SpringWorks CareConnections™
844-CARES-55 (844-227-3755)
Monday-Friday, 8 AM - 10 PM ET

Prior Authorization Tips and Checklist

You can also visit: **springworkstxcares.com/gomekli/hcp/resources**.

Prior authorization (PA) is a routine process used by insurers to confirm that certain drugs or services are medically necessary and otherwise covered. Coverage criteria may vary, so it is important to review the individual guidelines for each insurer and medication. This resource provides a checklist and relevant tips that may be useful when creating a letter of medical necessity or medical exception to support a prior authorization request. Use of the information in this checklist does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payor's specific requirements at that time.

☐ Complete a PA request form

- Complete and submit the PA request form to the insurer. Some plans accept a standardized PA form, while others require you to complete a form they provide. PA forms can be obtained through the insurer's website or by contacting the insurer's customer service.
  - Insurers may require a letter of medical necessity or medical exception. Even if it is not required, it can be helpful to compose a written letter demonstrating medical necessity or medical exception for the prescribed medication. A sample letter of medical necessity or medical exception is available at **springworkstxcares.com/gomekli/hcp/resources**.

☐ Provide a copy of the patient's records and ensure there is a valid GOMEKLI™ (mirdametinib) prescription

- Remember to provide copies of relevant patient records (eg, charts, test results), including a valid prescription for GOMEKLI. GOMEKLI is approved 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.
- Some insurers may require a letter demonstrating medical necessity of the prescribed therapy (ie, letter of medical necessity or medical exception).

☐ Provide identification number(s) and *International Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) diagnosis code(s)

- Indicate the individual provider ID number versus the group practice/facility provider ID number on the prescription form.
- Please include the ICD-10-CM code for neurofibromatosis, type 1, as well as the appropriate location-based code for the associated plexiform neurofibroma(s).

☐ Provide additional supporting documentation

- All supporting documents required by the specific insurer should be submitted with the PA request. Commonly required documents include:
  - ✓ Patient authorization and notice of release of information
  - ✓ Copy of the patient's health plan or prescription card (front and back)
  - ✓ Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
  - ✓ A copy of your chart notes with details about the patient's diagnosis, current condition, and laboratory values
  - ✓ Previously failed therapies or justification why other therapies are clinically inappropriate for your patient
  - ✓ GOMEKLI prescribing Information, pivotal ReNeu study publication, or peer-reviewed journal articles
  - ✓ Further evidence available in the GOMEKLI Evidence Compendium

☐ Follow up as needed

- Follow up with your patient's health plan if you have not received a decision in 5-7 days.

☐ Reauthorization requirements

- Remember to confirm reauthorization requirements specific to your patients' health plans. Certain plans may require reauthorization after 3, 6, or 12 months of use.

Please see Important Safety Information on pages 2 and 3 and click here for full Prescribing Information.

GOMEKLI™
(mirdametinib)
1 mg tablets for oral suspension
1 mg and 2 mg capsules

INDICATION

GOMEKLI (mirdametinib) 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.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Ocular Toxicity: GOMEKLI can cause ocular toxicity including retinal vein occlusion (RVO), retinal pigment epithelium detachment (RPED), and blurred vision. In the adult pooled safety population, ocular toxicity occurred in 28% of patients treated with GOMEKLI: 21% were Grade 1, 5% were Grade 2 and 1.3% were Grade 3. RVO occurred in 2.7%, RPED occurred in 1.3%, and blurred vision occurred in 9% of adult patients. In the pediatric pooled safety population, ocular toxicity occurred in 19% of patients: 17% were Grade 1 and 1.7% were Grade 2. Conduct comprehensive ophthalmic assessments prior to initiating GOMEKLI, at regular intervals during treatment, and to evaluate any new or worsening visual changes such as blurred vision. Continue, withhold, reduce the dose, or permanently discontinue GOMEKLI as clinically indicated.

Left Ventricular Dysfunction: GOMEKLI can cause left ventricular dysfunction. GOMEKLI has not been studied in patients with a history of clinically significant cardiac disease or LVEF <55% prior to initiation of treatment. In the ReNeu study, decreased LVEF of 10 to <20% occurred in 16% of adult patients treated with GOMEKLI. Five patients (9%) required dose interruption, one patient (1.7%) required a dose reduction, and one patient required permanent discontinuation of GOMEKLI. The median time to first onset of decreased LVEF in adult patients was 70 days. Decreased LVEF of 10 to <20% occurred in 25%, and decreased LVEF of ≥20% occurred in 1.8% of pediatric patients treated with GOMEKLI. One patient (1.8%) required dose interruption of GOMEKLI. The median time to first onset of decreased LVEF in pediatric patients was 132 days. All patients with decreased LVEF were identified during routine echocardiography, and decreased LVEF resolved in 75% of patients. Before initiating GOMEKLI, assess ejection fraction (EF) by echocardiogram. Monitor EF every 3 months during the first year and then as clinically indicated. Withhold, reduce the dose, or permanently discontinue GOMEKLI based on severity of adverse reaction.

Dermatologic Adverse Reactions: GOMEKLI can cause dermatologic adverse reactions including rash. The most frequent rashes included dermatitis acneiform, rash, eczema, maculo-papular rash and pustular rash. In the pooled adult safety population, rash occurred in 92% of patients treated with GOMEKLI (37% were Grade 2 and 8% were Grade 3) and resulted in permanent discontinuation in 11% of patients. In the pooled pediatric safety population, rash occurred in 72% of patients treated with GOMEKLI (22% were Grade 2 and 3.4% were Grade 3) and resulted in permanent discontinuation in 3.4% of patients. Initiate supportive care at first signs of dermatologic adverse reactions. Withhold, reduce the dose, or permanently discontinue GOMEKLI based on severity of adverse reaction.

Embryo-Fetal Toxicity: GOMEKLI can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to the initiation of GOMEKLI. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Also advise patients to use effective contraception during treatment with GOMEKLI and for 6 weeks after the last dose (females) or 3 months after the last dose (males).

ADVERSE REACTIONS

The most common adverse reactions (>25%) in adult patients were rash (90%), diarrhea (59%), nausea (52%), musculoskeletal pain (41%), vomiting (38%), and fatigue (29%). Serious adverse reactions occurred in 17% of adult patients who received GOMEKLI. The most common Grade 3 or 4 laboratory abnormality (>2%) was increased creatine phosphokinase.

The most common adverse reactions (>25%) in pediatric patients were rash (73%), diarrhea (55%), musculoskeletal pain (41%), abdominal pain (39%), vomiting (39%), headache (34%), paronychia (32%), left ventricular dysfunction (27%), and nausea (27%). Serious adverse reactions occurred in 14% of pediatric patients who received GOMEKLI. The most common Grade 3 or 4 laboratory abnormalities (>2%) were decreased neutrophil count and increased creatine phosphokinase.

USE IN SPECIFIC POPULATIONS

Verify the pregnancy status of patients of reproductive potential prior to initiating GOMEKLI. Due to the potential for adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with GOMEKLI and for 1 week after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact SpringWorks Therapeutics Inc. at 1-888-400-7989 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please click here for full Prescribing Information including Patient Information and Instructions for Use.

Reference: GOMEKLI. Prescribing Information. SpringWorks Therapeutics, Inc.

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