Melanoma Agents

Braftovi® (encorafenib)
Cotellic® (cobimetinib)
Mekinist® (trametinib)
Mektovi® (binimetinib)
Tafinlar® (dabrafenib)

Effective 01/01/2022

<table>
<thead>
<tr>
<th>Plan</th>
<th>☐ MassHealth</th>
<th>☑ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☑ Prior Authorization</th>
<th>☐ Quantity Limit</th>
<th>☐ Step Therapy</th>
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<tbody>
<tr>
<td>Benefit</td>
<td>☑ Pharmacy Benefit</td>
<td>☐ Medical Benefit (NLX)</td>
<td></td>
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Specialty Limitations: These medications have been designated specialty and must be filled at a contracted specialty pharmacy.

Specialty Medications

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Specialty Medications</th>
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</thead>
<tbody>
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<td>All Plans</td>
<td>Phone: 866-814-5506</td>
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Non-Specialty Medications

<table>
<thead>
<tr>
<th>Program Type</th>
<th>Non-Specialty Medications</th>
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<tbody>
<tr>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
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<tr>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
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<tr>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
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</table>

Medical Specialty Medications (NLX)

<table>
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<tr>
<th>Program Type</th>
<th>Medical Specialty Medications (NLX)</th>
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<tbody>
<tr>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
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</tbody>
</table>

Exceptions: N/A

Overview
Melanoma agents

Reference Table:

<table>
<thead>
<tr>
<th>Drugs that require PA</th>
<th>No PA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Braftovi® (encorafenib)</td>
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<tr>
<td>Tafinlar® (dabrafenib)</td>
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<tr>
<td>Zelboraf® (vemurafenib)</td>
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</table>

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**

**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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