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

Appeal Tips and Checklist

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

Filing an Appeal

An appeal should be pursued if a patient's prior authorization for medication is denied. This resource provides a checklist and relevant tips that may be useful when creating an appeal letter. 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.

☐ Understand the reason for denial

- While the reason for denial may often be included in the denial letter from the patient's health plan or the Explanation of Benefits, both of which can be obtained from the insurer, the specific reason for denial may sometimes be omitted. If a denial explanation is not included in the denial letter, inquire in writing as to the reason why the prior authorization request has been denied, including whether the plan is working with an Alternative Funding Program (AFP), and what the AFP is, if relevant. It is important to identify and/or correct the reason for denial to support coverage re-determination.

☐ Review the plan's appeals guidelines

- Contact the insurer to find out if the plan has a required appeal form, the deadline to submit an appeal, the timeline for review by the plan, the number of appeals permitted, and the fax number or address where the appeal should be sent. Also, inquire whether the appeal should be submitted by the patient or the healthcare provider and proceed accordingly.
  - It is helpful to communicate this information to the patient. Even if the healthcare provider submits the letter of appeal, the patient may also have an opportunity to write a supporting letter and may want to be aware of timelines.

☐ Compose a written letter of appeal

- Insurers require a written appeal from either the patient or the healthcare provider. Sample letters of appeal for healthcare providers can be found at **springworkstxcares.com/gomekli/hcp/resources**. As a reminder, the sample letters only serve as a guide. As the patient's healthcare provider, you can modify the content based on your medical judgment or you can write your own letter if the insurer does not require a specific form.

☐ Prepare an appeal package with additional supporting documentation

- A patient's appeal package should include all relevant medical documentation. Note that each appeal may need different information depending on the insurer and/or patient. Be sure to follow the requirements of the patient's insurer, as insurer requirements may vary. Common supporting documents in the appeals package include:
  - ✓ Statement of medical necessity (including patient DOB, insurance information, diagnosis)
  - ✓ 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
  - ✓ Patient authorization and notice of release of information
  - ✓ Copy of the patient's health plan or prescription card (front and back)
  - ✓ Documentation of the specific as well as the appropriate location-specific diagnosis code(s)
  - ✓ Denial information, including the patient's denial letter and/or Explanation of Benefits
  - ✓ Letter of appeal
  - ✓ Additional test results related to patient's condition
  - ✓ Mirdametinib (GOMEKLI) Prescribing Information, pivotal ReNeu study publication, NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), or peer-reviewed journal articles[1]
  - ✓ 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.

Please see Important Safety Information on page 2 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: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System Cancers V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed June 3, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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1 mg tablets for oral suspension
1 mg and 2 mg capsules