

Pharmacy Policy

Melanoma Agents – Unified Formulary

Policy Number: 9.714

Version Number: 2

Version Effective Date: 1/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan[†] Products</p>	
<p>Well Sense Health Plan</p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p>Boston Medical Center HealthNet Plan</p> <p><input checked="" type="checkbox"/> MassHealth- MCO</p> <p><input checked="" type="checkbox"/> MassHealth- ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>
<p>Benefit</p>	<p><input checked="" type="checkbox"/> Pharmacy Benefit</p> <p><input type="checkbox"/> Medical Benefit</p>

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)	

[†] Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Drugs that require PA	No PA
Zelboraf® (vemurafenib)	

Approval Criteria:

<p>Braftovi® (encorafenib)</p>	<ol style="list-style-type: none"> 1. Documented diagnosis of unresectable or metastatic melanoma; AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documentation of positive BRAF V600E or V600K mutation; AND c. Documentation that the agent will be used in combination with Mektovi® (binimetinib) <li style="text-align: center;">OR 2. Documented diagnosis of metastatic colorectal cancer (CRC); AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documentation of positive BRAF V600E mutation; AND c. Documentation that the agent will be used in combination with Erbitux® (cetuximab) or Vectibix® (panitumumab); AND d. Documented inadequate response or adverse reaction to at least ONE of the following regimens or a contraindication to ALL of the following regimens: <ol style="list-style-type: none"> i. capecitabine/oxaliplatin (CAPEOX) ii. leucovorin calcium (folinic acid)/fluorouracil/oxaliplatin (FOLFOX) iii. irinotecan-based therapy iv. oxaliplatin-based therapy
<p>Cotellic® (cobimetinib)</p>	<ol style="list-style-type: none"> 1. Documented diagnosis of unresectable or metastatic melanoma; AND 2. Prescriber is an oncologist; AND 3. Documentation of positive BRAF V600E or V600K mutation; AND 4. Documentation that the agent will be used in combination with Zelboraf® (vemurafenib)
<p>Mekinist® (trametinib)</p>	<ol style="list-style-type: none"> 1. Documented diagnosis of unresectable or metastatic melanoma; AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documentation of positive BRAF V600E or V600K mutation; AND c. ONE of the following: <ol style="list-style-type: none"> i. Documentation that the agent will be used in combination with Tafinlar® (dabrafenib); OR ii. ALL of the following: <ol style="list-style-type: none"> 1. Documentation that the agent will be used as a single agent (not in combination with Tafinlar® [dabrafenib]); AND

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	<p>2. 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; AND</p> <p>3. Clinical rationale for bypassing use of a BRAF inhibitor (i.e. Tafinlar[®] [dabrafenib] or Zelboraf[®] [vemurafenib])</p> <p style="text-align: center;">OR</p> <p>2. Documented diagnosis of melanoma (adjuvant treatment); AND</p> <p style="margin-left: 20px;">a. Prescriber is an oncologist; AND</p> <p style="margin-left: 20px;">b. Member has not exceeded the maximum of one year of treatment; AND</p> <p style="margin-left: 20px;">c. Documentation of positive BRAF V600E or V600K mutation; AND</p> <p style="margin-left: 20px;">d. Documentation that the agent will be used in combination with Tafinlar[®] (dabrafenib); AND</p> <p style="margin-left: 20px;">e. Documentation of involvement of lymph nodes following complete resection</p> <p style="text-align: center;">OR</p> <p>3. Documented diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC); AND</p> <p style="margin-left: 20px;">a. Prescriber is an oncologist; AND</p> <p style="margin-left: 20px;">b. Documentation of positive BRAF V600E mutation; AND</p> <p style="margin-left: 20px;">c. Documentation that the agent will be used in combination with Tafinlar[®] (dabrafenib); AND</p> <p style="margin-left: 20px;">d. Documentation member has no satisfactory locoregional treatment options</p> <p style="text-align: center;">OR</p> <p>4. Documented diagnosis of non-small cell lung cancer (NSCLC); AND</p> <p style="margin-left: 20px;">a. Prescriber is an oncologist; AND</p> <p style="margin-left: 20px;">b. Documentation of positive BRAF V600E mutation; AND</p> <p style="margin-left: 20px;">c. Documentation that the agent will be used in combination with Tafinlar[®] (dabrafenib)</p> <p style="text-align: center;">OR</p> <p>5. Documented diagnosis of glioma; AND</p> <p style="margin-left: 20px;">a. Prescriber is an oncologist; AND</p> <p style="margin-left: 20px;">b. Medical records provided documenting an inadequate response, adverse reaction, or contraindication to ALL of the following:</p> <p style="margin-left: 40px;">i. Procarbazine, lomustine and vincristine</p> <p style="margin-left: 40px;">ii. Temozolomide</p> <p style="margin-left: 40px;">iii. Radiation therapy</p>
--	---

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

<p>Mektovi® (binimetinib)</p>	<ol style="list-style-type: none"> 1. Documented diagnosis of unresectable or metastatic melanoma; AND 2. Prescriber is an oncologist; AND 3. Documentation of positive BRAF V600E or V600K mutation; AND 4. Documentation that the agent will be used in combination with Braftovi® (encorafenib)
<p>Tafinlar® (dabrafenib)</p>	<ol style="list-style-type: none"> 1. Documented diagnosis of unresectable or metastatic melanoma; AND <ol style="list-style-type: none"> a. Prescriber is an oncologist b. Documentation of positive BRAF V600E or V600K mutation <p style="text-align: center;">OR</p> 2. Documented diagnosis of non-small cell lung cancer; AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documentation of positive BRAF V600E mutation; AND c. Documentation Tafinlar® will be used in combination with Mekinist® (trametinib) <p style="text-align: center;">OR</p> 3. Documented diagnosis of melanoma (adjuvant treatment); AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documentation member has not exceeded the maximum one year of treatment; AND c. Documented positive BRAF V600E or V600K mutations; AND d. Documentation that the agent will be used in combination with Mekinist® (trametinib); AND e. Documentation member has involvement of lymph nodes following complete resection <p style="text-align: center;">OR</p> 4. Documented diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC); AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documentation of positive BRAF V600E mutation; AND c. Documentation that the agent will be used in combination with Mekinist® (trametinib); AND d. Member has no satisfactory locoregional treatment options
<p>Zelboraf® (vemurafenib)</p>	<ol style="list-style-type: none"> 1. Documented diagnosis of unresectable or metastatic melanoma; AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documented positive BRAF V600E mutation <p style="text-align: center;">OR</p> 2. Documented diagnosis of Erdheim-Chester Disease; AND <ol style="list-style-type: none"> a. Prescriber is an oncologist; AND b. Documented positive BRAF V600 mutation

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Duration/Quantity of Authorization:	Prior authorization may be issued for 6 months .
--	---

Appendix:

Additional Information

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus. Requests for other diagnoses must be submitted with appropriate clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

References

1. Braftovi (encorafenib) [prescribing information]. Boulder, CO: Array BioPharma Inc.; April 2020.
2. Cotellic (cobimetinib) [prescribing information]. San Fransico, CA: Genetech USA, Inc.; May 2016.
3. Mekinist (trametinib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.
4. Mektovi (binimetinib) [prescribing information]. Boulder, CO: Array BioPharma Inc.; 2018 June.
5. Tafinlar (dabrafenib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2018.
6. Zelboraf (vemurafenib) [package insert]. South San Francisco, CA: Genentech, Inc.; November 2017.

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

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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
10/1/2021	MH UPPL Update: One new agent, Zelboraf [®] , added to UPPL. Guideline updated to reflect addition of word “positive” to Tafinlar ATC approval criteria and minor change to wording for melanoma (adjuvant treatment) criteria for Mekinist and Tafinlar.	1/1/2022	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the “Sullivan Law”: (M.G.L. c.175, s.47K).

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

^{*} Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

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.

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.

^{*} *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.