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Section:	Prescription Drugs	**Effective Date:**	July 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	March 14, 2025
Subject:	Gomekli	**Page:**	1 of 4

Last Review Date: June 12, 2025

Gomekli

Description

Gomekli (mirdametinib)

Background
Gomekli (mirdametinib) is an inhibitor of mitogen-activated protein kinases 1 and 2 (MEK1/2). MEK1/2 proteins are upstream regulators of the extracellular signal-related kinase (ERK) pathway. In vitro, Gomekli inhibited kinase activity of MEK1 and MEK2 and downstream phosphorylation of ERK. In a mouse model of neurofibromatosis type 1 (NF1), oral dosing of Gomekli inhibited ERK phosphorylation and reduced neurofibroma tumor volume and proliferation (1).

Regulatory Status
FDA-approved indication: Gomekli is a kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection (1).

Prior to administration of Gomekli, a comprehensive ophthalmic assessment should be conducted and ejection fraction (EF) by echocardiogram should be assessed (1).

Gomekli carries warnings for ocular toxicity, left ventricular dysfunction, dermatologic adverse reactions, and embryo-fetal toxicity (1).

Gomekli can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to the initiation of Gomekli. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be

advised to use effective contraception during treatment with Gomekli and for 6 weeks after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Gomekli and for 3 months after the last dose (1).

The safety and effectiveness of Gomekli in pediatric patients less than 2 years of age have not been established (1).

Related policies
Koselugo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Gomekli may be considered **medically necessary** if the conditions indicated below are met.

Gomekli may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

Neurofibromatosis Type 1 (NF1)

AND ALL of the following**:**

a. Patient is symptomatic
b. Patient has plexiform neurofibromas (PN) that are not amenable to complete resection
c. Baseline ophthalmic assessment has been done and prescriber agrees to monitor for ocular toxicities
d. Baseline left ventricular ejection fraction (LVEF) has been assessed and prescriber agrees to monitor LVEF

e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Gomekli and for 6 weeks after the last dose
f. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Gomekli and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

Neurofibromatosis Type 1 (NF1)

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for ocular toxicities
c. Prescriber agrees to monitor left ventricular ejection fraction (LVEF)
d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Gomekli and for 6 weeks after the last dose
e. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Gomekli and for 3 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 8 mg per day (for first 21 days of 28 day cycle)

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Gomekli (mirdametinib) is a kinase inhibitor indicated for the treatment of patients 2 years of age and older with neurofibromatosis type 1 (NF1). Gomekli carries warnings for ocular toxicity, left ventricular dysfunction, and dermatologic adverse reactions. Gomekli can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Gomekli in pediatric patients less than 2 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Gomekli while maintaining optimal therapeutic outcomes.

References

1. Gomekli [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025.
2. NCCN Drugs & Biologics Compendium® Mirdametinib 2025. National Comprehensive Cancer Network, Inc. Accessed on April 17, 2025.

Policy History

Date	Action
March 2025	Addition to PA
June 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.