

Commercial PA Criteria

Effective: May 8, 2025

Prior Authorization: Gomekli

Products Affected: Gomekli (mirdametininb) tablets

Medication Description: Mirdametininb is an inhibitor of mitogen-activated protein kinase kinases 1 and 2 (MEK1/2). MEK1/2 proteins are upstream regulators of the extracellular signal-related kinase (ERK) pathway.

Covered Uses: Treatment of neurofibromatosis type 1 (NF1) in adults and pediatric patients 2 years of age and older with symptomatic plexiform neurofibromas (PN) not amenable to complete resection

Exclusion Criteria:

1. None

Required Medical Information:

1. Diagnosis

Prescriber Restriction: Prescribed by, or in consultation with, an oncologist or neurologist.

Age Restriction: 2 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

1. **Neurofibromatosis Type 1.** Approve for 1 year if the patient meets ALL of the following (A, B, C **AND** D):
 - A. Patient is ≥ 2 years of age; **AND**
 - B. According to the prescriber, patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli; **AND**
 - C. The tumor is not amenable to complete resection **AND**
 - D. Prescribed by, or in consultation with, an oncologist or neurologist

Renewal Criteria

1. Member has responded positively to therapy according to the prescriber; **AND**
2. Member has not experienced unacceptable toxicity from the medication

References:

1. Gomekli™ capsules [prescribing information]. Stamford, CT: SpringWorks Therapeutics; February 2025.
2. Moertel CL, Hirbe AC, Shuhaiber HH, et al. ReNeu: A pivotal, phase IIb trial of mirdametininb in adults and children with symptomatic neurofibromatosis type 1 – associated plexiform neurofibroma. J Clin Oncol. 2024 Nov 8;JCO2401034 [Epubh ahead of print].
3. Koselugo® capsules [prescribing information]. Wilmington, DE: AstraZeneca; January 2024.

April 2025



Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	05/08/2025