA request, approval may be considered if criteria 1-4 are met.
        iii. Clinical rationale for bypassing use of a BRAF inhibitor (i.e. Tafinlar® [dabrafenib] or Zelboraf® [vemurafenib])

Unresectable or metastatic solid tumors

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of unresectable or metastatic solid tumor
2. Prescriber is an oncologist
3. Member is ≥ 6 years of age
4. **ONE** of the following:
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day

b. For 2 mg tablets, requested quantity is ≤ 1 unit/day
c. For solution, requested quantity is ≤ 40 mLs/day

5. Positive BRAF V600E mutation
6. Documentation that the requested agent will be used in combination with Tafinlar® (dabrafenib)

Melanoma (adjuvant treatment)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of melanoma (for adjuvant treatment)
2. Prescriber is an oncologist
3. **ONE** of the following (*maximum one year of treatment*):
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day
    c. For 2 mg tablets, requested quantity is ≤ 1 unit/day
4. Positive BRAF V600E or V600K mutation
5. Documentation that the agent will be used in combination with Tafinlar® (dabrafenib)
6. Involvement of lymph nodes following complete resection

Anaplastic Thyroid Cancer (ATC)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer
2. Prescriber is an oncologist
3. **ONE** of the following:
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day
    b. For 2 mg tablets, requested quantity is ≤ 1 unit/day
4. Positive BRAF V600E mutation
5. Documentation that the requested agent will be used in combination with Tafinlar® (dabrafenib)
6. Member has no satisfactory locoregional treatment options

Non-small cell lung cancer (NSCLC)

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. **ONE** of the following:
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day
    b. For 2 mg tablets, requested quantity is ≤ 1 unit/day
4. Positive BRAF V600E mutation
5. Documentation that the requested agent will be used in combination with Tafinlar® (dabrafenib)

Glioma

Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of low-grade glioma
2. Prescriber is an oncologist
3. Positive BRAF V600E mutation
4. Documentation that the requested agent will be administered with Tafinlar (dabrafenib)
5. **ONE** of the following:
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day
    b. For 2 mg tablets, requested quantity is ≤ 1 unit/day
    c. For solution, requested quantity is ≤ 40 mLs/day

Low-Grade Serous Carcinoma of the ovary, fallopian tube, or primary peritoneum *(off-label)*
Requests for members with a diagnosis of low-grade serous carcinoma of the ovary, fallopian tube or primary peritoneum may be approved if the following criteria are met:

1. Diagnosis of low-grade serous carcinoma
2. Prescriber is an oncologist
3. Medical records documenting an inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. **ONE** platinum-containing regimen (e.g., paclitaxel/carboplatin +/- bevacizumab, docetaxel/carboplatin, carboplatin/liposomal doxorubicin)
    b. **ONE** hormonal therapy (aromatase inhibitors [anastrozole, letrozole, exemestane], leuprolide acetate, tamoxifen)
4. **ONE** of the following:
    a. For 0.5 mg tablets, requested quantity is ≤ 3 units/day
    b. For 2 mg tablets, requested quantity is ≤ 1 unit/day

Mektovi® (binimetinib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. Requested quantity is ≤ 6 units/day
4. Positive BRAF V600E or V600K mutation
5. Documentation that the requested agent will be used in combination with Braftovi® (encorafenib)

Low-Grade Serous Carcinoma of the ovary, fallopian tube, or primary peritoneum *(off-label)*
Requests for members with a diagnosis of low-grade serous carcinoma of the ovary, fallopian tube or primary peritoneum may be approved if the following criteria are met:

1. Diagnosis of low-grade serous carcinoma
2. Prescriber is an oncologist
3. Medical records documenting an inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. **ONE** platinum-containing regimen (e.g., paclitaxel/carboplatin +/- bevacizumab, docetaxel/carboplatin, carboplatin/liposomal doxorubicin)
    b. **ONE** hormonal therapy (aromatase inhibitors [anastrozole, letrozole, exemestane], leuprolide acetate, tamoxifen)
4. Requested dose is ≤ 45 mg twice daily

Tafinlar® (dabrafenib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. For 50 mg and 75 mg capsule, requested quantity is ≤ 4 units/day
4. For positive BRAF **V600K**, documentation that the requested agent will be used in combination with Mekinist® (trametinib)
5. For positive BRAF **V600E**, documentation of **ONE** of the following:

a. The requested agent will be used in combination with Mekinist® (trametinib)
b. The requested agent will be used as monotherapy

Unresectable or metastatic solid tumors
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable or metastatic solid tumor
2. Prescriber is an oncologist
3. Member is ≥ 1 years of age
4. **ONE** of the following:
    a. For 50 mg and 75 mg capsule, requested quantity is ≤ 4 units/day
    b. For 10 gm tablet for oral solution, requested quantity is ≤ 30 units/day
5. Positive BRAF V600E mutation
6. The requested agent will be used in combination with Mekinist®(trametinib)

NSCLC
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic NSCLC
2. Prescriber is an oncologist
3. For 50 mg and 75 mg capsule, requested quantity is ≤ 4 units/day
4. Positive BRAF V600E mutation
5. Documentation that the requested agent will be used in combination with Mekinist® (trametinib)

Melanoma (adjuvant treatment)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of melanoma (for adjuvant treatment)
2. Prescriber is an oncologist
3. For 50 mg and 75 mg capsule, requested quantity is ≤ 4 units/day *(maximum one year of treatment)*
4. Positive BRAF V600E or V600K mutations
5. Documentation that the requested agent will be used in combination with Mekinist® (trametinib)
6. Involvement of lymph nodes following complete resection

Anaplastic Thyroid Cancer (ATC)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of locally advanced or metastatic anaplastic thyroid cancer
2. Prescriber is an oncologist
3. For 50 mg and 75 mg capsule, requested quantity is ≤ 4 units/day
4. Positive BRAF V600E mutation
5. Documentation that the requested agent will be used in combination with Mekinist® (trametinib)
6. Member has no satisfactory locoregional treatment options

Glioma
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of low-grade glioma
2. Prescriber is an oncologist
3. ONE of the following:
    a. For 50 mg and 75 mg capsule, requested quantity is ≤ 4 units/day
    b. For 10 gm tablet for oral solution, requested quantity is ≤ 30 units/day
4. Positive BRAF V600E mutation

5. Requested agent will be used in combination with Mekinist® (trametinib)

Zelboraf® (vemurafenib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. Requested quantity is ≤ 8 units/day
4. Positive BRAF V600E mutation

Erdheim-Chester Disease
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis Erdheim-Chester disease
2. Prescriber is an oncologist
3. Requested quantity is ≤ 8 units/day
4. Positive BRAF V600 mutation

Low-grade or high-grade glioma *(off-label)*
Requests for members with a diagnosis of low-grade or high-grade gliomas may be approved if the following criteria are met:
1. Diagnosis of glioma
2. Prescriber is an oncologist
3. Positive BRAF V600E mutation
4. Appropriate dosing
5. Requested agent will be used in combination with Cotellic® (cobimetinib) ≤ 60 mg once daily

Continuation of Therapy
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Initial authorizations will be granted for:
    a. Kimmtrak: 3 months
    b. All other agents: 6 months.
2. Reauthorizations will be granted for:
    a. Kimmtrak: 4 months
    b. All other agents: 6 months

References

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Review History

11/17/2021 – Created and Reviewed Nov P&T; alignment with the MassHealth Uniform formulary. Effective 01/01/2022

11/16/2022 – Reviewed and updated for Nov P&T; matched MH. Effective 11/1/22. Guideline update to include off-label uses for Cotellic, Mekinist, Tafinlar and Zelboraf in members with glioma (BRAF mutation) and for Mekinist and Mektovi for members with low-grade serous carcinoma of the ovary, fallopian tube, or primary peritoneum. Clarified appropriate diagnosis and quantity limits on all agents within coverage guidelines. Effective 2/1/23. Updates include expanded indication for Mekinist and Tafinlar combination therapy for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation.

01/11/23 – Reviewed and updated for Jan P&T. Off label indications were combined into own section for: low grade/high grade glioma and low-grade serous carcinoma of the ovary, fallopian tube, primary peritoneum. Effective 3/1/23.

04/12/23 – Reviewed and updated for P&T. Added Kimmtrak®(tebentafusp-tebn). Updated references. Effective 5/1/23.

05/10/23 – Reviewed and updated for P&T. Added Imlygic to criteria through the medical benefit with PA. Effective 6/5/23

2/14/24 – Reviewed and updated for P&T. Kimmtrak will only be available on MB with PA. Added expanded indication of Mekinist in combination with Tafinlar for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. Age also updated for pediatric patients from 6 years of age to 1 year of age for both Mekinist and Tafinlar for unresectable or metastatic solid tumors. Criteria for expanded indication for Cotellic in the treatment of adults with histiocytic neoplasms, which include Erdheim-Chester disease, Rosai-Dorfman disease, and Langerhans cell histiocytosis added. Effective 3/4/24