SpringWorks CareConnections™

GOMEKLI™ (mirdametinib) Coverage Toolkit

This comprehensive coverage toolkit can help you and your team navigate through the prior authorization and appeals processes to help your patients start and stay on GOMEKLI.

Actor portrayal

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

How to use this guide

When prescribing GOMEKLI™ (mirdametinib) to your patients, each health insurance plan will have its own criteria for coverage, and SpringWorks CareConnections™ can help you and your team through the process.

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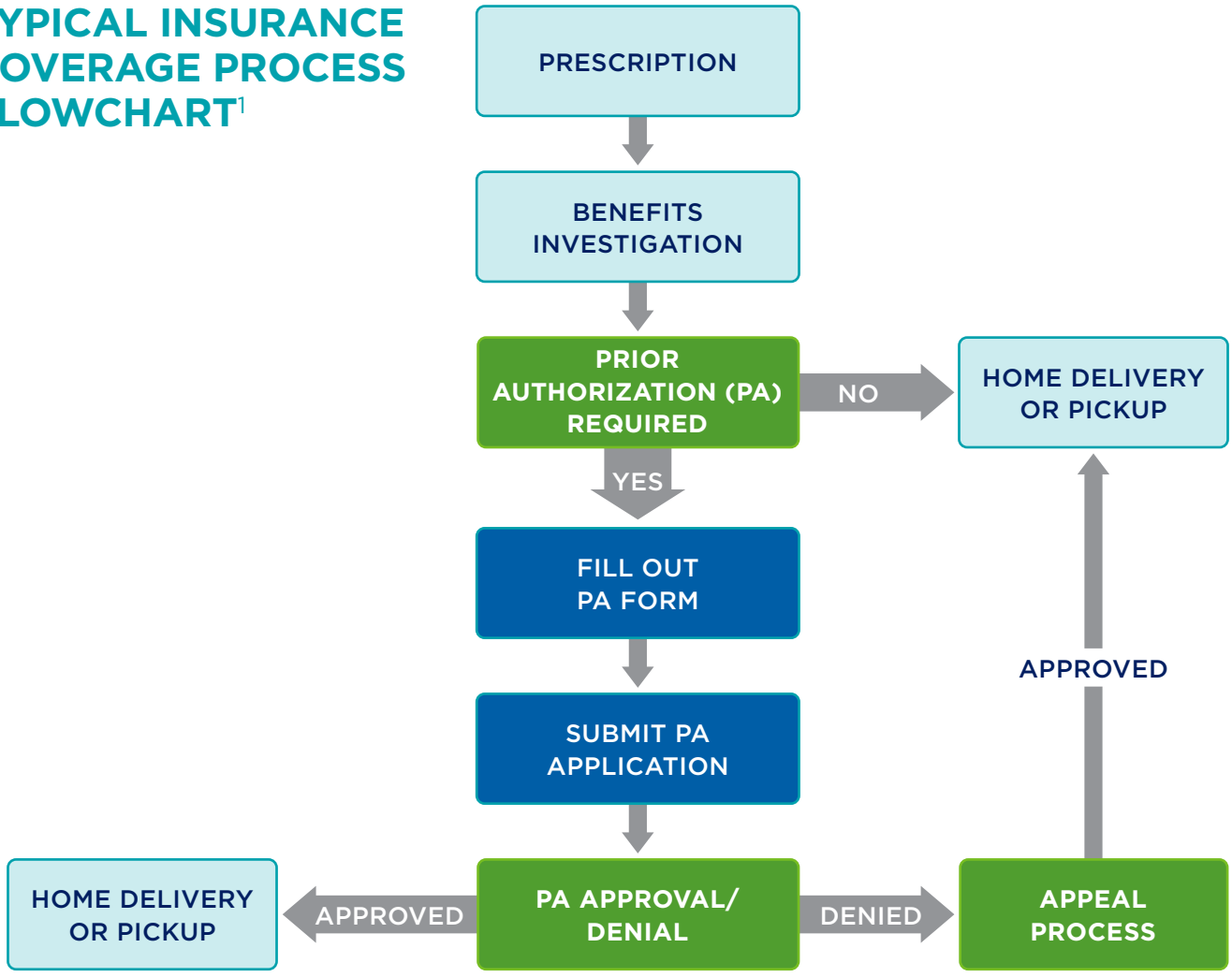
Typical Insurance Coverage Process Overview

When you prescribe GOMEKLI™ (mirdametinib), the insurance coverage process begins. Whether your patients are insured or not insured, there are ways to help many of your patients receive their medication. The insurance coverage process can sometimes be complex, but as you and your team navigate the process, SpringWorks CareConnections™ is available to help at every step.

SpringWorks CareConnections can help eligible commercially insured patients who experience a qualified delay in their insurance coverage get started on GOMEKLI at no cost for a limited period of time*

TYPICAL INSURANCE COVERAGE PROCESS FLOWCHART[1]



*Terms and conditions apply. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

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Potential Drug Coverage Policies

Each health insurance plan will have specific processes and supporting documentation requirements to secure coverage for GOMEKLI™ (mirdametinib). Below are potential coverage policies you and your team may encounter.

COVERED | Prior authorization may or may not be required

GOMEKLI is covered and included in the health insurance plan's formulary

- Prior authorization may or may not be required to secure coverage

NOT COVERED | Prior authorization required[2]

Patients must meet certain insurance policy requirements to have GOMEKLI covered

- A prior authorization is required to show the patient's health insurance plan that the medication is medically necessary, and your patient meets the plan's requirements for coverage

NOT COVERED | Non-formulary[3]

GOMEKLI is not covered, but still accessible through a medical exception process or additional requirements

- This may be the period before the Pharmacy and Therapeutics (P&T) Committee has added a medication to the health insurance plan's formulary
- A medical exception can be submitted to show that the medication is medically necessary for the patient

Insurance Navigators are additional members of the SpringWorks CareConnections™ team who can help you and your team navigate the insurance process and provide additional resources as needed

The above list is not exhaustive, and you may encounter situations not described in this list.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

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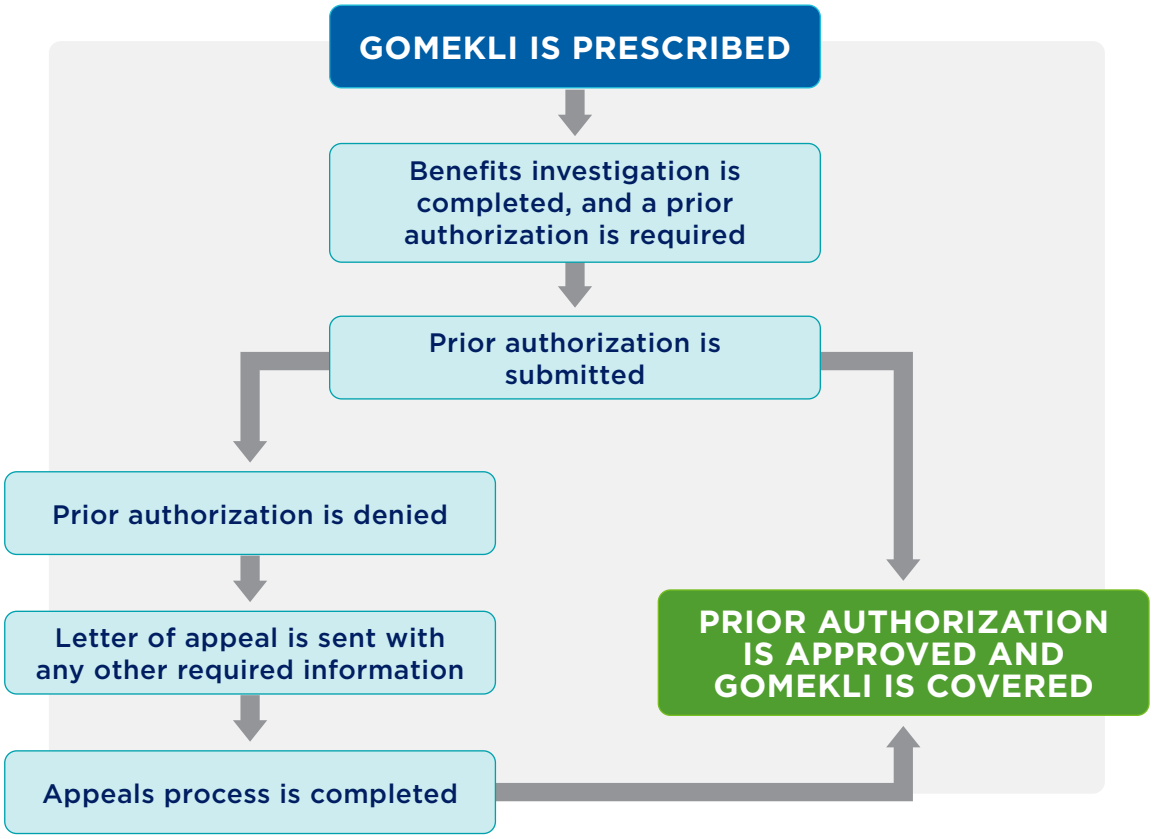
The Prior Authorization Process

Health plans will likely require a prior authorization to be submitted for GOMEKLI™ (mirdametinib).

The prior authorization process is used by health insurance companies to confirm that certain drugs or services are medically necessary and otherwise covered.[2] The flowchart below illustrates some potential scenarios you may encounter.

Please see the SpringWorks CareConnections™ prior authorization tips and checklist (page 10) for more information.

THE PRIOR AUTHORIZATION PROCESS



SpringWorks CareConnections Quick Start Program can help eligible commercially insured patients who experience a qualified delay in their insurance coverage get started on GOMEKLI at no cost for a limited period of time*

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The Medical Necessity/Exception Process

MEDICAL NECESSITY/EXCEPTION

A medication is deemed **medically necessary** when a physician using their professional judgment would determine that the medication is the **best option for a given patient and meets the accepted standards of medicine**.[4,5]

A **medical exception** is needed when a medication prescribed for your patient is not **covered in their health insurance plan's formulary**.[3]

When submitting a letter of medical necessity/exception, it is important to explain the importance of the medication prescribed and reasons for prescribing the medication instead of a medication preferred in the health insurance plan's formulary.[3,6]

See the sample letter of medical necessity/exception (page 11) for more information.

It's often possible to achieve coverage for patients with evidence of medical necessity

Insurance Denial Types

There is a potential for the payor to initially respond that they are not approving the medication. These responses can be classified as either **administrative or clinical denials.**[7]

ADMINISTRATIVE

Administrative denials typically occur when there is an issue processing an insurance claim and do not have to do with the necessity of the medication for your patient. When there is an administrative denial, the appeals process will not rectify the issue. Instead, correct any errors and resubmit the claim in a timely manner.[7]

Examples:

- Incorrect insurance information provided for patient
- Missing signature
- Incomplete information/sections left blank

CLINICAL

A clinical denial means that the health insurance plan does not deem the medication necessary for the patient. Reasons for clinical denials vary greatly, and can be complex.[7,8] To get the medication covered, further information is usually required to show medical necessity.

Examples:

- Incorrect ICD-10 diagnosis codes (eg, not an approved GOMEKLI™ [mirdametinib] indication)
- Lack of documentation supporting diagnosis (eg, lab values, incorrect dosage, proof of symptomatic plexiform neurofibromas)[9]
- Additional clinical documentation needed to prove medical necessity

Ensuring that any paperwork submitted to a health insurance plan is complete and accurate may help avoid any potential delays in treatment. Please contact your Field Access Manager or Insurance Navigator for additional support as needed

Your patient may need to appeal a plan exclusion denial.
Please see the sample AFP appeal letters on pages 15-17 for more information.

Potential Levels of Appeal

Every appeals process is different. Here we've illustrated a typical situation that you may encounter when beginning a patient's appeal process. Keep in mind that SpringWorks CareConnections™ can provide information on the appeals process if coverage, a prior authorization, or medical exception is denied.

1st Level

LETTER OF APPEAL OR PEER TO PEER[6]

- A formal letter of appeal can be submitted to the health plan to overturn a denial
- Refer to the **Letter of Appeal checklist on page 13** of this access toolkit
- To expedite the appeal, a Peer-to-Peer conversation can occur instead between the patient's healthcare provider and the medical director of the health insurance plan to explain why GOMEKLI™ (mirdametinib) is the best treatment option for their patient
- Refer to the **Peer-to-Peer checklist on page 14** of this access toolkit

2nd Level

INTERNAL MEDICAL DIRECTOR AT THE HEALTH PLAN REVIEW[6,10]

- If the first appeal is denied, another appeal letter and additional information can be sent directly to the patient's health insurance plan
- Each health insurance plan will have its own requirements for this process
- Refer to the **Appeals checklist on page 13** and **annotated sample letters on pages 11 and 12**

3rd Level

EXTERNAL INDEPENDENT REVIEW[6,10,11]

- When an internal appeal is denied, the formal denial letter will include information on how to begin the external review
- Information is sent to a third-party (or an Independent Review Organization) and they either approve or deny coverage for the prescribed care
- The health insurance plan may be required to accept the results of the external review

Patients who are uninsured, underinsured, or denied coverage for GOMEKLI may be eligible to receive medication at no cost through the SpringWorks CareConnections Patient Assistance Program*

*Terms and conditions apply. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

Plan Exclusion Impact on Patients

Employers with self-funded plans sometimes contract with third-party groups to implement various plan exclusion tactics (ie, Alternate Funding Program (AFP), specialty carve outs, etc). AFPs or carved-out medications are then categorized as a "nonessential health benefit," which removes coverage for specialty medications **leaving insured patients with no path for coverage, despite paying into their premiums.**[12,13]

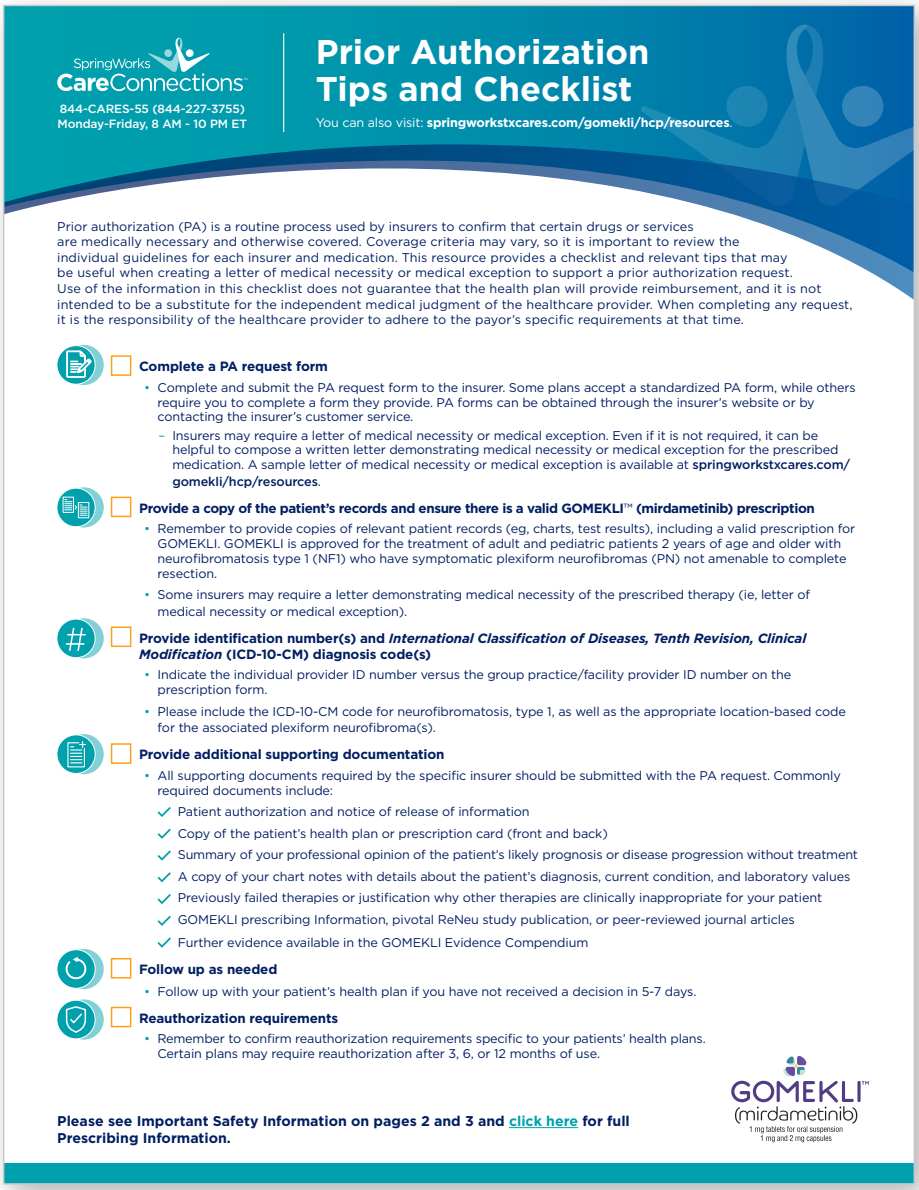
Employers may be unaware which medications are included in the various plan exclusions, meaning employees have to advocate for themselves.

Usually, your patient's first action after receiving an AFP denial will be sending a letter to their company's human resources department, asking for support in appealing the denial. **SpringWorks CareConnections™ has resources available to help,** including sample letters you and your patient can use to appeal an AFP denial and secure coverage for their GOMEKLI™ (mirdametinib) prescription.

See sample HCP AFP letter on page 15.
See sample patient AFP letters on pages 16 and 17.

When an AFP denies your patient's coverage for GOMEKLI, SpringWorks CareConnections can provide help throughout the appeals process

Prior Authorization Tips and Checklist



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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

Make sure to double check that the prior authorization request form is complete and correct before submitting

Include both the ICD-10-CM diagnosis code(s) and the location-specific code for associated plexiform neurofibroma(s)

To access the digital version of this GOMEKLI™ (mirdametinib) **Prior Authorization Tips and Checklist**, please visit **springworkstxcares.com/gomekli/hcp/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

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Sample Letter of Medical Necessity or Medical Exception

Sample Letter of Medical Necessity or Medical Exception for GOMEKLI™ (mirdametinib)

For informational use only.

This is an example of a letter to a patient's insurance company supporting the medical necessity or medical exception for GOMEKLI. The information in this letter provides suggestions for the type of information to consider when a letter of medical necessity or medical exception is requested. Use of the information in this letter does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for, or an influence on, 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.

[Physician letterhead]

Attn: [Insert medical director's name]
[Insert name of insurance company]
[Insert street address]
[Insert city, state, ZIP]

RE: [Insert patient name]
DOB: [Insert patient's date of birth]
Policy number: [Insert subscriber policy number]
To whom it may concern:

I am writing on behalf of the above-mentioned patient, [insert patient name], to [document the medical necessity and support coverage for] [request a medical exception to cover] GOMEKLI™ (mirdametinib).

The efficacy and safety of GOMEKLI was demonstrated in ReNeu, a multicenter, single-arm, pivotal Phase 2 study (N=114) in patients 2 years of age and older with symptomatic NF1-PN causing significant morbidity. GOMEKLI is the FIRST and ONLY FDA-approved treatment for 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.

[Insert patient name] has been under my care since [date]. Treatment of [insert patient name] with GOMEKLI is medically appropriate and necessary and should be covered and reimbursed based on [insert patient name]'s medical history, diagnosis, and rationale for treatment, as detailed below.

[Clinical considerations for pediatric and adult patients may differ:]

- ☐ [Patient's diagnosis, date of diagnosis, ICD-10-CM diagnosis code(s), condition, and any other relevant medical history]
- ☐ [Management/previous therapies used for treating the symptoms associated with plexiform neurofibromas]
- ☐ [If patient has difficulty swallowing due to age or tumor growth location and requires liquid suspension]
- ☐ [Patient's response to previous therapies, including reasons for discontinuation]
- ☐ [Brief description of the patient's recent symptoms and conditions (eg, pain, impaired mobility, changes in appearance, organ compression, cognitive deficits, tumor growth)]
- ☐ [Summary of your professional opinion explaining the patient's need for treatment]
- ☐ [Additional relevant, medically necessary clinical determinations]

[Consider using this paragraph to include additional clinical information that demonstrates progression of your patient's plexiform neurofibroma(s), such as documented growth, worsening of symptoms, or impaired functioning in daily life.]

As you consider this request for coverage, please also refer to the enclosed materials for additional information.

[For ease of review, please see below for the location of each enclosure within the submission.]

[History of NF1-PN Diagnosis]	[Document Page Number]
• [Document Name]	• [X]
• [Document Name]	• [X]
[Symptoms Management/Previous Therapies Used]	[Document Page Number]
• [Document Name]	• [X]
• [Document Name]	• [X]
[Response to Previous Therapies Used]	[Document Page Number]

Include complete and accurate patient information including DOB, policy number, and group number

Include any prior treatments the patient has tried and failed

ICD-10-CM codes, description of current symptoms, and medical history should be included when necessary

It can be useful to mention if your patient has difficulty swallowing, as GOMEKLI™ (mirdametinib) is also available as a dispersible tablet for oral suspension

Information like GOMEKLI Prescribing Information and data from the clinical trial can strengthen your patient's case

To access the digital version of this GOMEKLI **Sample Letter of Medical Necessity/Letter of Medical Exception**, please visit **springworkstxcares.com/gomekli/hcp/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

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Sample Letter of Appeal

Sample Letter of Appeal for GOMEKLI™ (mirdametinib)

For informational use only.

This is an example of information that may be included in an appeal letter to a patient's insurance company. The information in this letter provides suggestions for the type of information to consider when a letter of appeal is appropriate. Use of the information in this letter does not guarantee that the health plan will provide reimbursement, and it is not intended to be a substitute for, or an influence on, the independent medical judgment of the healthcare provider. When completing any request, it is the responsibility of the healthcare provider to adhere to the payer's specific requirements at that time.

[Physician letterhead]

[Date]
Attn: [Insert medical director's name]
[Insert name of insurance company]
[Insert street address]
[Insert city, state, ZIP]

RE: [Insert patient name]
DOB: [Insert patient's date of birth]
Policy number: [Insert subscriber policy number]
Group number: [Insert subscriber group number]
Claim number: [Insert patient claim number]

To whom it may concern:

This letter serves as the [select one: 1st /2nd] appeal of the prior authorization denial for the treatment of my patient, [insert patient name], with GOMEKLI (mirdametinib). I understand from your denial letter[s] dated [month, day, year] that the prior authorization for GOMEKLI has been denied because [quote denial reason as communicated in the denial letter]. After reviewing the letter[s], I maintain that GOMEKLI is the appropriate treatment for my patient for the reasons detailed below, including [insert patient's name]'s diagnosis and medical history.

[For pediatric patients:]

- [Patient's diagnosis, date of diagnosis, ICD-10-CM diagnosis code(s), condition, and history]
- [Management/previous therapies used for treating the symptoms associated with plexiform neurofibromas]
- [Patient's response to prior therapies, including reasons for discontinuation]
- [Brief description of the patient's recent symptoms and condition (eg, pain, cognitive deficits, tumor growth)]
- [Summary of your professional opinion of the patient's prognosis and need for treatment with GOMEKLI]
- [If patient has difficulty swallowing due to age or tumor growth and requires liquid suspension]
- [Insert any additional, relevant medically necessary clinical determinations]

[For adult patients:]

- [Patient's diagnosis, date of diagnosis, ICD-10-CM diagnosis code(s), condition, and history]
- [Management/previous therapies used for treating the symptoms associated with plexiform neurofibromas]
- [Patient's response to prior therapies, including reasons for discontinuation]
- [Brief description of the patient's recent symptoms and condition]
- [If patient has difficulty swallowing due to tumor growth and requires liquid suspension]
- [Summary of your professional opinion of the patient's prognosis and need for treatment with GOMEKLI]
- [Insert any additional, relevant medically necessary clinical determinations]

[Some plans may request additional clinical information demonstrating progression of your patient's plexiform neurofibroma[s]. Consider using this paragraph to describe your patient's worsening of symptoms, impaired functioning in daily life, or other evidence, based on your clinical discretion.]

Treatment information

The efficacy and safety of GOMEKLI informing FDA approval was demonstrated in ReNeu, a multicenter, open-label, pivotal, Phase 2b trial of mirdametinib in adults and children with NF1-PN. [For adult patients, mention: In this study GOMEKLI resulted in significant confirmed objective response rates by blinded independent central review in 41% of patients, and in the long-term follow-up phase, 2 additional patients achieved a confirmed objective response.] [For pediatric patients: In pediatric patients, GOMEKLI provided significant improvement in worst tumor pain severity and this pain reduction was sustained through the entire ReNeu study duration.] GOMEKLI is the first and only US Food and Drug Administration (FDA)–approved treatment for adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN).[1]

As you consider this request for coverage, please also refer to the enclosed materials for additional information. Please feel free to contact me, [insert physician name], at [insert office phone number], for any additional information you may require. I look forward to receiving your timely response and coverage determination.

Sincerely,

[Insert physician's name]

Letter should be addressed to the contact given in the denial letter and ensure you mention the reason given for the original denial

Include complete and accurate patient information

ICD-10-CM codes, description of current symptoms, and clinical support for the prescribed treatment

It can be useful to mention if your patient has difficulty swallowing, as GOMEKLI™ (mirdametinib) is also available as a dispersible tablet for oral suspension

Include your contact information so the insurer can reach out with any questions

If your patient's coverage was denied by an AFP, please see the AFP sample letters on pages 15-17

To access the digital version of this GOMEKLI **Sample Letter of Appeal**, please visit **springworkstxcares.com/gomekli/hcp/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

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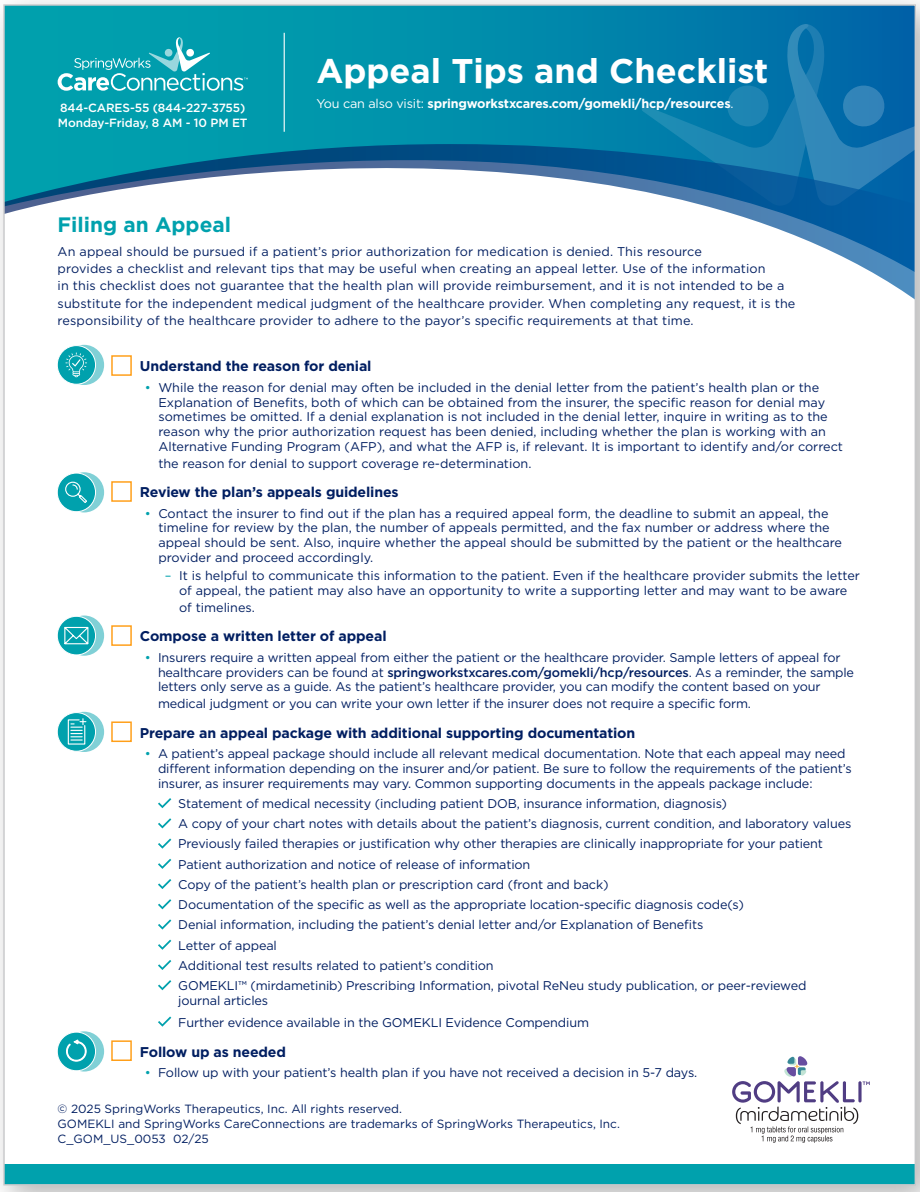
Appeal Tips and Checklist



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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
  - ✓ GOMEKLI™ (mirdametinib) 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.

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Each health insurance plan may have their own requirements for the appeals process, you can contact the insurer to ask any questions about this

Be sure that all required information included in the appeal package is correct and complete

To access the digital version of this GOMEKLI **Appeal Tips and Checklist**, please visit **springworkstxcares.com/gomekli/hcp/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

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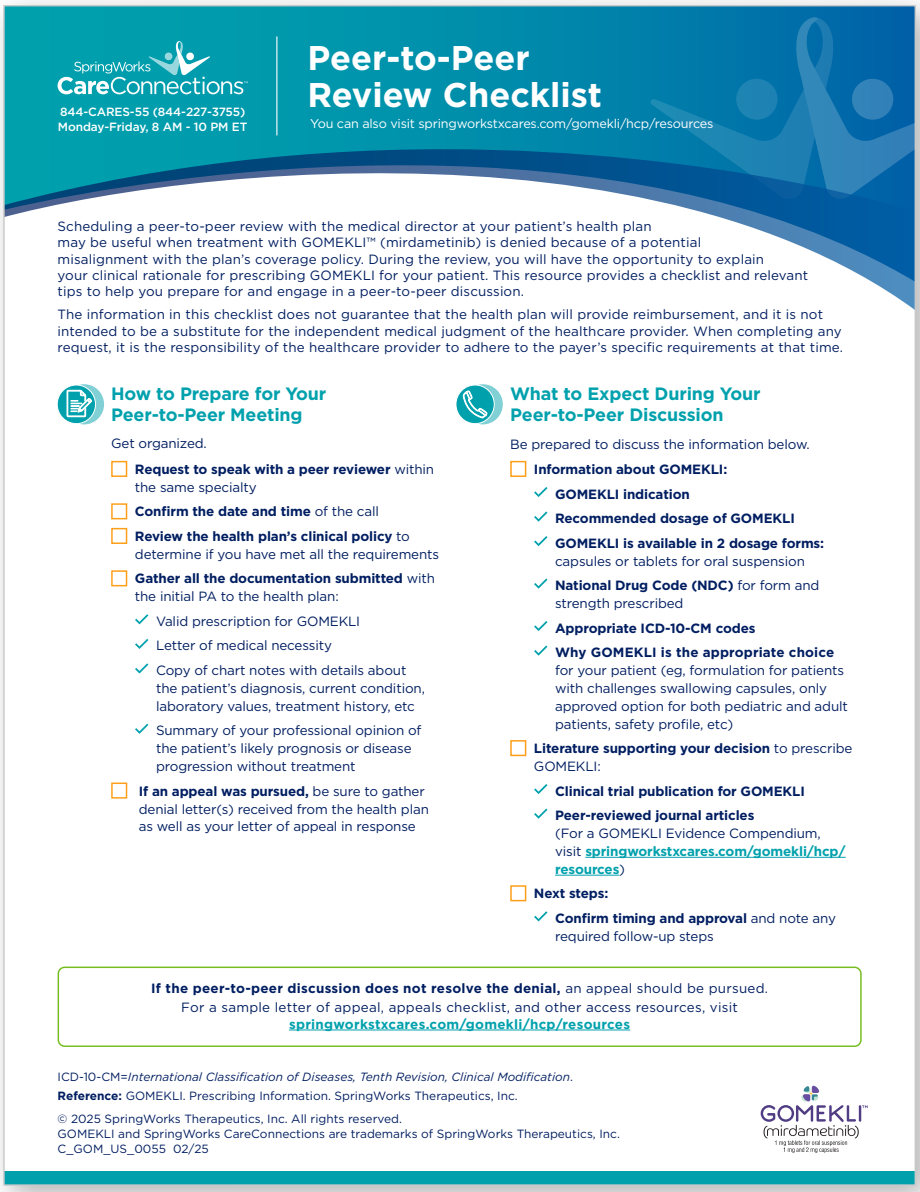
Peer-to-Peer Checklist



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Peer-to-Peer Review Checklist

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

Scheduling a peer-to-peer review with the medical director at your patient's health plan may be useful when treatment with GOMEKLI™ (mirdametinib) is denied because of a potential misalignment with the plan's coverage policy. During the review, you will have the opportunity to explain your clinical rationale for prescribing GOMEKLI for your patient. This resource provides a checklist and relevant tips to help you prepare for and engage in a peer-to-peer discussion.

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 payer's specific requirements at that time.

How to Prepare for Your Peer-to-Peer Meeting

Get organized.

- ☐ **Request to speak with a peer reviewer** within the same specialty
- ☐ **Confirm the date and time** of the call
- ☐ **Review the health plan's clinical policy** to determine if you have met all the requirements
- ☐ **Gather all the documentation submitted** with the initial PA to the health plan:
  - ✓ Valid prescription for GOMEKLI
  - ✓ Letter of medical necessity
  - ✓ Copy of chart notes with details about the patient's diagnosis, current condition, laboratory values, treatment history, etc
  - ✓ Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment
- ☐ **If an appeal was pursued,** be sure to gather denial letter(s) received from the health plan as well as your letter of appeal in response

What to Expect During Your Peer-to-Peer Discussion

Be prepared to discuss the information below.

- ☐ **Information about GOMEKLI:**
  - ✓ **GOMEKLI indication**
  - ✓ **Recommended dosage of GOMEKLI**
  - ✓ **GOMEKLI is available in 2 dosage forms:** capsules or tablets for oral suspension
  - ✓ **National Drug Code (NDC)** for form and strength prescribed
  - ✓ **Appropriate ICD-10-CM codes**
  - ✓ **Why GOMEKLI is the appropriate choice** for your patient (eg, formulation for patients with challenges swallowing capsules, only approved option for both pediatric and adult patients, safety profile, etc)
- ☐ **Literature supporting your decision** to prescribe GOMEKLI:
  - ✓ **Clinical trial publication for GOMEKLI**
  - ✓ **Peer-reviewed journal articles** (For a GOMEKLI Evidence Compendium, visit springworkstxcares.com/gomekli/hcp/resources)
- ☐ **Next steps:**
  - ✓ **Confirm timing and approval** and note any required follow-up steps

If the peer-to-peer discussion does not resolve the denial, an appeal should be pursued. For a sample letter of appeal, appeals checklist, and other access resources, visit springworkstxcares.com/gomekli/hcp/resources

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification.*

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

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

Scheduling a peer-to-peer review allows you to speak directly with the medical director at your patient's health plan

Before your call, gather all information needed and verify the date and time of the call

Be prepared to discuss information about GOMEKLI™ (mirdametinib), literature that supports your decision, and potential next steps

If the peer-to-peer discussion does not resolve the denial, an appeal should be pursued

To access the digital version of this GOMEKLI **Peer-to-Peer Checklist**, please visit **springworkstxcares.com/gomekli/hcp/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

SpringWorks CareConnections™

HCP Sample Letter of Appeal for GOMEKLI™ (mirdametinib) to Health Plan Participating in an AFP

Sample Letter of Appeal for GOMEKLI™ (mirdametinib) to Health Plan Participating in an AFP

For informational use only.

This is an example of a letter of appeal to a patient's insurance company that participates in an Alternative Funding Program (AFP) and has denied coverage of GOMEKLI. The information in this letter provides suggestions for the type of information to consider including in a letter of appeal. Use of the information in this letter does not guarantee that the health plan will cover GOMEKLI, and it is not intended to be a substitute for, or an influence on, 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.

[Physician letterhead]

[Date]
Attn: [Insert health insurance plan contact name]
[Insert name of insurance company]
[Insert street address]
[Insert city, state, ZIP]

RE: [Insert patient name]
DOB: [Insert patient date of birth]
Policy number: [Insert subscriber policy number]
Group number: [Insert subscriber group number]

[Health plan contact name],

I am writing on behalf of the above-mentioned patient, [insert patient name], to appeal the decision to deny coverage of GOMEKLI™ (mirdametinib).

[Patient name] was diagnosed with neurofibromatosis type 1 (NF1) with symptomatic plexiform neurofibromas (PNs) that are not amenable to complete resection on [insert date], and I have prescribed GOMEKLI, a treatment that is medically appropriate and necessary for my patient. GOMEKLI 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 for the treatment of NF1-PN. Unfortunately, [health plan name] has denied coverage for this medication.

Since denying coverage, it appears that [health plan name] has directed [patient name] to an Alternative Funding Program (AFP) to try and obtain their GOMEKLI medication.

However, after applying through the manufacturer's Patient Assistance Program (PAP), my patient was notified on [insert date] that they did not meet the program eligibility requirements, and the application for PAP was denied. Additionally, [insert health plan name] is still refusing to cover my patient's GOMEKLI medication.

Since my patient is not eligible for the PAP and [insert health plan name] has denied coverage, they have no way of accessing their 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 the following 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 an 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.

In review of the above and the information enclosed, I believe [insert conclusion regarding medical necessity for patient and lack of alternative access to GOMEKLI].

Sincerely,

[Insert physician's name]

- Enclosures: [clinical documentation, medical literature, patient coverage denial letter, patient PAP denial letter]

Include accurate and complete patient information, including diagnosis

Note that the patient's health plan directed your patient to try gaining coverage for their medication through an AFP

Mention that your patient was denied after applying through the manufacturer's patient assistance program

Regulations can support the case that your patient needs coverage for their GOMEKLI prescription, include any that are relevant to your patient's case

To access the digital version of this GOMEKLI **Sample Letter of Appeal to Health Plan Participating in an AFP**, please visit **springworkstxcares.com/gomekli/hcp/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

SpringWorks CareConnections™

Patient Sample Letter to Employer Regarding GOMEKLI™ (mirdametinib) Coverage Denial

Sample Letter to Employer Regarding 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 in a communication to the HR contact at your employer regarding a coverage denial of GOMEKLI. Use of this letter does not guarantee that your health insurance company will approve your request for coverage. However, it may present an opportunity to provide additional context and rationale to your employer for reconsideration of coverage for GOMEKLI. You should always defer to any requirements for submitting appeals that are established by your employer or 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 (PN) not amenable to complete resection.

To: [Insert HR contact email]
Subject line options:

- [TIME SENSITIVE: Health Insurance Coverage Policy Request]
- [IMPORTANT: Regarding Health Insurance Coverage Policy]
- [IMPORTANT: Regarding Appeal of Coverage Denial]

Dear [HR contact name]:

My name is [Insert full name] and I am writing to request reconsideration of the decision to deny coverage for GOMEKLI™ (mirdametinib) for the treatment of my neurofibromatosis type 1 (NF1) with symptomatic plexiform neurofibromas (PNs) that are not amenable to complete resection. As you may be aware, I receive my healthcare benefits through [Insert health insurance plan name]. On [insert date], I was diagnosed with a NF1-PN and was prescribed GOMEKLI by my healthcare provider.

On [insert date] I was notified that [insert 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 obtain the medication.

However, on [insert date], I was notified that I am 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 the health plan 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 an 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.

GOMEKLI is the first and only FDA-approved treatment for both adult and pediatric patients 2 years of age and older with NF1-PN. I am seeking your support in overriding the decision to deny coverage for GOMEKLI. [OPTIONAL: To the extent you are comfortable sharing this information with your employer, insert a sentence about why taking GOMEKLI is important to you].

In summary, I would greatly appreciate your assistance in overriding the coverage denial from [Insert health insurance plan name] and requesting that they approve coverage for this medication that my doctor has deemed medically necessary.

As you consider this request, please also refer to other enclosed materials for more context. Please feel free to contact me at [Insert phone number or email address] for any additional information. I look forward to receiving your timely response, and your support in helping me access the medication I need.

Sincerely,
[Insert your name]

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

Direct your patient to clearly explain why they are writing the appeal letter and any challenges they are facing in getting their GOMEKLI prescription covered

Any supporting documentation that your patient is comfortable sharing with their HR department should be sent with the appeal letter, including a copy of their insurance card, paperwork from your office explaining their diagnosis, etc

After explaining the reason for the appeal, your patient should request that their employer override the insurance plan's decision to deny coverage

To access the digital version of this GOMEKLI **Sample Letter to Employer Regarding Coverage Denial**, please visit **springworkstxcares.com/gomekli/patient/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

SpringWorks CareConnections™

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

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 requirements for submitting appeals 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]
[Insert name of insurance company]
[Insert street address]
[Insert city, state, ZIP]

RE: [Insert your name]
DOB: [Insert your date of birth]
Policy number: [Insert subscriber policy number]
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, and any other information that supports your request]

Prior to writing and sending this letter, your patients may want to reach out to their employer's HR department asking for them to override their health insurance company's decision to deny coverage

Your patient can reach out to their insurance company at any point to ask any questions about the appeals process

After sending this letter, your patients can follow up with a phone call to confirm receipt

To access the digital version of this GOMEKLI **Sample Letter of Reconsideration for a Coverage Denial**, please visit **springworkstxcares.com/gomekli/patient/resources**.

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information.

SpringWorks CareConnections™

The Reauthorization Process

Most prior authorizations expire after 12 months. When a prior authorization expires, you may need to request a renewal of their prior authorization. This is called a **reauthorization** or an authorization renewal.[14]

If you need to submit a reauthorization, check with the patient's health insurance plan to ensure all necessary paperwork is included.[14] The documentation often includes lab values, imaging, or anything that shows that the medication is effective for your patient.

SpringWorks CareConnections™ provides personalized support services and resources to help your patients get started and stay on track with GOMEKLI™ (mirdametinib).

Connections at each point of care with GOMEKLI

- Resources, education, and assistance to support timely access to GOMEKLI
- Dedicated team of Nurse Advocates who provide treatment support as it relates to your patient's condition can provide assistance to patients and caregivers throughout their treatment journey
- Field Access Managers can provide in-person or virtual support to help facilitate access to GOMEKLI by providing you and your office staff regional payer education and timely responses to questions

Enrolling your patient in SpringWorks CareConnections is simple and Nurse Advocates are available to help!

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).

Please click here for full Prescribing Information.

SpringWorks CareConnections™

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Whether your patients are insured or not insured, or if there have been lapses or delays in coverage for GOMEKLI™ (mirdametinib), SpringWorks CareConnections™ can help many of your eligible patients receive their medication at **no charge.**

Each health insurance plan will have different coverage policies for GOMEKLI and may require specific paperwork. SpringWorks CareConnections™ can help navigate this process.

By filling out all paperwork correctly and accurately, you and your office can increase the likelihood of your patient's health insurance plan approving coverage for GOMEKLI.

Call SpringWorks CareConnections today at 844-CARES-55 (844-227-3755), Monday-Friday, 8 AM-10 PM ET, or visit springworkstxcares.com/gomekli/hcp

References: 1. The ultimate prior authorization cheat sheet. Superbill blog. Updated February 1, 2024. Accessed October 24, 2024. https://www.thesuperbill.com/blog/the-ultimate-prior-authorization-cheat-sheet **2.** Drug plan coverage rules. Medicare.gov. Accessed October 24, 2024. https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover/drug-plan-coverage-rules **3.** Filing a formulary exception. Patient Advocate Foundation. Accessed October 24, 2024. https://www.patientadvocate.org/explore-our-resources/insurance-denials-appeals/filing-a-formulary-exception **4.** Wilkinson DJC. What is 'medical necessity'? *Clinical Ethics*. 2023;18(3):285-286. doi:10.1177/14777509231190521 **5.** Medically necessary. Healthcare.gov. Accessed October 24, 2024. https://www.healthcare.gov/glossary/medically-necessary/ **6.** Engaging with insurers: appealing a denial. Patient Advocate foundation. Accessed October 24, 2024. https://www.patientadvocate.org/download-view/engaging-with-insurers-appealing-a-denial/ **7.** Wilson D. Categorization of pediatric denial types. American College of Physician Advisors. Accessed October 24, 2024. https://www.acpadvisors.org/a-primer-on-denials **8.** Reiner G, Bird S. 4 Clinical reasons for denials. HFMA.org. Published November 2, 2018. Accessed October 24, 2024. https://www.hfma.org/revenue-cycle/denials-management/62347/ **9.** GOMEKLI. Prescribing Information. SpringWorks Therapeutics, Inc. **10.** Appealing a health plan decision. Healthcare.gov. Accessed October 24, 2024. https://www.healthcare.gov/appeal-insurance-company-decision/appeals/ **11.** Has your health insurer denied payment for a medical service? You have a right to appeal. Centers for Medicare & Medicaid Services. Accessed October 24, 2024. https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/appeals06152012a **12.** Alternative funding programs. Know your rights. A resource for consumers, caregivers, and health care providers. AimedAlliance.org. Accessed December 10, 2024. https://aimedalliance.org/wp-content/uploads/2023/12/AA-KnowYourRights-AltFunding-FINAL-2023.pdf **13.** The high costs of alternative funding programs. Alliance for Patient Access. Accessed December 10, 2024. https://allianceforpatientaccess.org/wp-content/uploads/2023/06/AfPA_High-Costs-of-Alternative-Funding-Programs_June-2023.pdf **14.** Levine H. Prior authorization: what is it, when might you need it, and how do you get it? Harvard Health Publishing. Published August 5, 2024. Accessed October 24, 2024. https://www.health.harvard.edu/staying-healthy/prior-authorization-what-is-it-when-might-you-need-it-and-how-do-you-get-it#

Please see Important Safety Information on pages 19 and 20 and click here for full Prescribing Information including Patient Information and Instructions for Use.

SpringWorks CareConnections™

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