**The sample letter provided on the next page can be used to communicate to your health insurance company that:**

1. You have been prescribed GOMEKLI™ (mirdametinib) by your healthcare provider
2. Your health insurance plan through the employer has denied coverage of GOMEKLI
3. Your health insurance plan directed you to an Alternative Funding Program (AFP) to obtain GOMEKLI
4. The AFP instructed you to enroll in the manufacturer's patient assistant program (PAP)
5. You were notified that you are not eligible to participate in the manufacturer’s PAP because you do not meet the requirements
6. You have no way of accessing the medication that has been prescribed to you
7. You are requesting that they override the denial and approve coverage for GOMEKLI

**We encourage you to follow the steps above so that you can access your medication.**

**Here Are Some Tips for Submitting a Letter to Your Health Insurance Company:**

* You may consider first contacting your human resources (HR) department to request that they override the
plan’s decision to deny coverage of GOMEKLI. You can download a “**Sample Letter to Employer Regarding
GOMEKLI**™ **(mirdametinib) Coverage Denial**” at springworkstxcares.com/gomekli/patient/resources to help you write this communication
* Please make sure to always contact your health insurance company to understand the appeal process and any requirements for appealing a denial
* You can use the letter on the next page to start a patient-led appeal to your health insurance plan
* For your letter to the health insurance plan, be sure to obtain and include the name(s) of the intended recipient(s), if possible; do not include a generic salutation such as, “To Whom It May Concern”
* If you prefer to send the letter electronically, remember to copy your employer’s HR contact on the email, or request to be copied on the communication if they are submitting a letter on your behalf
* Provide supporting documents with the letter that describe your diagnosis and treatment plan
* Once you have sent the letter to the health insurance plan, consider following up with a phone call to confirm receipt and document who you spoke to
* Contact your healthcare provider to inform them that you have submitted an appeal to your health insurance plan and request that they provide the health insurance plan with any additional information in support of the appeal

**Sample Letter of Reconsideration for GOMEKLI**™ **(mirdametinib) Coverage Denial**

For informational use only.

**Please note:** The information in this letter provides suggestions for the type of information to consider including when a patient-led appeal of a coverage denial may be warranted. Use of this letter does not guarantee that your health insurance company will approve your request for coverage for GOMEKLI. However, it may present an opportunity to provide additional context and rationale to the plan for further consideration. You should always defer to any requirementsfor submittingappeals that are established by your health plan. Nothing in this letter is intended to substitute your prescriber’s independent clinical decision making. This letter is intended to be used by adult patients or policyholders for pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PNs) not amenable to complete resection and have been prescribed GOMEKLI.

[Date]

Attn: [Insert health insurance plan contact name] RE: [Insert your name]

[Insert name of insurance company] DOB: [Insert your date of birth]

[Insert street address] Policy number: [Insert subscriber policy number]

[Insert city, state, ZIP] Group number: [Insert subscriber group number] Prescriber name: [Insert prescriber name]

 Prescriber address: [Insert prescriber address]

 Prescriber phone: [Insert prescriber phone #]

Dear [Health insurance plan contact name],

My name is [insert full name], and I am currently under the care of [Healthcare provider name] for neurofibromatosis type 1 (NF1) with symptomatic plexiform neurofibromas (PNs) not amenable to complete resection. I was diagnosed with NF1-PN [length of time since diagnosis] ago, and my doctor prescribed GOMEKLI™ (mirdametinib), which is currently the only treatment approved by the US Food and Drug Administration for both adults and pediatric patients 2 years of age and older with NF1-PN.

On [insert date], I was notified that [Health insurance plan name] has denied coverage of my prescription for GOMEKLI and they have directed me to an Alternative Funding Program (AFP) to try to obtain the medication. Per the mandated process, I applied to the manufacturer patient assistance program (PAP) to try and access GOMEKLI.

However, on [insert date], I was notified that I was not eligible for the manufacturer PAP and my application for the PAP was denied. Additionally, [insert health insurance plan name] is still refusing to cover my medication. Per my physician, GOMEKLI has been prescribed to treat my NF1-PN. Since I am not eligible for the PAP and [insert health insurance plan name] has denied coverage, I have no way of accessing the medication and cannot afford to pay out of pocket. Regulations at 45 CFR § 156.122(c) mandate that:

* A health plan providing essential health benefits must have processes in place that allow an enrollee, the enrollee’s designee, or the enrollee’s prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by the health plan (i.e., a request for exception);
* In the event that exception request is granted, the plan must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing towards the plan’s annual limitation on cost-sharing under § 156.130 and when calculating the plan’s actuarial value under § 156.135; and
* The health plan must respond within 72 hours and if the medication is deemed medically necessary, the plan is required to cover the prescription for the duration of the plan year, including refills.

[OPTIONAL: To the extent you are comfortable sharing this information with your health insurance plan, insert a sentence about why taking GOMEKLI is important to you]. As you consider this request for coverage, please also refer to the enclosed materials for additional information. My healthcare provider may also reach out to share information pertaining to my request.

Please contact me at [contact information such as phone number or email address] if you need any additional information. Thank you in advance for your help. I look forward to your timely response and coverage determination that provides me access to the medication I need.

Sincerely,

[Insert your name]

Enclosures: [If possible, include denial letter[s], proof of diagnosis from prescriber, GOMEKLI Prescribing Information, which can be found at [springworkstx.com/gomekli-prescribing-info](https://springworkstx.com/gomekli-prescribing-info), and any other information that supports your request]

**What is GOMEKLI?**

GOMEKLI (mirdametinib) is a prescription medicine used to treat adults and children 2 years of age and older with neurofibromatosis type 1 (NF1) who have plexiform neurofibromas that cause symptoms and cannot be completely removed by surgery.

It is not known if GOMEKLI is safe and effective in children under 2 years of age.

 **IMPORTANT SAFETY INFORMATION**

**Before taking GOMEKLI tell your healthcare provider about all of your medical conditions, including if you:**

* have eye problems
* have heart problems
* are pregnant or plan to become pregnant. GOMEKLI can harm your unborn baby.

**Females who are able to become pregnant:**

* Your healthcare provider should check to see if you are pregnant before you begin treatment with GOMEKLI.
* Use effective birth control (contraception) during treatment with GOMEKLI and for 6 weeks after your last dose.
* Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with GOMEKLI.

**Males with Female partners who are able to become pregnant:**

* Use effective birth control (contraception) during treatment with GOMEKLI and for 3 months after your last dose.
* Tell your healthcare provider right away if your female partner becomes pregnant or thinks she may be pregnant during treatment with GOMEKLI.
* are breastfeeding or plan to breastfeed. It is not known if GOMEKLI passes into your breastmilk.
* Do not breastfeed during treatment with GOMEKLI and for 1 week after your last dose.
* Talk to your healthcare provider about the best way to feed your baby during this time.

 **Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

 **How should I take GOMEKLI?**

* Take GOMEKLI exactly as your healthcare provider tells you to take it. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with GOMEKLI if you develop certain side effects.
* Take GOMEKLI twice a day, about 12 hours apart, for 21 days, followed by 7 days off treatment, to complete a 28-day treatment cycle. Your healthcare provider will decide how many treatment cycles are right for you.
* Take GOMEKLI with or without food.
* GOMEKLI comes in two different dosage forms, GOMEKLI capsules and GOMEKLI tablets for oral suspension. Your healthcare provider will decide the dosage form and dose of GOMEKLI that is right for you.
* **If you take GOMEKLI capsules**: Swallow each capsule whole with drinking water. If more than 1 capsule is required, swallow 1 capsule at a time. Do not open, break or chew the capsules.
* **If you take GOMEKLI tablets for oral suspension,** **either**:
	+ Swallow each tablet for oral suspension whole with drinking water. If more than 1 tablet is required, swallow 1 tablet at a time.

**OR**

* + Disperse the tablets for oral suspension in drinking water to make a liquid (suspension) before you take or give GOMEKLI.

See the “Instructions for Use” that come with your medicine for instructions on how to prepare and take GOMEKLI tablets for oral suspension.

* If you miss a dose of GOMEKLI, skip the missed dose and take your next dose at your regularly scheduled time.
* If you vomit at any time after taking GOMEKLI, do not take an additional dose. Take your next dose at your regularly scheduled time.

 **What are the possible side effects of GOMEKLI?**

**GOMEKLI may cause serious side effects, including:**

* **eye problems.** GOMEKLI may cause eye problems that can lead to blindness. Your healthcare provider will check your vision before and during treatment with GOMEKLI. Tell your healthcare provider right away if you get any of the following signs or symptoms of eye problems:
	+ blurred vision
	+ loss of vision
	+ other changes to your vision
* **heart problems.** GOMEKLI may lower the amount of blood pumped by your heart, which is common in children during treatment with GOMEKLI and can also be severe.Your healthcare provider will do tests before you start GOMEKLI treatment, every 3 months during your first year of treatment, and then as needed to make sure your heart is working properly. Tell your healthcare provider right away if you get any of the following signs or symptoms of heart problems:
	+ coughing or wheezing
	+ shortness of breath
	+ swelling of your ankles and feet
	+ tiredness
	+ increased heart rate
* **skin problems.** Skin rashes are common with GOMEKLI in both adults and children and can also be severe. GOMEKLI can also cause hair loss (alopecia). Tell your healthcare provider if you develop any of the following signs or symptoms of skin problems:
	+ flat skin rash
	+ raised bumps on the skin
	+ skin bumps that look like acne
	+ skin redness
	+ itchy rash
	+ peeling skin

 **The most common side effects of GOMEKLI in adults include:**

* + diarrhea
	+ nausea
	+ muscle, joint, and bone pain
	+ vomiting
	+ tiredness

**The most common severe abnormal blood tests in adults** include an increased enzyme called creatine phosphokinase (CPK).

**The most common side effects of GOMEKLI in children include:**

* + diarrhea
	+ muscle, joint, and bone pain
	+ stomach (abdominal) pain
	+ vomiting
	+ headache
	+ skin redness, swelling, or pain around the fingernails or toenails
	+ nausea

**The most common severe abnormal blood tests in children** include decreased white blood cell (neutrophil) counts and increased CPK.

GOMEKLI may cause fertility problems in females, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of GOMEKLI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**Please** [**click here**](https://springworkstx.com/gomekli-prescribing-info) **for full Prescribing Information including Patient Information and Instructions for Use.**

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