Melanoma Agents
Braftovi® (encorafenib)
Cotellic® (cobimetinib)
Mekinist® (trametinib)
Mektovi® (binimetinib)
Tafinlar® (dabrafenib)
Effective 01/01/2022

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)	
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 AllWays Health Partners 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

Braftovi® (encorafenib)

Unresectable or Metastatic Melanoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E or V600K mutation
5. Documentation that the agent will be used in combination with Mektovi® (binimetinib)

Metastatic CRC
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E mutation
5. Documentation that the 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. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E or V600K mutation
5. Documentation that the agent will be used in combination with Zelboraf® (vemurafenib)

Mekinist® (trametinib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E or V600K mutation
5. **ONE** of the following:
    a. Documentation that the agent will be used in combination with Tafinlar® (dabrafenib)
    b. **ALL** of the following:
        i. Documentation that the 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 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])

Melanoma (adjuvant treatment)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing *(maximum one year of treatment)*
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

ATC
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E mutation
5. Documentation that the agent will be used in combination with Tafinlar® (dabrafenib)
6. Member has no satisfactory locoregional treatment options

NSCLC
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E mutation
5. Documentation that the 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. Maximum dose of 1.5 mg daily
4. Medical records documenting an inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. Procarbazine, lomustine and vincristine
    b. Temozolomide
    c. Radiation therapy

Mektovi® (binimetinib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E or V600K mutation
5. Documentation that the agent will be used in combination with Braftovi® (encorafenib)

Tafinlar® (dabrafenib)

Unresectable or metastatic melanoma or NSCLC
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. If the diagnosis is melanoma, positive BRAF V600E or V600K mutation
    b. If the diagnosis is NSCLC, positive BRAF V600E mutation
5. For the diagnosis of NSCLC, Tafinlar® MUST be used in combination with Mekinist® (trametinib)

Melanoma (adjuvant treatment)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing *(maximum one year of treatment)*
4. Positive BRAF V600E or V600K mutations
5. Documentation that the agent will be used in combination with Mekinist® (trametinib)
6. Involvement of lymph nodes following complete resection

ATC
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E mutation
5. Documentation that the agent will be used in combination with Mekinist® (trametinib)
6. Member has no satisfactory locoregional treatment options

Zelboraf® (vemurafenib)

Unresectable or metastatic melanoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600E mutation

Erdheim-Chester Disease
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Positive BRAF V600 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

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

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