BlueCross BlueShield Federal Employee Program

GOMEKLI
(mirdametinib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Gomekli (mirdametinib) is an inhibitor of mitogen-activated protein kinases 1 and 2 (MEK1/2). MEK1/2 proteins are upstream regulators of the extracellular signal-related kinase (ERK) pathway. In vitro, Gomekli inhibited kinase activity of MEK1 and MEK2 and downstream phosphorylation of ERK. In a mouse model of neurofibromatosis type 1 (NF1), oral dosing of Gomekli inhibited ERK phosphorylation and reduced neurofibroma tumor volume and proliferation (1).

Regulatory Status

FDA-approved indication: Gomekli is a kinase inhibitor 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 (1).

Prior to administration of Gomekli, a comprehensive ophthalmic assessment should be conducted and ejection fraction (EF) by echocardiogram should be assessed (1).

Gomekli carries warnings for ocular toxicity, left ventricular dysfunction, dermatologic adverse reactions, and embryo-fetal toxicity (1).

Gomekli can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to the initiation of Gomekli. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Gomekli and for 6 weeks after the last dose. Males with female partners of reproductive potential should be advised to use effective contraception during treatment with Gomekli and for 3 months after the last dose (1).

The safety and effectiveness of Gomekli in pediatric patients less than 2 years of age have not been established (1).

Summary

Gomekli (mirdametinib) is a kinase inhibitor indicated for the treatment of patients 2 years of age and older with neurofibromatosis type 1 (NF1). Gomekli carries warnings for ocular toxicity, left

ventricular dysfunction, and dermatologic adverse reactions. Gomekli can cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Gomekli in pediatric patients less than 2 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Gomekli while maintaining optimal therapeutic outcomes.

References

1. Gomekli [package insert]. Stamford, CT: SpringWorks Therapeutics, Inc.; February 2025.
2. NCCN Drugs & Biologics Compendium® Mirdametinib 2025. National Comprehensive Cancer Network, Inc. Accessed on February 14, 2025.