Pharmacy Policy

Melanoma Agents – Unified Formulary

Policy Number: 9.714
Version Number: 2
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Braftovi® (encorafenib)	
Cotellic® (cobimetinib)	
Mekinist® (trametinib)	
Mektovi® (binimetinib)	
Tafinlar® (dabrafenib)	

Procedure:

Approval Diagnosis:	• **Erdheim-Chester Disease** (Zelboraf®) • **Locally advanced or metastatic anaplastic thyroid cancer (ATC)** (Mekinist®, Tafinlar®) • **Melanoma (adjuvant treatment)** (Mekinist®, Tafinlar®) • **Metastatic colorectal cancer (CRC) (Braftovi®)** • **Non-small cell lung cancer (NSCLC)** (Mekinist®, Tafinlar®)

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	• **Unresectable or metastatic melanoma** (Braftovi®, Cotellic®, Mekinist®, Mektovi®, Tafinlar®)
Approval Criteria: **Braftovi®** (encorafenib)	**<u>Unresectable or Metastatic Melanoma</u>** 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) **<u>Metastatic CRC</u>** 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 *Note:* • ***Please send requests for the combination of Braftovi® (encorafenib) + Mektovi® (binimetinib) + (Erbitux® [cetuximab] or Vectibix® [panitumumab]) to Clinical Review for further evaluation.*
Approval Criteria: **Cotellic®** (cobimetinib)	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)
Approval Criteria: **Mekinist®** (trametinib)	**<u>Unresectable or metastatic melanoma</u>** 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]) noted on PA request or in all claims history*
   iii. Clinical rationale for bypassing use of a BRAF inhibitor (i.e. Tafinlar® [dabrafenib] or Zelboraf®[vemurafenib])

Notes:

- *If member has not completed therapy with a BRAF inhibitor but has experienced an adverse drug event (*not* disease progression) during such therapy, approval of Mekinist® may be considered if criteria 1 to 4 are met. See Appendix for additional information.

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. Member has lymph node involvement and 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)

Mekinist® (trametinib) Requests for Members with Gliomas

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
Approval Criteria: **Mektovi®** (binimetinib)	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)
Approval Criteria: **Tafinlar®** (dabrafenib)	**<u>Unresectable or metastatic melanoma or NSCLC</u>** 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) **<u>Melanoma (adjuvant treatment)</u>** 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. Member has lymph node involvement and complete resection **<u>ATC</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. BRAF V600E mutation

	5. Documentation that the agent will be used in combination with Mekinist® (trametinib) 6. Member has no satisfactory locoregional treatment options
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration/Quantity of Authorization:	Prior authorization may be issued for **6 months.**
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and request can be recertified for **6 months.**

Appendix:

Stability

Stability on Braftovi® (encorafenib), Cotellic® (cobimetinib), Mekinist® (trametinib), Mektovi® (binimetinib) or Tafinlar® (dabrafenib) is not sufficient rationale to bypass approval criteria. However, requests for members who have already started treatment on these agents should be reviewed with clinical review and approval strongly considered for any member with any FDA-approved indication.

Grandfathering

Information is not applicable.

Additional Information

Mekinist® (trametinib)

Mekinist® (trametinib) with prior BRAF inhibitor use

According to prescribing information, Mekinist® (trametinib) is not indicated for treatment of patients who have experienced disease progression with prior BRAF inhibitor therapy. The principal indication for Mekinist® (trametinib) as a *primary* treatment for BRAF-mutated metastatic melanoma is intolerance to BRAF inhibitors.

Therefore**, if a member has not completed therapy with a BRAF inhibitor due to an adverse drug event (*not* disease progression) that caused cessation of this therapy, such a request for Mekinist® can be approved if an appropriate diagnosis and BRAF V600E or V600K mutation is documented.** If the request or the response to previous BRAF inhibitor therapy is unclear, please contact the office for clarification before considering denial.

Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
5/13/2021	Moved clinical criteria from the appendix to Approval Criteria section of the policy for Mekinist.	9/1/2021	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

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The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.