Clinical Policy: Mirdametinib (Gomekli)

Reference Number: CP.PHAR.718
Effective Date: 06.01.25
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Mirdametinib (Gomekli™) is a mitogen-activated protein (MAP) kinase enzyme 1/2 inhibitor.

FDA Approved Indication(s)

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

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Gomekli is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Neurofibromatosis Type 1 (must meet all)**:**

1. Diagnosis of NF1;
2. Prescribed by or in consultation with an oncologist or neurologist;
3. Age ≥ 2 years;
4. For Gomekli requests, member must use mirdametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
5. Member has body surface area ≥ 0.40 m^2;
6. Member meets one of the following (a or b):
   a. Positive genetic testing for NF1;
   b. Member has at least one other diagnostic criterion for NF1 (*see Appendix D*);
7. Member has at least one inoperable and measurable PN, defined as a lesion ≥ 5 mL in volume;
8. Complete resection of PN is not considered to be feasible without substantial risk or morbidity (e.g., due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN);
9. Gomekli is not prescribed concurrently with Koselugo®;
10. Dose does not exceed both of the following (a and b):
    a. 4 mg/m^2 (up to a maximum of 8 mg) per day for the first 21 days of each 28-day cycle;
    b. 6 capsules or 8 tablets per day for the first 21 days of each 28-day cycle.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Neurofibromatosis Type 1 (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Gomekli for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy as evidenced by decreased or maintained volume of PN(s) from baseline;
3. For Gomekli requests, member must use mirdametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, new dose does not exceed both of the following (a and b):
   a. 4 mg/m^2 (up to a maximum of 8 mg) per day for the first 21 days of each 28-day cycle;
   b. 6 capsules or 8 tablets per day for the first 21 days of each 28-day cycle.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the

relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
MAP: mitogen-activated protein
NF1: neurofibromatosis type 1
PN: plexiform neurofibroma

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: National Institute of Health (NIH) Consensus Conference NF1 Diagnostic Criteria

At least one of the following:

- Six or more café-au-lait macules with a diameter > 5 mm in prepubertal and > 15 mm in post-pubertal individuals, respectively
- Freckling in axilla or inguinal regions
- Optic glioma
- Two or more Lisch nodules
- A distinctive bony lesion (dysplasia of the sphenoid bone or dysplasia of thinning of long bone cortex)
- A first degree relative with NF1

Appendix E: Recommended Dosage Based on Body Surface Area

Body Surface Area	Recommended Dosage
0.40 – 0.69 m^2	1 mg twice daily
0.70 – 1.04 m^2	2 mg twice daily
1.05 – 1.49 m^2	3 mg twice daily
≥ 1.50 m^2	4 mg twice daily

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NF1	2 mg/m^2 PO BID for the first 21 days of each 28-day cycle. Continue until disease progression or unacceptable toxicity	8 mg/day

VI. Product Availability

- Capsules: 1 mg, 2 mg
- Tablet for oral suspension: 1 mg

VII. References

1. Gomekli Prescribing Information. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025. https://www.gomekli.com/. Accessed January 23, 2026.
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; 43(6): 716-729.
3. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed January 29, 2026.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed January 29, 2026.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.25.25	05.25
2Q 2026 annual review: no significant changes; for Medicaid/HIM, extended initial approval duration from 6 to 12 months; references reviewed and updated. Added ICHRA line of business.	03.30.26	05.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.