Melanoma Agents
Braftovi® (encorafenib)
Cotellic® (cobimetinib)
Mekinist® (trametinib)
Mektovi® (binimetinib)
Tafinlar® (dabrafenib)
Zelboraf® (vemurafenib)
Effective 02/01/2023

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Melanoma agents

Reference Table:

Drugs that require PA	No PA
Braftovi® (encorafenib)	Alternatives vary by specific malignancy and may include systemic chemotherapy
Cotellic® (cobimetinib)	
Mekinist® (trametinib)	
Mektovi® (binimetinib)	
Tafinlar® (dabrafenib)	
Zelboraf® (vemurafenib)	

Coverage Guidelines
Authorizations requests will be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with the 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:

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)

Low-grade or high-grade glioma
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. **BOTH** of the following:
    a. Documentation that the requested agent will be administered with Zelboraf (vemurafenib)

b. For Cotellic, requested dosing is ≤ 60 mg once daily and for Zelboraf, requested dosing is ≤ 960 mg every 12 hours

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
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)

Low-grade or high-grade glioma
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. **BOTH** of the following:
    a. Documentation that the requested agent will be administered with Tafinlar (dabrafenib)
    b. For Mekinist, requested dosing is ≤ 2 mg once daily and for Tafinlar, requested dosing is ≤ 150 mg every 12 hours

Low-Grade Serous Carcinoma of the ovary, fallopian tube, or primary peritoneum
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. Dose of 2 mg once daily

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
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. Dose of 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. Requested quantity is ≤ 4 units/day
4. If the request is positive BRAF V600K, documentation that the requested agent will be used in combination with Mekinist® (trametinib)
5. If the request is 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 ≥ 6 years of age
4. Requested quantity is ≤ 4 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. 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. 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. 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

Low-grade or high-grade glioma
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

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
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

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

Limitations
1. Initial authorizations and reauthorizations will be granted for 6 months.
2. The following quantity limits apply:

Braftovi	180 capsules per 30 days (75 mg) 120 capsules per 30 days (50 mg)
Cotellic	90 tablets per 30 days
Mekinist	90 tablets per 30 days (0.5 mg) 30 tablets per 30 days (2 mg)
Mektovi	180 tablets per 30 days
Tafinlar	120 capsules per 30 days
Zelboraf	240 tablets per 30 days

References

1. Braftovi® (encorafenib) Prescribing Information. Array BioPharma, Inc.; April 2020.
2. Cotellic Prescribing Information. Genentech, Inc. 2016.
3. Mekinist [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2020.
4. Mektovi (binimetinib) [prescribing information]. Boulder, CO: Array BioPharma Inc; October 2020.
5. Tafinlar [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2021.
6. Zelboraf (vemurafenib) [prescribing information]. South San Francisco, CA: Genentech USA Inc; May 2020.

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. Effective 02/01/23

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.