PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Mektovi Prior Authorization Policy
- Mektovi® (binimetinib tablets – Array BioPharma)

REVIEW DATE: 08/14/2024

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Mektovi, a kinase inhibitor, is indicated for the following uses: [1]

- **Melanoma,** in combination with Braftovi® (encorafenib capsules) for the treatment of patients with unresectable or metastatic disease with a *BRAF V600E* or *V600K* mutation as detected by an FDA-approved test.
- **Non-small cell lung cancer (NSCLC),** in combination with Braftovi, for the treatment of adult patients with metastatic NSCLC with a *BRAF V600E* mutation, as detected by an FDA-approved test.

Guidelines

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

- **Histiocytic Neoplasms:** Guidelines (version 2.2024 – July 19, 2024) recommend Cotellic® (cobimetinib tablets) "Preferred" or Mektovi as one of the "Other Recommended Regimens" (category 2A) 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 2.2024 – April 3, 2024) recommend BRAF/MEK inhibitor combinations among the "Preferred" therapies

for first-line (category 1) and subsequent treatment (category 2A) of metastatic or unresectable melanoma with a *V600* activating mutation.[2] This combination is also recommended for adjuvant treatment (category 2B). Mektovi as a single agent is a category 2B recommendation for NRAS-mutated tumors (for progression following immune checkpoint inhibitor therapy). While combination BRAF/MEK inhibition is preferred, if a combination is contraindicated, monotherapy with a BRAF inhibitor is an option, especially in patients who are not appropriate candidates for checkpoint immunotherapy.

- **Non-Small Cell Lung Cancer:** Guidelines (version 7.2024 – June 26, 2024) recommend Braftovi + Mektovi and Tafinlar® (dabrafenib capsules) + Mekinist® (trametinib tablets) for first-line "Preferred" regimens and as subsequent therapies (both category 2A) for *BRAF V600E* mutation-positive disease.[4] Zelboraf® (vemurafenib tablets) or Tafinlar monotherapy is also recommended under "Useful in Certain Circumstances" (both category 2A).

POLICY STATEMENT

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

- **Mektovi® (binimetinib tablets – Array BioPharma)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

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

2. **Non-Small Cell Lung Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has *BRAF V600E* mutation-positive metastatic disease; AND
   C) The medication will be taken in combination with Braftovi (encorafenib capsules).

Other Uses with Supportive Evidence

3. **Histiocytic Neoplasm.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND

B) Patient has Langerhans cell histiocytosis and meets ONE of the following (i, ii, or iii):
- **i.** Multisystem disease; OR
- **ii.** Pulmonary disease; OR
- **iii.** Central nervous system lesions.

CONDITIONS NOT COVERED

- **Mektovi® (binimetinib tablets – Array BioPharma)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following; criteria will be updated as new published data are available.

REFERENCES

1. Mektovi® tablets [prescribing information]. Boulder, CO: Array BioPharma; October 2023.
2. The NCCN Melanoma Clinical Practice Guidelines in Oncology (version 2.2024 – April 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 9, 2024.
3. The NCCN Histiocytic Neoplasms Clinical Practice Guidelines in Oncology (version 2.2024 – July 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 9, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 7.2024 – June 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org/. Accessed on August 9, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	07/19/2023
Selected Revision	**Non-Small Cell Lung Cancer:** Added new FDA-approved indication and criteria	10/18/2023
Annual Revision	No criteria changes	08/14/2024