

Generic Name: Mirdametinib

Preferred: N/A

Therapeutic Class or Brand Name: Gomekli

Non-preferred: N/A

Applicable Drugs: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

- I. Documentation of the following 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 clinical practice guidelines.
- 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 (m ²)	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

- Gomekli. Prescribing Information. SpringWorks Therapeutics, Inc. February 2025. Accessed April 17, 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2025/219379Orig1s000lbl.pdf
- 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

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.