

Prior Authorization and Appeals Guide

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

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

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

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

Online
www.fabhalta-hcp.com

Please see full Important Safety Information on pages 15-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules



Not an actual health care professional or patient.

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.

3 Overview of the Reimbursement Process

4 Tips for Completing a PA Request

5 Preparing PA Submissions

8 Submitting an Exception

9 Submitting an Appeal

10 Sample Letters and Resources

13 Glossary

15 Indications and Important Safety Information

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.

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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.

Submit your patient's prescription

Based on a patient's medical circumstances and the provider's clinical expertise, FABHALTA has been determined as the appropriate treatment option for them.

The Specialty Pharmacy or Novartis Patient Support will conduct and share a benefits verification for your patient

If you need assistance with this step, the **Novartis Patient Support team can help**. Simply complete the FABHALTA Start Form to enroll your patients in **Novartis Patient Support**.

A benefits verification helps your practice determine a patient's health plan coverage.

Select each key word (**Prior Authorization**, **Exception**, or **Appeal**) to jump to that section of the guide.

Address the health plan's coverage policies

Prior authorization (PA) required

See tips and checklist on the following pages if the plan requires a PA to confirm that certain criteria have been met to cover FABHALTA for your patient.

Exception appropriate

See tips and a checklist for an exception request if FABHALTA:

- Is excluded from the formulary
- Is not affordable for your patient due to the cost designated to its assigned tier

FABHALTA is approved

Once your patient's health plan approves coverage, FABHALTA may be administered to your patient. The specialty pharmacy (SP) will fill and deliver FABHALTA directly to your patient.

If denied, submit an Appeal

See tips and checklist for submitting a formal appeal to the health plan if the PA request is denied.

Please see full Important Safety Information on pages 15-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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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.

Include the FABHALTA Prescribing Information (PI) and/or relevant treatment guidelines, highlighting appropriate clinical information that support the treatment choice

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.health**
- Log in to your account
- Select "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests

CoverMyMeds:

- Complete PA requests in minutes and get a response as quickly as a few hours
- No paper, no fax, no duplicate services
- Electronic paper signatures

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 and download a sample **PA Request Letter** for your office:

A PA may be denied for FABHALTA based on various reasons, but you and your patient always have the option to submit an appeal. Common causes of a PA denial are shown below.

Medical Necessity	Administrative Errors	Step Therapy
Health plans may deny access if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.	An incorrect billing code, spelling errors, insufficient information, or other administrative inaccuracies can result in a denied PA request.	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 a formulary, 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 15-18 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Preparing a **PA Request for IgAN**

The checklist below is intended to provide examples of what information is usually required when submitting a PA for FABHALTA immunoglobulin A nephropathy (IgAN). Please note that this is only an example, and it's important to check the payer's specific requirements before submission. Your chosen SP can also guide you through this process and to gather the appropriate content for coverage requests. This guide also contains a sample letter that you may reference when crafting your own letter to the patient's health plan.

FABHALTA IgAN PA Checklist

- ☐ Relevant medical records and clinical notes that support treatment
- ☐ Appropriate clinical information from the **Prescribing Information**
- ☐ 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 excretion** (g/d) or **urine protein-to-creatinine ratio** (UPCR) (g/g) value
  - ☐ Recent and prior 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
    - ☐ **ACEi** 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**



90% of all prior authorizations are approved for **FABHALTA IgAN**[1,*]

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; MEST-C, mesangial hypercellularity (M), endocapillary hypercellularity (E), segmental glomerulosclerosis (S), tubular atrophy and interstitial fibrosis (T), and crescents (C); SGLT2i, sodium-glucose cotransporter-2 inhibitor.

*Between August 2023 and March 2026.

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Preparing a **PA Request for C3G**

The checklist below is intended to provide examples of what information is usually required when submitting a PA for FABHALTA complement 3 glomerulopathy (C3G). Please note that this is only an example, and it's important to check the payer's specific requirements before submission. Your chosen SP can also guide you through this process and to gather the appropriate content for coverage requests. This guide also contains a sample letter that you may reference when crafting your own letter to the patient's health plan.

FABHALTA C3G PA Checklist

- ☐ Relevant medical records and clinical notes that support treatment
- ☐ Appropriate clinical information from the **Prescribing Information**
- ☐ Disease-specific criteria, which can include information such as the following:
  - ☐ 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 and prior 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
    - ☐ **ACEi** 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
    - ☐ Documentation showing prior **mycophenolate mofetil therapy** or reasons for ineligibility for **mycophenolate mofetil** and other therapies
- ☐ Treatment prescribed by or in consultation with a **nephrologist**



91% of all prior authorizations are approved for **FABHALTA C3G**[1,*]

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; C3, complement 3; C3GN, C3 glomerulonephritis; DDD, dense deposit disease; eGFR, estimated glomerular filtration rate; SGLT2i, sodium-glucose cotransporter-2 inhibitor.

*Between August 2023 and March 2026.

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Preparing a **PA Request for PNH**

The checklist below is intended to provide examples of what information is usually required when submitting a PA for FABHALTA paroxysmal nocturnal hemoglobinuria (PNH). Please note that this is only an example, and it's important to check the payer's specific requirements before submission. Your chosen SP can also guide you through this process and to gather the appropriate content for coverage requests. This guide also contains a sample letter that you may reference when crafting your own letter to the patient's health plan.

FABHALTA PNH PA Checklist

- ☐ Relevant medical records and clinical notes that support treatment
- ☐ Appropriate clinical information from the **Prescribing Information**
- ☐ Disease-specific criteria, which can include information such as the following:
  - ☐ Confirm patient is **18 years or older**
  - ☐ Documentation of PNH diagnosis confirmed by flow cytometry, including clone size
  - ☐ Examples of **features of PNH**
  - ☐ Documentation of **history of thrombotic events**
  - ☐ Transfusion history
  - ☐ Lab values (eg, LDH, hemoglobin, ARC)
  - ☐ List current and previous therapies or if the patient is intolerant to current therapies. Confirm that the patient has not achieved adequate results from current or prior therapies
  - ☐ Treatment prescribed by or in consultation with a **hematologist**



95% of all prior authorizations are approved for **FABHALTA PNH**[1,*]

ARC, absolute reticulocyte count; LDH, lactate dehydrogenase.

*Between August 2023 and March 2026.

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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 copayment 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

Include the FABHALTA Prescribing Information (PI) and/or relevant treatment guidelines, highlighting appropriate clinical information that supports the treatment choice

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 and download a checklist with helpful tips for your patient when writing to their health plan

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

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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

Include the FABHALTA Prescribing Information (PI) and/or relevant treatment guidelines, highlighting appropriate clinical information that supports the treatment choice

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

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

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Sample Letters and Resources

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 PAs, Appeals, and Letter of Medical Necessity for your office:

FABHALTA IgAN Sample Letters

FABHALTA C3G Sample Letters

FABHALTA PNH Sample Letters



Example of IgAN Letter of Medical Necessity

Click the link below to download patient resource for your office:

Patient Letter Checklist



Example of Patient Letter Checklist

Scan the QR code to access the FABHALTA Coverage Lookup Tool, or click the relevant link below:

IgAN Coverage Lookup Tool

PNH Coverage Lookup Tool

Reach out to your dedicated Novartis **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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Potential ICD-10-CM Diagnosis Codes for **FABHALTA® (iptacopan)**

Review the health plan's guidance to ensure appropriate codes are selected based on a patient's medical record.

Indication	ICD-10-CM Code	Description
IgAN[2]	N02.B	Recurrent and persistent immunoglobulin A nephropathy
	N02.B1	Recurrent and persistent immunoglobulin A nephropathy with glomerular lesion
	N02.B2	Recurrent and persistent immunoglobulin A nephropathy with focal and segmental glomerular lesion
	N02.B3	Recurrent and persistent immunoglobulin A nephropathy with diffuse membranoproliferative glomerulonephritis
	N02.B4	Recurrent and persistent immunoglobulin A nephropathy with diffuse membranous glomerulonephritis
	N02.B5	Recurrent and persistent immunoglobulin A nephropathy with diffuse mesangial proliferative glomerulonephritis
	N02.B6	Recurrent and persistent immunoglobulin A nephropathy with diffuse mesangiocapillary glomerulonephritis
	N02.B9	Other recurrent and persistent immunoglobulin A nephropathy

Indication	ICD-10-CM Code	Description
C3G[2]	N00.A	Acute nephritic syndrome with C3GN
	N01.A	Rapidly progressive nephritic syndrome with C3GN
	N02.A	Recurrent and persistent hematuria with C3GN
	N03.A	Chronic nephritic syndrome with C3GN
	N04.A	Nephrotic syndrome with C3GN

The codes listed above are provided for educational purposes only and are not a guarantee of coverage or reimbursement. Coverage and reimbursement may vary significantly by health plan, patient, and setting of care. It is the sole responsibility of the HCP to select the proper codes and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

HCP, health care provider.

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Potential ICD-10-CM Diagnosis Codes for **FABHALTA® (iptacopan)** (continued)

Review the health plan's guidance to ensure appropriate codes are selected based on a patient's medical record.

Indication	ICD-10-CM Code	Description
C3G[2] (continued)	N05.A	Unspecified nephritic syndrome with C3GN
	N06.A	Isolated proteinuria with C3GN
	N07.A	Hereditary nephropathy, not elsewhere classified with C3GN
	N00.6	Acute nephritic syndrome with DDD
	N01.6	Rapidly progressive nephritic syndrome with DDD
	N02.6	Recurrent and persistent hematuria with DDD
	N03.6	Chronic nephritic syndrome with DDD
	N04.6	Nephrotic syndrome with DDD
	N05.6	Unspecified nephritic syndrome with DDD
	N06.6	Isolated proteinuria with DDD
	N07.6	Hereditary nephropathy, not elsewhere classified with DDD

Please note: the ICD-10 code listed below is not a renal indication.

Indication	ICD-10-CM Code	Description
PNH[2]	D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]

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C3GN, C3 glomerulonephritis; DDD, dense deposit disease.

Glossary

- **Appeal:** A request to a patient's health plan to reconsider their decision to deny coverage.
- **Copayment:** 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 non-preferred 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 copayments. Tiers are commonly based on brand or generic medications, preferred or non-preferred medications, and traditional or specialty medications.



We're Here to Help

Click the links below to download sample letters for PAs, Appeals, and Letter of Medical Necessity for your office:

FABHALTA IgAN Sample Letters

FABHALTA C3G Sample Letters

FABHALTA PNH Sample Letters

Questions?

For questions or support, reach out to your dedicated Novartis Access and Reimbursement team or contact Novartis Patient Support at 833-99FABHA (833-993-2242), Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays, or visit www.fabhalta-hcp.com.

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INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

FABHALTA is indicated for:

- The treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- Slowing kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression.
- 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.

INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONTINUED)

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 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.

INDICATIONS AND IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Monitoring of PNH Manifestations After FABHALTA Discontinuation

- In PNH patients, after discontinuing FABHALTA, closely monitor patients for at least 2 weeks after the last dose for signs and symptoms of hemolysis. These signs include elevated lactate dehydrogenase (LDH) levels along with a sudden decrease in hemoglobin or PNH clone size, fatigue, hemoglobinuria, abdominal pain, dyspnea, major adverse vascular events (such as thrombosis, stroke, and myocardial infarction), dysphagia, or erectile dysfunction. If discontinuation of FABHALTA is necessary, consider alternative therapy.
- If hemolysis occurs after discontinuation of FABHALTA, consider restarting treatment with FABHALTA, if appropriate, or initiating another treatment for PNH.

Hyperlipidemia

- FABHALTA may increase total cholesterol, LDL cholesterol, and serum triglycerides.
- Of the 88 FABHALTA-treated patients in PNH clinical trials who had normal total cholesterol at baseline, 31 patients developed grade 1 hypercholesterolemia during the randomized or core treatment period, and 1 patient worsened from grade 1 at baseline to grade 2.
- Of the 96 FABHALTA-treated patients in PNH clinical trials with LDL cholesterol ≤130 mg/dL at baseline during the randomized or core treatment period, 14 patients developed LDL cholesterol >130-160 mg/dL, 6 patients developed LDL cholesterol >160-190 mg/dL, and 4 patients developed LDL cholesterol >190 mg/dL.
- Of the 89 FABHALTA-treated patients in PNH clinical trials with normal triglycerides during the randomized or core treatment period, 22 patients developed grade 1 elevated triglycerides. Three patients experienced an increase in triglycerides from grade 1 to grade 2.
- Of the 102 FABHALTA-treated patients in PNH clinical trials, 2 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 PNH receiving FABHALTA were headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, and rash.
- The most common adverse reactions (≥5%) in adults with IgAN receiving FABHALTA were abdominal pain and dizziness.
- The most common adverse reactions (≥10%) in adults with C3G receiving FABHALTA were nasopharyngitis and viral infection.

INDICATIONS AND 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.

Please see full Prescribing Information, including Boxed WARNING and Medication Guide.

References: 1. Data on file. FABHALTA Novartis Hub Patient Services and Specialty Pharmacy payer coverage outcome data. Novartis Pharmaceuticals Corp; 2026. **2.** Centers for Disease Control and Prevention. ICD-10-CM. Accessed July 20, 2026. www.cdc.gov/nchs/icd/icd-10-cm/index.html#cdc_generic_section_4-find-icd-10-cm-codes

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