FABHALTA® (iptacopan) 200 mg capsules

Help your adult patients with PNH

ONBOARDING GUIDE

Getting started with FABHALTA and available support for you and your patients

INCLUDED IN THIS ONBOARDING GUIDE:

- Explore **resources** and real-world **coverage and persistence data**
- Enroll one time in the **FABHALTA REMS**
- Get started with **vaccination** and/or **antibiotic prophylaxis**

INDICATION

FABHALTA is indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

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 click here for additional Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA coverage

Real-world data demonstrate how patients with PNH are able to start treatment with FABHALTA[1,2]

Treatment coverage

- FABHALTA for adults with PNH is covered for 83% of commercially insured patients nationwide*
- Inform your eligible patients about Co-Pay Plus.† Privately insured patients may pay as little as $0 for FABHALTA

Prior authorizations (PA) approval and time to first fill

- 87% of initiated PAs were approved for adults with PNH who were prescribed FABHALTA*
- Adults with PNH received insurance approval for FABHALTA in less than 5 days on average*
- Adults with PNH who were prescribed FABHALTA started treatment in 13 days on average from time of prescription*

The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients.

SEE TERMS & CONDITIONS

LOCAL COVERAGE VERIFICATION, AT YOUR FINGERTIPS

Use our coverage navigator to check FABHALTA coverage by plan name, ZIP code, or NPI number

*Coverage information is subject to change by the relevant plan and is based on data up to September 2024. The information provided in this communication is not a guarantee of coverage or payment (partial or full). Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims.

†**Co-Pay Plus:** Limitations apply. 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 (excluding administrative fees). Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program.
Valid only in the United States, Puerto Rico, and select territories. Void where prohibited by law. Additional restrictions may apply. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

FABHALTA adherence and persistence

The majority of patients stay on FABHALTA, the first and only oral monotherapy for adults with PNH[3-5]

Adherence

How patients take treatment (eg, correct dosage and frequency)

92%

of adults with PNH prescribed FABHALTA have been adherent (PDC of >0.8*) to therapy, based on specialty pharmacy fill data.[†,‡]

Persistence

How patients continue treatment over time

85%

of adults with PNH who started FABHALTA stayed on therapy after their first refill, based on specialty pharmacy data.[§,‖]

> ***I take one capsule two times a day. It's easy to travel with. It's made my life feel more normal and it's made me able to say yes to things.***
>
> **KIM, ACTUAL PATIENT TAKING FABHALTA**
>
> COMPENSATED FOR HER TIME BY NOVARTIS.
> INDIVIDUAL RESULTS MAY VARY.

*PDC (Proportion of Days Covered) refers to the percentage of time a patient has access to their prescribed medication.
†Adherence measured using PDC, which calculates the proportion of days a patient has access to their prescribed medication over a defined period of interest.[1] PDC cannot confirm that the medication was administered as prescribed; however, it can provide insight into how often a patient had medication available.
‡Source: Commercial Specialty Pharmacy Data from January 2024 to January 2025; n=359, which represents approximately 95% of FABHALTA fills.
§Treatment persistence is defined as patients who received a refill within 15 days of the 30-day period following their last fill consistently since their first dose.
‖Data source: Shipment data as of March 2025.
PDC, proportion of days covered.

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

REMS certification

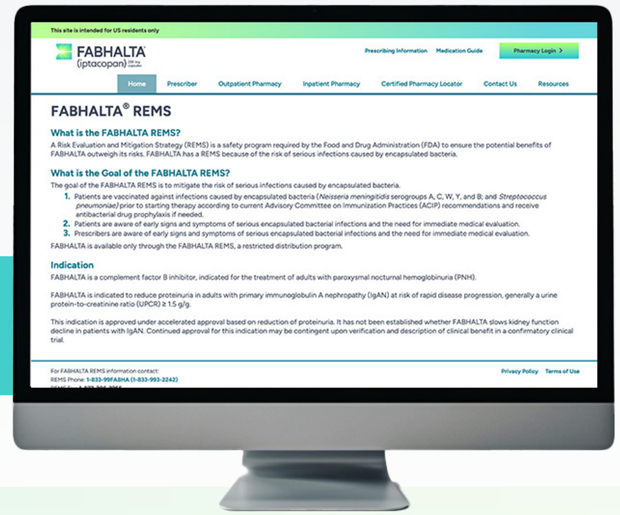
Because of the risk of serious infections caused by encapsulated bacteria, you will need to become certified in the FABHALTA REMS and fulfill its requirements.[6]

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.[6]

REMS information and support

- For more information, view the full REMS program details and requirements at **www.FABHALTA-REMS.com**
- For any certification questions, contact the REMS Coordinating Center at **1-833-99FABHA**

REMS certification is a one-time process.



At all times during your patient's journey, a health care professional should report suspected adverse reactions, including cases of serious bacterial infection, and the patient's clinical outcomes to Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.[6]

REMS Support

REMS Enrollment

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

REMS certification (continued)

Enrolling in REMS

1. REVIEW

- FABHALTA Prescribing Information
- Health Care Provider Brochure
- Patient Safety Guide
- Patient Safety Card

2. SUBMIT

- Complete Prescriber Enrollment Form at **www.FABHALTA-REMS.com** or fax to **1-877-206-3255**

Once enrolled[6]

3. COUNSEL

- Inform patients about the risk of serious infections caused by encapsulated bacteria, vaccination requirements, and early signs and symptoms of serious infections

4. PROVIDE

- Supply patients with REMS educational materials and the Patient Safety Card
- Instruct patients to always carry the card during treatment and for 2 weeks following the last dose of FABHALTA

COMPLETE YOUR REMS CERTIFICATION at **www.FABHALTA-REMS.com**

FABHALTA prescription and support

Choose one of 2 ways to submit Rx

Complete Start Form with Novartis Patient Support

Please visit
www.FABHALTA-startform.com
to download the **Start Form**

Phone: **1-833-99FABHA (1-833-993-2242)**
Fax: **1-877-44FABHA (1-877-443-2242)**

Send the Rx directly to one of the limited-network specialty pharmacies*

Onco360 ONCOLOGY PHARMACY

Website: **onco360.com**
Phone: 1-877-662-6633
Fax: 1-877-662-6355

OR

Biologics By McKesson

Website: **biologics.mckesson.com**
Phone: 1-800-850-4306
Fax: 1-800-823-4506

*Inform your patient which specialty pharmacy will be dispensing their FABHALTA prescription, and tell them to expect a phone call to arrange delivery of their prescription. Pharmacies that dispense FABHALTA must be certified in the FABHALTA REMS and must verify that prescribers are certified.[6]

NOVARTIS PATIENT SUPPORT™

A dedicated team for you and your patients

Novartis Patient Support is a comprehensive program that is designed to help your eligible patients start, stay, and save on FABHALTA.

We support you and your patient's journey with:

Insurance support

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

Financial support

FABHALTA Co-Pay Plus* offer

Assistance with relevant savings options for your eligible patients, including $0 Co-Pay Plus offer and affordability programs

Start FABHALTA at no cost for your eligible patients

FABHALTA Bridge Program offers up to 12 months of FABHALTA for free to your privately insured eligible patients while insurance coverage is pursued†

Vaccination support‡

For eligible patients, our dedicated Novartis Patient Support team can help schedule in-home administration appointments, find local vaccination locations, and offer guidance on accessing existing vaccination records.

Ongoing support

Dedicated assistance from our team, which includes:

- A Welcome Kit with resources to help them get started and stay on treatment
- A dose reminder program to help them remember to take their medication
- A choice of texts, calls, virtual calls, and/or emails to get ongoing resources

Get your patients started with guidance along the way. Download the FABHALTA Start Form, OR fill out the electronic Start Form on the CoverMyMeds® portal by visiting **covermymeds.health**.

Questions? Call Novartis Patient Support at 1-833-99FABHA (1-833-993-2242), Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays.

*__Limitations apply.__ Up to a $20,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state programs. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at www.fabhalta.com for details.

†__Limitations apply.__ Patients with commercial insurance, a valid prescription for FABHALTA, and a denial of insurance coverage based on a prior authorization requirement may receive a monthly maintenance dose for up to 12 months or until insurance coverage approval, whichever occurs first. Not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, VA, DoD or any other federal or state program, or where prohibited by law. A prior authorization and/or appeal of coverage denial must be submitted within 90 days to remain in the program. No purchase necessary. Program is not health insurance, nor is participation a guarantee of insurance coverage. Additional restrictions may apply. Novartis reserves the right to rescind, revoke, or amend this Program without notice.

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

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

REMS REQUIRED

Vaccination and antibiotic prophylaxis to start treatment

Getting started[6]

It is REQUIRED to complete or update vaccinations at least 2 weeks before starting FABHALTA against:

- ✓ *Streptococcus pneumoniae*
- ✓ *Neisseria meningitidis* (serogroups A, C, W, Y, and B)

Is your patient fully vaccinated?*

YES	NO	
Start FABHALTA	**Complete required vaccinations, wait at least 2 weeks, then start FABHALTA**	**If urgent treatment with FABHALTA is required at any point, provide antibiotic prophylaxis + FABHALTA and administer these vaccines as soon as possible**

***Patient must wait at least 2 weeks since the last required vaccination dose was administered prior to starting FABHALTA.**

For additional details on antibacterial drug prophylaxis, please see the FABHALTA Prescribing Information, Warnings and Precautions (Section 5.1).

Vaccination support†

Our dedicated Novartis Patient Support team offers support to help your patients locate vaccinations. Call Novartis Patient Support at 1-833-99FABHA (1-833-993-2242) for more information.

See page 9 for more information on vaccination support from Novartis.

Comply with the most current ACIP recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.

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

REMS REQUIRED

Vaccination and antibiotic prophylaxis to start treatment (continued)

During treatment with FABHALTA[6]

1. MONITOR

- As vaccination does not eliminate the risk of serious encapsulated bacterial infections, closely monitor patients for early signs and symptoms

2. INFORM

- Inform patients of these signs and symptoms, and instruct patients to seek immediate medical care if they occur

3. EVALUATE

- **Evaluate and treat immediately if infection is suspected**, as serious infection may become rapidly life threatening or fatal if not recognized and treated early
- Promptly treat known infections

4. CONSIDER

- It may be necessary to interrupt FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated
- While on therapy, patients are required to be revaccinated as needed

VIEW ACIP GUIDELINES:

Streptococcus pneumoniae

Neisseria meningitidis (serogroups A, C, W, Y, and B)

Indication and Important Safety Information

INDICATION

FABHALTA is indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

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- **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

- 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.
- 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.

ADDITIONAL IMPORTANT SAFETY INFORMATION

Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

Important Safety Information (continued)

WARNINGS AND PRECAUTIONS (continued)

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. Prescribers must 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 last dose of FABHALTA.
- Further information is available by telephone: 1-833-993-2242 or online at www.FABHALTA-REMS.com.

Monitoring of PNH Manifestations After FABHALTA Discontinuation

- 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 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 88 FABHALTA-treated patients who had normal total cholesterol at baseline, 31 developed grade 1 hypercholesterolemia during the randomization or core treatment period and 1 patient worsened from baseline grade 1 to grade 2.
- Of 96 FABHALTA-treated patients with LDL cholesterol ≤ 130 mg/dL at baseline during the randomization 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 89 FABHALTA-treated patients with normal triglycerides during the randomization 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 APPLY-PNH and APPOINT-PNH, 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.

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 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 click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

HELP PATIENTS GET STARTED ON **FABHALTA**

VERIFY LOCAL COVERAGE
at **www.FABHALTA-hcp.com**

ENROLL IN REMS
at **www.FABHALTA-REMS.com**

DOWNLOAD THE START FORM
at **www.FABHALTA-startform.com**

Please click here for Important Safety Information. Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.

References: 1. Data on file. FABHALTA PNH MMIT coverage. Novartis Pharmaceuticals Corp; June 2025. **2.** Data on file. FABHALTA PNH Commercial Specialty Pharmacy PA and TAT Data. Novartis Pharmaceuticals Corp; June 2025. **3.** Data on file. Pharmacy Quality Alliance Website; 2022. **4.** Canfield SL, Zuckerman A, Anguiano RH, et al. Navigating the wild west of medication adherence reporting in specialty pharmacy. *J Manag Care Spec Pharm*. 2019;25(10):1073-1077. doi:10.18553/jmcp.2019.25.10.1073 **5.** Prieto-Merino D, Mulick A, Armstrong C, et al. Estimating proportion of days covered (PDC) using real-world online medicine suppliers' datasets. *J Pharm Policy Pract*. 2021;14(1):113. doi:10.1186/s40545-021-00385-w **6.** Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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