

DRUG POLICY

Gomekli® (mirdametinib)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Gomekli (mirdametinib) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Gomekli is 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.

POLICY

Criteria for Initial Approval

Neurofibromatosis Type 1

Authorization of 12 months may be granted for treatment of neurofibromatosis type 1 (NF1) when all of the following criteria are met:

1. Member is 2 years of age and older
2. Member has symptomatic plexiform neurofibromas (PN) not amenable to complete resection
3. Member will not use the requested medication in combination with Koselugo (selumetinib)

Continuation of Therapy

Neurofibromatosis Type 1

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of neurofibromatosis type 1 (NF1) when all of the following criteria are met:

1. Member has not experienced unacceptable toxicity or disease progression while on the current regimen
2. Member will not use the requested medication in combination with Koselugo (selumetinib)

Other

Gomekli (mirdametinib) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Gomekli (mirdametinib) 1 mg capsules	42 capsules per 28 days	2 mg/m ² orally twice daily for the first 21 days of each 28-day cycle. The maximum dose is 4 mg twice daily.
Gomekli (mirdametinib) 2 mg capsules	84 capsules per 28 days	• Body surface area (BSA) 0.40 to 0.69 m²: 1 mg twice daily • BSA 0.70 to 1.04 m²: 2 mg twice daily • BSA 1.05 to 1.49 m²: 3 mg twice daily • BSA greater than or equal to 1.50 m²: 4 mg twice daily
Gomekli (mirdametinib) 1 mg tablets for oral suspension	168 tablets per 28 days	

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

Gomekli [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025.

Moertel CL, et al. ReNeu: a pivotal, Phase IIb trial of mirdametinib in adults and children with symptomatic neurofibromatosis Type 1-associated plexiform neurofibroma [published correction appears in *J Clin Oncol*. 2025;43(2):239. doi:10.1200/JCO-24-02561.]. *J Clin Oncol*. doi:10.1200/JCO.24.01034

Weiss BD, et al. NF106: a neurofibromatosis clinical trials consortium Phase II trial of the MEK inhibitor mirdametinib (PD-0325901) in adolescents and adults with NF1-related plexiform neurofibromas. *J Clin Onc*. 2021;39(7):797–806. doi.org/10.1200/JCO.20.02220

POLICY HISTORY

Policy #: 05.05.77

Original Effective Date: May 21, 2025

Reviewed: August 2026

Revised:

Current Effective Date: May 21, 2025