PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Gomekli Prior Authorization Policy
- Gomekli™ (mirdametinib tablets – SpringWorks Therapeutics)

REVIEW DATE: 02/19/2025

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

Gomekli, a kinase inhibitor, is indicated for the treatment of neurofibromatosis type 1 (NF1) in adults and pediatric patients 2 years of age and older with symptomatic plexiform neurofibromas (PN) not amenable to complete resection.[1]

Disease Overview

NF1 is an autosomal dominant genetic condition due to loss-of-function variants in the *NF1* gene.[2] The birth incidence for NF1 is approximately 1 per 2,500. This gene variant results in persistent mitogen-activated protein kinase (MAPK) pathway activation and neurofibromin dysfunction. PNs are non-malignant nerve sheath tumors that develop in 30% to 50% of patient with NF1; this type of tumor causes pain, organ displacement/compression, impaired physical function, disfigurement, and deteriorated quality of life. PN tumors can transform into malignant peripheral nerve sheath tumors. Surgery is the primary treatment for NF1 with PN. However, it is associated with life-altering morbidities and tumor regrowth. Koselugo® (selumetinib capsules) is FDA-approved for the treatment of pediatric patients 2 years and older with NF1 and symptomatic, inoperable PN.[3]

POLICY STATEMENT

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

- **Gomekli™ (mirdametinib tablets - SpringWorks Therapeutics)**

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 Indication

1. **Neurofibromatosis Type 1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 2 years of age; AND
   B) According to the prescriber, patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli; AND
   C) The tumor is not amenable to complete resection.

CONDITIONS NOT COVERED

- **Gomekli™ (mirdametinib tablets - SpringWorks Therapeutics)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Gomekli™ capsules [prescribing information]. Stamford, CT: SpringWorks Therapeutics; February 2025.
2. Moertel CL, Hirbe AC, Shuhaiber HH, et al. ReNeu: A pivotal, phase IIb trial of mirdametinib in adults and children with symptomatic neurofibromatosis type 1 – associated plexiform neurofibroma. *J Clin Oncol.* 2024 Nov 8:JCO2401034 [Epubh ahead of print].
3. Koselugo® capsules [prescribing information]. Wilmington, DE: AstraZeneca; January 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/19/2025