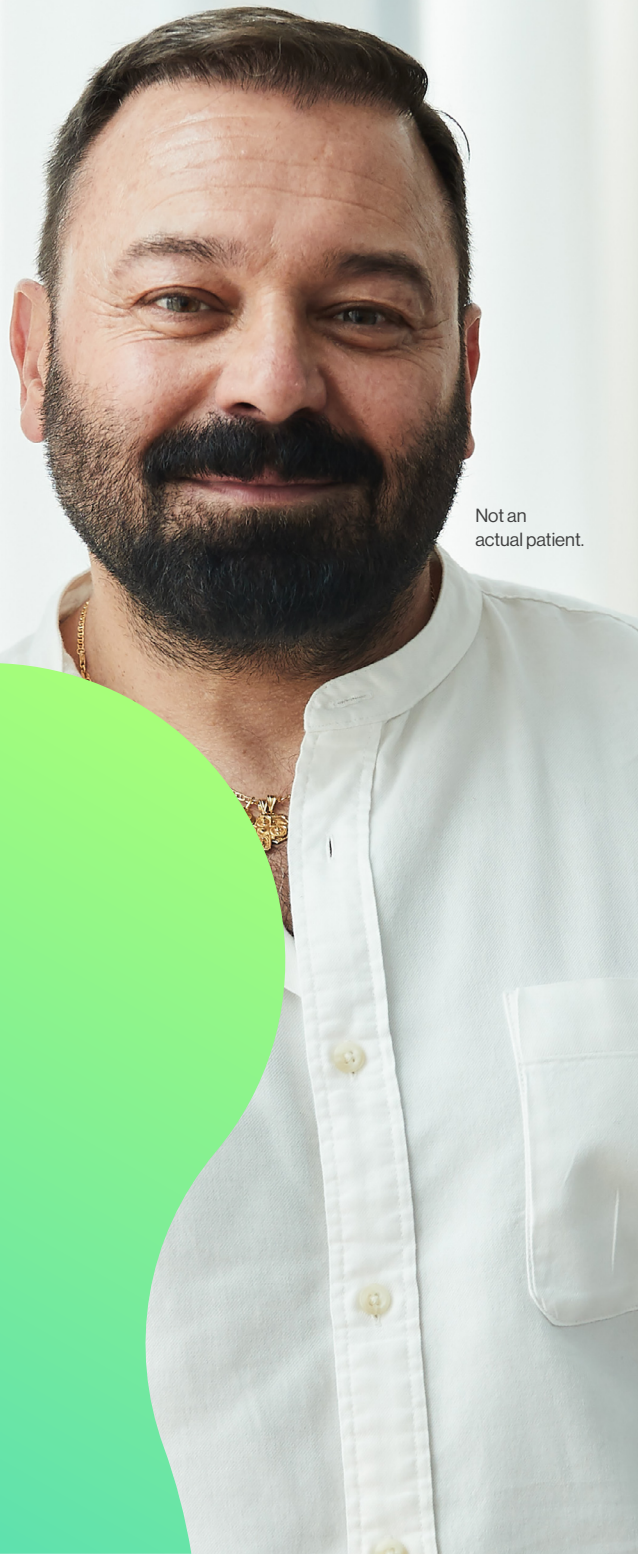
Novartis Patient Support™

Prior Authorization and Appeals Guide

Information and sample letters to help you navigate coverage for your patients on FABHALTA® (iptacopan)



Not an actual patient.

Phone:
833-99FABHA (833-993-2242)

Fax:
877-44FABHA (877-443-2242)

Online:
www.fabhalta.com

For questions or support, reach out to your dedicated Access and Reimbursement Team or contact Novartis Patient Support.

FABHALTA® (iptacopan) 200 mg capsules

Please see full Important Safety Information on pages 12-14 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Table of Contents

This guide intends to be a resource for you to use if your patient is faced with common insurance restrictions like a prior authorization (PA), step edit, or a plan not having a policy in place for FABHALTA® (iptacopan). Whether using an electronic PA form or submitting requests manually, the tips, checklists, and sample letters included in this guide are designed to help you and your patients gather relevant documentation for complete communications with your patient's health plan.

The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Select a tab on the bottom of each page to go to the section that interests you. Press the home icon button to return to this page. This guide is interactive—keep an eye out for callouts to see where you can click.

Please see full Important Safety Information on pages 12-14 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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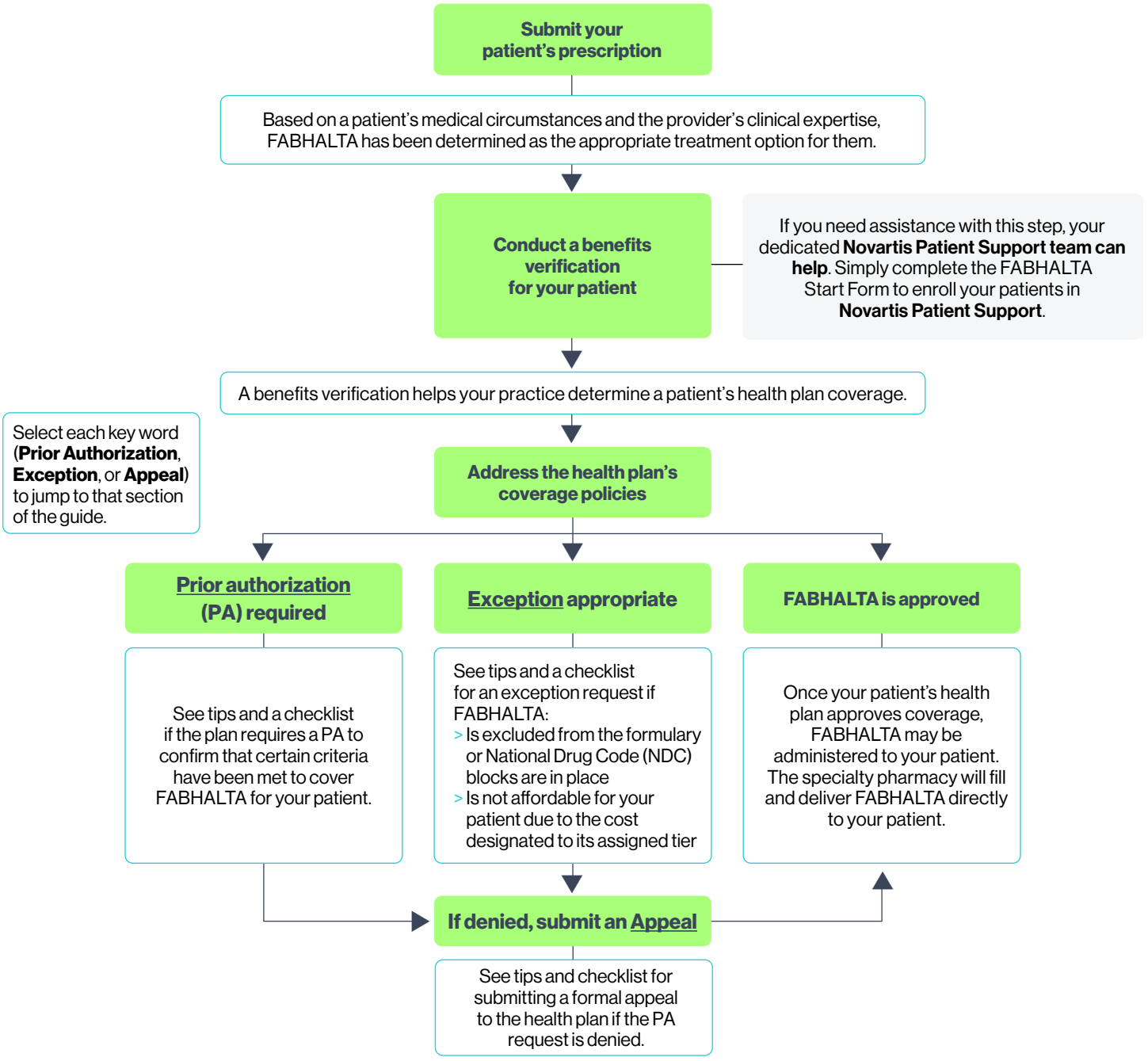
Overview of the Reimbursement Process

Various health insurance providers may manage access to FABHALTA differently. Use this page to review the coverage process and identify which steps apply to your patient.



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Tips for Completing a PA Request

If a patient's health plan requires a PA for FABHALTA, review the specific forms and information required by the health plan to ensure that the PA request is as complete as possible.

Tips

- **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for FABHALTA

- **Ensure** that you understand and satisfy all plan-specific requirements
  - The patient's health plan may have a unique PA form that can be located on their website or by contacting their customer service
  - In certain states, a standardized PA form may be required for submission to a health plan along with clinical documentation
  - Some health plans encourage the use of electronic PA submission platforms (eg, CoverMyMeds®)

Start a request

Visit covermymeds.com
Log in to your account
Select "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests

CoverMyMeds: Automating part of the prior authorization (PA) process

CoverMyMeds' nationwide pharmacy integrations support the start of a prior authorization (PA) request that is sent to the provider for completion – which may help patients access their medications faster*.

*Compared to phone and fax

- **Consider** including a personalized letter with PA documentation; you may prefer to, or your patient's health plan may require you to submit a Letter of Medical Necessity to explain your rationale supporting your patient's clinical need for FABHALTA

Click here to download sample **Letter(s) of Medical Necessity** for your office:

A PA may be denied for FABHALTA based on various reasons. Common causes of a PA denial are shown below.

Medical Necessity	Health plans may deny access if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.
Administrative Errors	An incorrect billing code, spelling errors, insufficient information, or other administrative inaccuracies can result in a denied PA request.
Step Therapy	Depending on a health plan's formulary, patients are often required to receive a less expensive drug before a more expensive treatment can be prescribed.

Health plans take time to formulate their PA policies and coverage decisions. If a drug is not listed on formulary or is NDC blocked, you may be able to submit an exception for these scenarios.

See the following page for a helpful PA request checklist.

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Preparing a PA Submission

Submission checklist

Consider the following points when preparing to submit a PA for your patient. The checklist below is provided to help ensure your PA Request Letter is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The list below is intended to provide examples of what information is usually required.

- **Fill out the plan- and/or state-specific PA form**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements for FABHALTA
- **Check that the following information is accurate and complete:**
  - Patient and insurance information (name, address, DOB, insurance information, etc)
  - Prescriber information (name, address, specialty, office contact, NPI, etc)
- **Document the treatment strength, frequency, quantity, and estimated length of therapy, including the appropriate NDC**
- **Attach relevant clinical documentation supporting treatment with FABHALTA, such as:**
  - Relevant medical records and clinical notes that support treatment with FABHALTA
  - Appropriate clinical information from the Prescribing Information for FABHALTA
  - Disease-specific criteria, including information such as the following:
    - Confirm patient is 18 years old
    - Record of biopsy confirmed C3G (C3GN or DDD)
    - Recent urine protein-to-creatinine ratio (UPCR) lab results
    - Recent assessment of patient renal function, including eGFR
    - Recent serum C3 level
    - Indicator of rapid disease progression/kidney function loss
    - List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies. Confirm that the patient has not achieved adequate results from current or prior therapy
      - ACE inhibitor or ARB, or reason that the patient is not taking an ACEi/ARB or SGLT2i
      - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
      - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

Click here to download a customizable PA letter for your office in Word doc format.

Click here for a list of ICD-10-CM codes.

Reach out to your dedicated Access and Reimbursement team—they can help you understand plan requirements and coverage criteria

For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

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Submitting an Exception

If the patient's health plan has placed restrictions on FABHALTA, such as formulary exclusion, higher tier placement, or step therapy requirements, you will need to submit an exception request to ensure coverage.

Step Therapy Exception Request

Use this type of exception request to support patients seeking approval for FABHALTA without having to try other health plan preferred alternatives first.

Tiering Exception Request

Use this type of exception request to support patients seeking approval for FABHALTA as a preferred drug that has a lower co-payment than its assigned tier.

Formulary Exception Request

Use this type of exception request to support patients seeking approval for FABHALTA or to remove any applicable NDC blocks if FABHALTA is excluded from the formulary of your patient's health plan.

Tips

- **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for FABHALTA
- **Check** to see if the patient's health plan has its own **Exception Request Form**—it can be located on their website or by contacting their customer service
- **You may also submit** a **Step Therapy Exception Request/Tiering Exception Request** or **Formulary Exception Request** if your patient's health plan previously approved FABHALTA but has since changed its formulary to exclude or move FABHALTA to a higher tier without grandfathering in current patients
- **Consider** asking your patient to write their own exception request letter that is signed by the physician
- **Click here** to view a checklist with helpful tips for your patient when writing to their health plan
- If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform

See the following page for a helpful exception request checklist.

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Exception Request Checklist

Consider the following points when preparing to submit an exception request. The checklist below is provided to help ensure your exception request is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- **Fill out the health plan's exception request form, if required**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
- **Complete a Letter of Medical Necessity with relevant patient information and clinical support, which can include information such as:**
  - Patient's name, date of birth, health plan information (policy number)
  - A statement of the exception you are requesting for the patient and the reason for the request
  - Diagnosis and corresponding ICD-10-CM code(s)
    - **Click here** for a list of ICD-10-CM codes
  - Rationale for choosing FABHALTA
  - Summary of the patient's current condition and relevant treatment history
  - If appropriate, a statement of the patient's financial hardship
- **Attach relevant clinical documentation:**
  - Relevant medical records and clinical notes that support treatment with FABHALTA
  - Appropriate clinical information from the Prescribing Information for FABHALTA
  - Disease-specific criteria, including information such as the following:
    - Confirm patient is 18 years old
    - Record of biopsy confirmed C3G (C3GN or DDD)
    - Recent urine protein-to-creatinine ratio (UPCR) lab results
    - Recent assessment of patient renal function, including eGFR
    - Recent serum C3 level
    - Indicator of rapid disease progression/kidney function loss
    - List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies. Confirm that the patient has not achieved adequate results from current or prior therapy
      - ACE inhibitor or ARB, or reason that the patient is not taking an ACEi/ARB or SGLT2i
      - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
      - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

Click here to download sample **Letter(s) of Medical Necessity** for your office.

- Reach out to your dedicated Access and Reimbursement team—they can help you identify and understand plan requirements and coverage criteria

- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

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Submitting an Appeal

If the patient's PA or exception request for FABHALTA has been denied, you can consider an appeal. Your patient's health plan will provide a written explanation and include information about how to request an appeal. Review the health plan's guidelines on the appeals process to ensure the appeal is as complete as possible.

Tips

- **Conduct a benefits verification** of your patient's health plan to help determine the specific coverage criteria for FABHALTA

- **Promptly submit the appeal** upon receipt of the denial before the health plan's deadline

- **Clearly address the plan's specific reason(s)** for denial when writing the appeal letter

- **Review the appeals process** for your patient's health plan

- **Always refer to the health plan's website** to locate their appeal form or information for submitting your own document
  - Many health plans will allow **up to 3 levels of appeal of PA denials**; the third level of appeal may include a review by an independent, noninsurance-affiliated external review board or hearing
  - Your patient's appeals rights and the appeals process are covered in health plan documents and on each Explanation of Benefits (EOB) form

- If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform

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Appeal Submission Checklist

Consider the following points when preparing to submit an appeal. The checklist below is provided to help ensure your appeal submission is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- **Fill out an Appeal Form in response to the denial, if required by the health plan**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
  - Make sure that you review and attach the denial letter
- **Complete an Appeal Letter with relevant patient information and clinical support, such as:**
  - Patient's name, date of birth, health plan information (policy number)
  - Denial date and denial reference number
  - Summary of patient's diagnosis and corresponding ICD-10-CM code(s)
    - **Click here** for a list of ICD-10-CM codes
  - Summary of patient's treatment history
  - Detail why each of the health plan's suggested alternative therapies are not appropriate for your patient
  - Rationale for choosing FABHALTA
- **Attach relevant clinical documentation:**
  - Relevant medical records and clinical notes that support treatment with FABHALTA
  - Appropriate clinical information from the Prescribing Information for FABHALTA
  - Disease-specific criteria, including information such as the following:
    - Confirm patient is 18 years old
    - Record of biopsy confirmed C3G (C3GN or DDD)
    - Recent urine protein-to-creatinine ratio (UPCR) lab results
    - Recent assessment of patient renal function, including eGFR
    - Recent serum C3 level
    - Indicator of rapid disease progression/kidney function loss
    - List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies. Confirm that the patient has not achieved adequate results from current or prior therapy
      - ACE inhibitor or ARB, or reason that the patient is not taking an ACEi/ARB or SGLT2i
      - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
      - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

- Reach out to your dedicated Access and Reimbursement team—they can help you identify and understand plan requirements and coverage criteria

- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

Click here to download sample **Letter(s) of Appeal** for your office.

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Sample Letters

The sample letter links below are available for you to reference when crafting your own letter to the patient's health plan. The sample letters are intended to provide examples of the types of information that are often required.

Click the links below to download sample letters for your office:

Sample Letters

Sample PA Request Letter

Sample Letter of Medical Necessity Complement 3 Glomerulopathy (C3G)

Sample Appeal Letter Complement 3 Glomerulopathy (C3G)


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NOTE: This Sample Letter of Medical Necessity is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

FABHALTA® (iptacopan) Sample Letter of Medical Necessity Complement 3 Glomerulopathy (C3G)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, FABHALTA is required for the treatment of this patient for [diagnosis and ICD-10-CM codes]. [If you are writing this letter for a formulary or tiering exception request, provide a detailed explanation for the exception you are requesting and the reason for the request.] The following information supports my recommendation for treatment with FABHALTA:

Summary of Patient's Medical History and Diagnosis
[Include a summary of the patient's diagnosis and their current condition. Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:

- ☐ Confirm patient is 18 years or older
- ☐ Record of biopsy-confirmed C3G (C3GN or DDD)
- ☐ Most recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Recent serum C3 level
- ☐ Indicator of rapid disease progression/kidney function loss
- ☐ List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies
- ☐ Confirm that the patient has not achieved adequate results from current or prior therapy
  - ACE inhibitor or ARB, or reason that the patient is not taking an ACE/ARB or SGLT2i
  - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
  - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

Rationale for Treatment
[Provide your rationale for choosing FABHALTA:

- ☐ Include clinical support for prescribing FABHALTA (This may be clinical trial data found in the FABHALTA Prescribing Information)
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Explain why the health plan's preferred therapies are not appropriate for your patient
- ☐ If your patient is already taking FABHALTA, describe their response to FABHALTA and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with FABHALTA
- ☐ If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name]'s current condition and treatment history, I believe FABHALTA is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of FABHALTA for this patient. The coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: [Medical records, FABHALTA Prescribing Information]

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Example of Letter of Medical Necessity Complement 3 Glomerulopathy (C3G)

Click the links below to download patient resources for your office:

Patient Resources

Patient Letter Checklist


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Tips for writing to your health plan

Your doctor may be working with your health plan on your behalf to help with coverage. Writing a letter yourself can also help.

Not an actual patient.

If your doctor has suggested that you write a letter to your health plan for FABHALTA® (iptacopan), use this checklist to make sure you're providing the necessary information:

- Include important details about yourself, name, health plan membership/policy number, date of birth, and if appropriate, the denial reference number and the date of denial
- Close the letter with a summary of the recommendation from your doctor and provide their contact information (eg, phone number or email address), should any additional information be required
- Explain your request—be sure you have read the plan's coverage policy or denial letter, and refer to those specifics
- If you are writing to your health plan regarding your co-pay for FABHALTA, be sure to include any important information about your financial situation
- State your diagnosis and describe your personal experience(s) with your condition
- Mention any past medications you have tried and your experience with them

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Example of Patient Letter Checklist

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Glossary

- **Appeal:** A request to a patient's health plan to reconsider their decision to deny coverage
- **Co-payment:** A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—like doctor visits, prescription medications, and other health care services
- **Exception:** A coverage request made to a patient's health plan to remove a plan restriction placed on a treatment
- **Explanation of benefits (EOB):** A statement from the health plan sent to members to track the use of medications and/or health care services, and the associated costs and payments
- **Formulary:** A list of prescription medications covered by an insurer/health plan
- **National Drug Code (NDC):** Universal product identifier with a unique set of numbers used for human drugs in the United States
- **Preferred drug:** A medication designated as a valuable, cost-effective treatment option. In a multi-tier plan, preferred drugs are assigned to a lower tier than nonpreferred drugs
- **Prior authorization (PA):** Also called preauthorization, an administrative tool used by health plans to determine if they will cover a prescribed procedure, service, or medication based on the patient's medical necessity
- **Step therapy:** A health plan policy requiring patients to follow a stepwise approach to trying (and failing) a medication before the plan will cover any alternative medications
- **Tiers:** Most health plans' formularies are divided into different categories, called tiers, with increasingly scaled co-payments. Tiers are commonly based on brand or generic medications, preferred or nonpreferred medications, and traditional or specialty medications

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

FABHALTA is indicated for the treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

FABHALTA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccinations for encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, unless the risks of delaying therapy with FABHALTA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving FABHALTA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the FABHALTA REMS.

CONTRAINDICATIONS

- In patients with serious hypersensitivity to FABHALTA or any of the excipients.
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae* type b.

WARNINGS AND PRECAUTIONS

Serious Infections Caused by Encapsulated Bacteria

- FABHALTA, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis* (caused by any serogroup, including nongroupable strains), and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of FABHALTA is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Serious Infections Caused by Encapsulated Bacteria (CONTINUED)

- Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to the start of FABHALTA, according to the current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with FABHALTA. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent FABHALTA therapy is indicated in a patient who is not up-to-date with vaccinations against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible. The benefits and risks of treatment with FABHALTA, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.
- Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated.

FABHALTA REMS

- FABHALTA is available only through a restricted program under a REMS called FABHALTA REMS because of the risk of serious infections caused by encapsulated bacteria.
- Under the FABHALTA REMS, prescribers must enroll in the program; counsel patients about the risks, signs, and symptoms of serious infections caused by encapsulated bacteria; provide patients with the REMS educational materials; ensure patients are vaccinated against encapsulated bacteria; prescribe antibacterial drug prophylaxis if patients' vaccination status is not up-to-date and treatment must be started urgently; and provide instructions to always carry the Patient Safety Card during treatment and for 2 weeks following the last dose of FABHALTA.
- Further information is available by telephone: 1-833-993-2242 or online at www.FABHALTA-REMS.com.

Hyperlipidemia

- FABHALTA may increase total cholesterol, LDL cholesterol, and serum triglycerides. In clinical trials, some patients required cholesterol-lowering medications.
- Monitor serum lipid parameters periodically during treatment with FABHALTA and initiate cholesterol-lowering medications, if indicated.

ADVERSE REACTIONS

- The most common adverse reactions (≥10%) in adults with C3G receiving FABHALTA were nasopharyngitis and viral infection.

IMPORTANT SAFETY INFORMATION (CONTINUED)

DRUG INTERACTIONS

- Concomitant use of CYP2C8 inducers (eg, rifampin) may decrease iptacopan exposure, which may result in loss of or reduced efficacy of FABHALTA. Monitor the clinical response and discontinue use of the CYP2C8 inducer if loss of efficacy of FABHALTA is evident.
- Concomitant use of strong CYP2C8 inhibitors (eg, gemfibrozil) may increase iptacopan exposure, which may result in an increased risk for adverse reactions with FABHALTA. Coadministration with a strong CYP2C8 inhibitor is not recommended.

USE IN SPECIFIC POPULATIONS

- Because of the potential for serious adverse reactions in a breastfed child, breastfeeding should be discontinued during treatment and for 5 days after the final dose.
- FABHALTA is not recommended in patients with severe hepatic impairment (Child-Pugh class C). No dose adjustment is required for patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

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NOTE: This Sample Letter of Medical Necessity is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

FABHALTA® (iptacopan) Sample Letter of Medical Necessity Complement 3 Glomerulopathy (C3G)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, FABHALTA is required for the treatment of this patient for [diagnosis and ICD-10-CM codes]. [***If you are writing this letter for a formulary or tiering exception request, provide a statement of the exception you are requesting and the reason for the request.***] The following information supports my recommendation for treatment with FABHALTA:

Summary of Patient's Medical History and Diagnosis

[***Include a summary of the patient's diagnosis and their current condition:*** *Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:*

- ☐ Confirm patient is 18 years or older
- ☐ Record of biopsy confirmed C3G (C3GN or DDD)
- ☐ Recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Recent serum C3 level
- ☐ Indicator of rapid disease progression/kidney function loss
- ☐ List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies
- ☐ Confirm that the patient has not achieved adequate results from current or prior therapy
    - ACE inhibitor or ARB, or reason that the patient is not taking an ACEi/ARB or SGLT2i
    - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
    - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

Rationale for Treatment

[***Provide your rationale for choosing* FABHALTA:**

- ☐ Include clinical support for prescribing FABHALTA (This may be clinical trial data found in the FABHALTA Prescribing Information)
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Explain why the health plan's preferred therapies are not appropriate for your patient
- ☐ If your patient is already taking FABHALTA, describe their response to FABHALTA and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with FABHALTA
- ☐ If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name's] current condition and treatment history, I believe FABHALTA is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of FABHALTA for this patient. The coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: [Medical records, FABHALTA Prescribing Information]

Novartis Patient Support™

FABHALTA® (iptacopan) 200 mg capsules

NOTE: This Sample Letter of Appeal is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

FABHALTA® (iptacopan) Sample Letter of Appeal Complement 3 Glomerulopathy (C3G)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I prescribed FABHALTA for this patient to treat [diagnosis and ICD-10-CM codes] and submitted a [Prior Authorization/Formulary Exception Request/Tiering Exception Request] on [date of submission]. The request was denied on [date of denial and reference number] and the reason given was [reason from the health plan's denial letter]. I request a formal appeal of your denial for FABHALTA, based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that FABHALTA is the appropriate therapy for [Patient's name]. The following information supports my recommendation for treatment with FABHALTA:

Summary of Patient's Medical History and Diagnosis

[***Include a summary of the patient's diagnosis and current condition:*** *Be sure to attach relevant medical records that support this information.*
The following topics are examples of information you may want to include:

- ☐ Confirm patient is 18 years or older
- ☐ Record of biopsy confirmed C3G (C3GN or DDD)
- ☐ Recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Recent serum C3 level
- ☐ Indicator of rapid disease progression/kidney function loss
- ☐ List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies
- ☐ Confirm that the patient has not achieved adequate results from current or prior therapy
    - ACE inhibitor or ARB, or reason that the patient is not taking an ACEi/ARB or SGLT2i
    - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
    - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

Rationale for Treatment

[***Provide your rationale for choosing*** **FABHALTA:**

- ☐ Include clinical support for prescribing FABHALTA *(This may be clinical trial data found in the FABHALTA Prescribing Information)*
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- ☐ If your patient is already taking FABHALTA, describe their response to FABHALTA and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with FABHALTA]

Given [Patient's name's] current condition and treatment history, I believe FABHALTA is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient and would appreciate your prompt reconsideration of this denial.

I have included a copy of the denial letter along with relevant medical notes in response to the denial. Please feel free to contact me, [HCP's name, NPI number], by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of FABHALTA for this patient. The appeal decision may be faxed to [fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: Denial letter, Medical records, FABHALTA Prescribing Information

Novartis Patient Support™

FABHALTA® (iptacopan) 200 mg capsules

NOTE: This Sample Prior Authorization Request Letter is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

FABHALTA® (iptacopan) Sample Prior Authorization Request Letter Complement 3 Glomerulopathy (C3G)

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name] and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I am writing to request prior authorization of FABHALTA [dose/frequency] for the treatment of this patient for [diagnosis and ICD-10-CM codes]. As per the requirements of the plan, I have tried [required step-therapies] for my patient before prescribing FABHALTA. Included please find a statement explaining why these preferred therapies are not appropriate for my patient. The following information supports my recommendation for treatment with FABHALTA:

I have attached relevant medical records, including the patient's diagnosis, test results, and treatment history.
[***Include a summary of the patient's treatment history:***

- ☐ Confirm patient is 18 years or older
- ☐ Record of biopsy confirmed C3G (C3GN or DDD)
- ☐ Recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Recent serum C3 level
- ☐ Indicator of rapid disease progression/kidney function loss
- ☐ List of all current and previous treatments for C3G, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies
- ☐ Confirm that the patient has not achieved adequate results from current or prior therapy
    - ACE inhibitor or ARB, or reason that the patient is not taking an ACEi/ARB or SGLT2i
    - Documentation showing prior steroid therapy or reasons for noneligibility for corticosteroids and other therapies
    - Documentation showing prior mycophenolate mofetil therapy or reasons for noneligibility for mycophenolate mofetil and other therapies

Given [Patient's name's] current condition and treatment history, I believe FABHALTA should be authorized to treat [diagnosis] for this patient. Please do not hesitate to contact me by calling [office phone number] if you require additional information or would like to discuss this case further.

The prior authorization decision may be faxed to [fax number] or mailed to [HCP business office address]. Thank you for your prompt attention to this matter.

Sincerely,

[HCP's name and signature]
[Specialty, name of practice, phone number]

Encl: Medical records, FABHALTA Prescribing Information