Novartis Patient Support™

Prior Authorization and Appeals Kit

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

Not an actual patient.

INDICATION

FABHALTA is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FABHALTA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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.

Please see full Important Safety Information on pages 16-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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How to Use This Kit

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) for IgAN. This kit provides you with helpful tools to assist you and your patients with common health plan criteria and to support access for your patients prescribed FABHALTA. Whether using an electronic PA form or submitting requests manually, the tips, checklists, and sample letters included in this kit are designed to help you and your patients gather relevant documentation for complete communications with your patient's health plan.

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 kit is interactive—keep an eye out for callouts to see where you can click.

Table of Contents

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

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.

Phone:
1-833-99FABHA
(1-833-993-2242)

Fax:
1-877-44FABHA
(1-877-443-2242)

Online:
www.fabhalta.com

Please see full Important Safety Information on pages 16-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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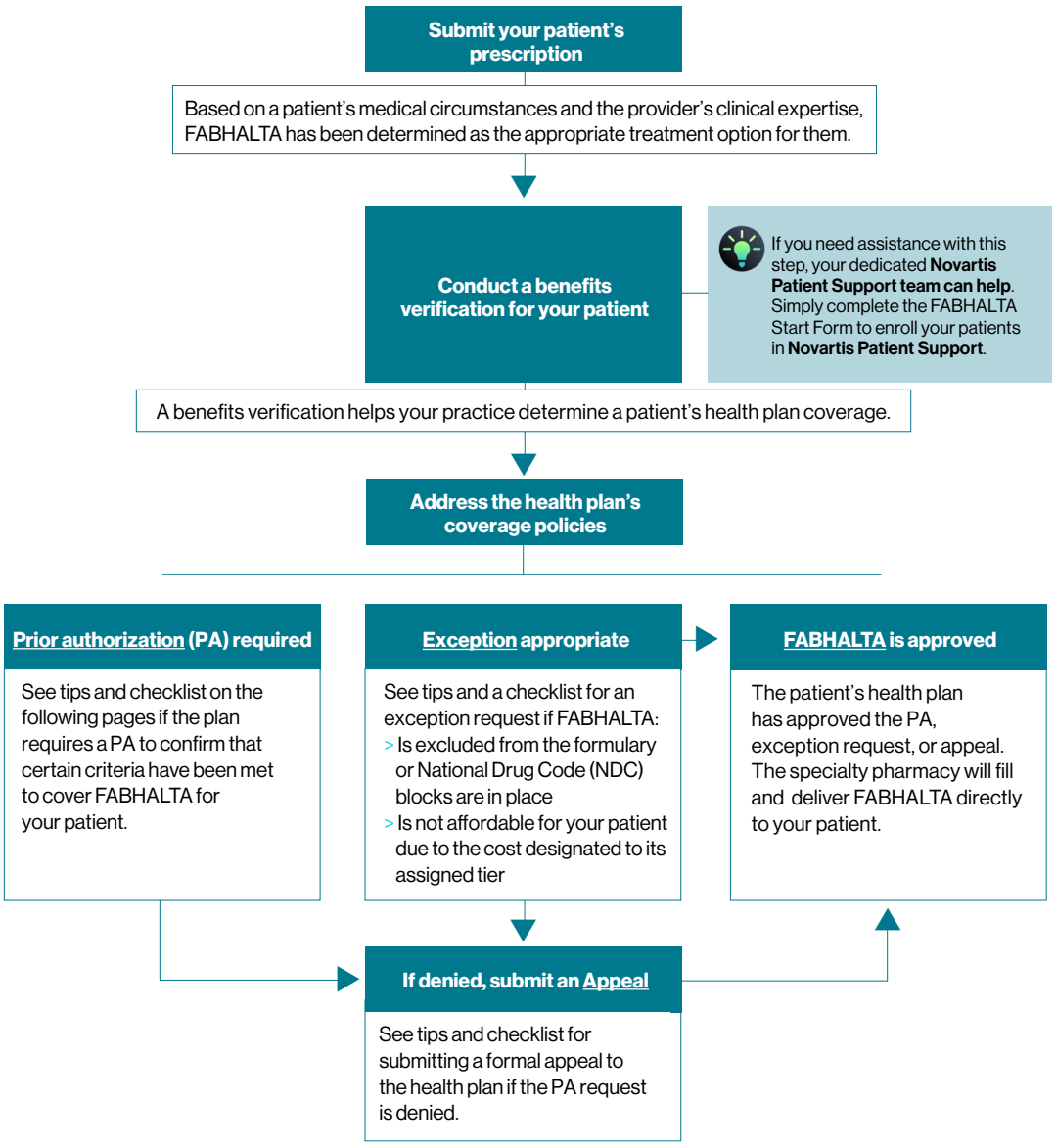
Overview of the Reimbursement Process

Various health insurance providers may manage access to FABHALTA® (iptacopan) 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® (iptacopan), 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
  - Some health plans encourage the use of electronic PA submission platforms
  - In certain states, a standardized PA form may be required for submission to a health plan along with clinical documentation
- **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 view a sample **Letter 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.

Please see full Important Safety Information on pages 16-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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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 help ensure that you satisfy all of the health plan's requirements for FABHALTA® (iptacopan)
- **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, which can include information such as the following:
    - Confirm patient is 18 years or older
    - Record of diagnosis by kidney biopsy, including MEST-C scoring if available
    - Recent urine protein-to-creatinine ratio (UPCR) lab results
    - Recent assessment of patient renal function, including eGFR
    - Indicator of inflammatory lesions and persistent hematuria
    - Indicator of rapid kidney function loss
    - List of all current and previous treatments for IgAN, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, 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 non-eligibility for corticosteroids and other therapies
    - Treatment prescribed by or in consultation with a nephrologist

Reference: Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

Please see full Important Safety Information on pages 16-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Preparing a PA Submission (continued)

Click here to view **ICD-10-CM Flashcard**

Click here to view a sample **PA Request Letter** for your office

- Reach out to your dedicated Access & 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

Reference: Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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Submitting an Exception

If the patient's health plan has placed certain restrictions on FABHALTA® (iptacopan), such as formulary exclusion or tier assignment, you will need to submit an exception request.

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 you 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 **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

See the following page for a helpful exception request checklist.

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, if required**
  - Conduct a benefits verification to help 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 codes
  - Rationale for choosing FABHALTA® (iptacopan)
    - Summary of the patient's current condition and relevant treatment history
      - **Click here** to view **ICD-10-CM Flashcard**
  - If appropriate, a statement of the patient's financial hardship
- **Attach relevant clinical documentation, 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 or older
    - Record of diagnosis by kidney biopsy, including MEST-C scoring if available
    - Recent urine protein-to-creatinine ratio (UPCR) lab results
    - Recent assessment of patient renal function, including eGFR
    - Indicator of inflammatory lesions and persistent hematuria
    - Indicator of rapid kidney function loss
    - List of all current and previous treatments for IgAN, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, 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 non-eligibility for corticosteroids and other therapies
    - Treatment prescribed by or in consultation with a nephrologist

Reference: Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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Exception Request Checklist (continued)

Click here to view a sample **Letter of Medical Necessity** for your office

- Reach out to your dedicated Access & 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

Reference: Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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Submitting an Appeal

If the patient's PA or exception request for FABHALTA® (iptacopan) 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 you determine the specific coverage criteria for FABHALTA**
- It is important to promptly submit the appeal upon receipt of the denial
- When writing the appeal letter, be sure to clearly address the plan's specific reason(s) for denial
- 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, non–insurance-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**

See the following page for a helpful appeal checklist.

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 help 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 codes
    - **Click here** to view **ICD-10-CM Flashcard**
  - 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® (iptacopan)
- **Attach relevant clinical documentation, 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 or older
    - Record of diagnosis by kidney biopsy, including MEST-C scoring if available
    - Recent urine protein-to-creatinine ratio (UPCR) lab results
    - Recent assessment of patient renal function, including eGFR
    - Indicator of inflammatory lesions and persistent hematuria
    - Indicator of rapid kidney function loss
    - List of all current and previous treatments for IgAN, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, 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 non-eligibility for corticosteroids and other therapies
    - Treatment prescribed by or in consultation with a nephrologist

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Appeal Submission Checklist (continued)

Click here to view a sample **Letter of Appeal** for your office

- Reach out to your dedicated Access & 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

Reference: Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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Sample Letters

The sample letters linked 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 what information is usually required.

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

Sample Physician Letters

Sample PA Request Letter

Sample Letter of Medical Necessity

Sample Appeal Letter

Patient Letters

Patient Letter Checklist

A dedicated team for you and your patients

Not an actual Novartis Patient Support team member.

Novartis Patient Support is a comprehensive program that can help your patients start and stay on treatment.

We support you and your patients throughout their journey with:

Insurance Support

Help navigating the insurance process, including benefits verification and support with the prior authorization and appeals processes.

Financial Support

Inform your eligible patients about **Co-Pay Plus***. Privately insured patients may pay as little as **$0** for FABHALTA® (iptacopan).

Vaccination Support†

Our dedicated Novartis Patient Support team offers support to help your patients locate vaccinations.

Ongoing Support

A dedicated Novartis Patient Support Team and educational resources to help your patients get started on treatment and support them along the way.

* **Co-Pay Plus:** Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Patients with commercial insurance coverage for FABHALTA may receive up to $20,000 in annual co-pay benefits for the cost of FABHALTA and up to $1,000 for qualifying vaccination costs. Patients with commercial insurance and a prior authorization requirement may receive up to 12 months of free product while coverage is pursued. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at www.fabhalta.com for details.

† Vaccination Support: Limitations apply. Please contact Novartis Patient Support at 1-833-99FABHA (1-833-993-2242) for more information.

Get your patients started with guidance along the way.

Go to the FABHALTA website to view the Start Form

Questions?

For more information, call Novartis Patient Support at **1-833-99FABHA** (1-833-993-2242), Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays.

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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.
- **Pharmacy Benefit Manager (PBM):** A third-party organization hired to manage pharmacy benefits.
- **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.
- **Quantity limit:** A restriction on the volume or quantity of medication that is covered by a health plan during a designated time period.
- **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.

Reference: Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

FABHALTA is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether FABHALTA slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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.

Please see full Important Safety Information on pages 16-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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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.
- 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 vaccines 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.

Please see full Important Safety Information on pages 16-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

WARNINGS AND PRECAUTIONS (CONTINUED)

- 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' vaccine 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. 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 (≥5%) in adults with IgAN receiving FABHALTA were upper respiratory tract infection, lipid disorder, and abdominal pain.

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 to physician: This template may be used to help create your institution's independent prior authorization request letter to be sent to a patient's health plan should a prior authorization request letter be required by a patient's health plan to determine/request coverage.

All blue, bracketed content needs to be filled out based on the details of each specific patient. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax).

FABHALTA® (iptacopan) Sample Prior Authorization Request Letter

[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]. I have reviewed the patient's diagnosis, care plan, and clinical guidelines for treatment. 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 diagnosis by kidney biopsy, including MEST-C scoring if available
- ☐ Recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Indicator of inflammatory lesions and persistent hematuria
- ☐ Indicator of rapid kidney function loss
- ☐ List of all current and previous treatments for IgAN, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, 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 non-eligibility for corticosteroids and other therapies
- ☐ Treatment prescribed by or in consultation with a nephrologist]

In my medical judgment, this patient is an appropriate candidate for treatment with FABHALTA. 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

This letter is provided as an example and is meant 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 include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

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Note to physician: This template may be used to help create your institution's independent letter of medical necessity to be sent to a patient's health plan should a letter of medical necessity be required by a patient's health plan to determine/request coverage.

All blue, bracketed content needs to be filled out based on the details of each specific patient. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax).

FABHALTA® (iptacopan) Sample Letter of Medical Necessity

[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 diagnosis by kidney biopsy, including MEST-C scoring if available
- ☐ Recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Indicator of inflammatory lesions and persistent hematuria
- ☐ Indicator of rapid kidney function loss
- ☐ Confirm the patient has maintained a stabilized dose of an ACE inhibitor or ARB for at least 3 months
- ☐ List of all current and previous treatments for IgAN, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, 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 non-eligibility for corticosteroids and other therapies
- ☐ Treatment prescribed by or in consultation with a nephrologist]

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 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

Novartis Patient Support™

FABHALTA® (iptacopan) 200 mg capsules

Note to physician: This template may be used to help create your institution's independent letter of medical necessity to be sent to a patient's health plan should a letter of medical necessity be required by a patient's health plan to determine/request coverage.

All blue, bracketed content needs to be filled out based on the details of each specific patient. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax).

FABHALTA® (iptacopan) Sample Letter of Appeal

[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 diagnosis by kidney biopsy, including MEST-C scoring if available
- ☐ Recent urine protein-to-creatinine ratio (UPCR) lab results
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ Indicator of inflammatory lesions and persistent hematuria
- ☐ Indicator of rapid kidney function loss
- ☐ List of all current and previous treatments for IgAN, including instances of intolerance to therapies, such as immunosuppressants, corticosteroids, 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 non-eligibility for corticosteroids and other therapies
- ☐ Treatment prescribed by or in consultation with a nephrologist]

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 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