Prior Authorization
Oncology – Mektovi® (binimetinib tablets)

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Product Identifier(s)

61464

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Cigna covers binimetinib (Mektovi®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior Authorization is recommended for prescription benefit coverage of Mektovi. All approvals are provided the duration noted below.

FDA Indication(s)

1. **Melanoma.** Approve for 1 year if the individual meets the following (A, B, C, and D):
   - **A)** Individual is ≥ 18 years of age; AND
   - **B)** Individual has unresectable, advanced, or metastatic melanoma; AND
   - **C)** Individual has *BRAF V600* mutation-positive disease; AND
   - **D)** The medication will be used in combination with Braftovi (encorafenib capsules).

Other Uses with Supportive Evidence

2. **Histiocytic Neoplasm.** Approve for 1 year if the individual meets the following (A and B):
   A) Individual is ≥ 18 years of age; AND
   B) Individual has Langerhans cell histiocytosis and one of the following (i, ii, or iii):
      i. Multisystem disease; OR
      ii. Pulmonary disease; OR
      iii. Central nervous system lesions.

Conditions Not Covered

Binimetinib (Mektovi®) is considered experimental, investigational or unproven for ANY other use.

Background

Overview
Mektovi, a kinase inhibitor, is indicated in combination with Braftovi® (encorafenib capsules) for treatment of adults with unresectable or metastatic **melanoma** with a *BRAF V600E* or *V600K* mutation as detected by an FDA-approved test.[1]

Guidelines
National Comprehensive Cancer Network guidelines support use of Mektovi in the following cancers.

- **Histiocytic Neoplasms:** Guidelines (version 1.2022 – May 20, 2022) recommend Cotellic® (preferred) or Mektovi (other recommended regimen) for histiocytic neoplasms (if there is a MAP kinase pathway mutation, or no detectable mutation, or testing is not available) for the following types: Langerhans cell histiocytosis (including multisystem, pulmonary, or central nervous system lesions).[3]
- **Melanoma, Cutaneous:** Guidelines (version 3.2022 – April 11, 2022) recommend BRAF/MEK inhibitor combinations among the preferred therapies for first-line and subsequent treatment of metastatic or unresectable melanoma with a *V600* activating mutation.[2] While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is an option. Tafinlar® (dabrafenib capsules) + Mekinist® (trametinib tablets) is also recommended in guidelines as adjuvant therapy (including for nodal recurrence) in some patients with Stage III disease, including use post-surgery or use after complete lymph node dissection. If unacceptable toxicity to Tafinlar/Mekinist, other BRAF/MEK combinations can be considered.

References

1. Mektovi® tablets [prescribing information]. Boulder, CO: Array BioPharma; January 2019.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 3.2022 – April 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 30, 2022.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – May 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 30, 2022.
4. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – July 13, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on July 30, 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Melanoma:** A requirement was added that the patient is ≥ 18 years of age.	08/04/2021

Selected Revision	Approval duration was changed from 3 years to 1 year.	06/22/2022
Annual Revision	**Histiocytic Neoplasm:** To align with NCCN guidelines, this indication was added to the policy.	08/03/2022