Generic Name: Mirdametinib

Therapeutic Class or Brand Name: Gomekli

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: 2/19/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

I. Documentation of the following FDA-approved diagnoses AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Neurofibromatosis

i. Documentation of neurofibromatosis type 1 (NF1)

ii. Documentation of symptomatic plexiform neurofibromas (PN)

iii. Documentation that disease is not amenable to complete resection

iv. Documentation that disease is causing significant morbidity (ex, pain, motor dysfunction, airway dysfunction, visual impairment, etc.)

v. Gomekli will be used as monotherapy.

II. Minimum age requirement: 2 years old or older.

III. Treatment must be prescribed by or in consultation with an oncologist, neurologist or physician specializing in NF1.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

- Quantities limited to 30-day supply
    - Capsules: 1 mg, 2 mg; Tablets for oral suspension: 1 mg
    - Dose: 2mg/m2 orally twice daily (maximum dose 4 mg twice daily) for the first 21 days of each 28-day cycle

BSA (m2)	Dose (capsules or tablets)
0.4 to 0.69	1 mg twice daily
0.7 to 1.04	2 mg twice daily
1.05 to 1.49	3 mg twice daily
≥ 1.5	4 mg twice daily *maximum dose*

    - Dose has not been established for < 0.4 m2

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

Appendix

N/A

References

1. Gomekli. Prescribing Information. SpringWorks Therapeutics, Inc. 2025. Accessed February 19, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2025/219379Orig1s000lbl.pdf
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;43(6):716-729. DOI: 10.1200/JCO.24.01034
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 3.2025. Updated December 5, 2025. Accessed February 19, 2026. www.nccn.org/professionals/physician_gls/pdf/cns.pdf