VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Gomekli Prior Authorization Policy
- Gomekli™ (mirdametinib tablets – SpringWorks Therapeutics)

REVIEW DATE: 02/19/2025

OVERVIEW

Gomekli, a kinase inhibitor, is indicated for the 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.[1]

Disease Overview

NF1 is an autosomal dominant genetic condition due to loss-of-function variants in the *NF1* gene.[2] The birth incidence for NF1 is approximately 1 per 2,500. This gene variant results in persistent mitogen-activated protein kinase (MAPK) pathway activation and neurofibromin dysfunction. PNs are non-malignant nerve sheath tumors that develop in 30% to 50% of patient with NF1; this type of tumor causes pain, organ displacement/compression, impaired physical function, disfigurement, and deteriorated quality of life. PN tumors can transform into malignant peripheral nerve sheath tumors. Surgery is the primary treatment for NF1 with PN. However, it is associated with life-altering morbidities and tumor regrowth. Koselugo® (selumetinib capsules) is FDA-approved for the treatment of pediatric patients 2 years and older with NF1 and symptomatic, inoperable PN.[3]

Guidelines

The National Comprehensive Cancer Network (NCCN) central nervous system (CNS) cancers guidelines (version 5.2024 – March 18, 2025) recommend Gomekli as "Useful in Certain Circumstances" for miscellaneous CNS tumors for its FDA-approved use (category 2A).[4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Gomekli. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Gomekli is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Neurofibromatosis Type 1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Gomekli is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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 mirdametinib 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.
4. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 5.2024 – March 18, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 27, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/19/2025
DEU Update	03/27/2025: Added Guidelines section in Overview to address Gomekli.	--