Novartis
Patient Support™

Not actual patients.

Vaccination Resource Guide

Information to support you and your patients through the vaccination process for FABHALTA® (iptacopan)

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA®
(iptacopan) 200 mg capsules

Helping you, your practice, and your patients navigate the vaccination process

As a complement inhibitor, FABHALTA increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. Therefore, certain vaccinations are required before FABHALTA can be administered, and you must be REMS-certified to prescribe this treatment.[1] This guide is designed to help your practice navigate the vaccination process.

Table of Contents

ACIP, Advisory Committee on Immunization Practices; REMS, Risk Evaluation and Mitigation Strategy.

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Vaccination considerations and requirements with FABHALTA

Getting REMS-certified is required to prescribe FABHALTA

To enroll in REMS:

Click here to review the FABHALTA Prescribing Information, Health Care Provider Safety Brochure, Patient Guide, and Patient Safety Card.

Submit the completed Prescriber Enrollment form to the FABHALTA REMS at **www.fabhalta-rems.com**, or by fax to 877-206-3255.

After Enrollment[1]:

Counsel patients about the risk of serious infections caused by encapsulated bacteria, the need for vaccinations, and the early signs and symptoms of serious infections.

Provide patients with the Patient Safety Card. Instruct patients to always carry this card with them during treatment and for 2 weeks following the last dose of FABHALTA.

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Complete or update vaccinations before starting treatment with FABHALTA

Comply with the most current ACIP recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.[1]

Complete or update vaccination against encapsulated bacteria at least 2 weeks before starting FABHALTA, unless the risk of delaying FABHALTA outweighs the risk of developing a serious infection.[1]

It is REQUIRED that you vaccinate your patients against:

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

If urgent FABHALTA therapy is indicated in a patient who is not up to date with these vaccines, provide antibacterial drug prophylaxis and administer the vaccines according to ACIP recommendations as soon as possible.[1] For additional details on antibacterial drug prophylaxis, please see the FABHALTA Prescribing Information, Warnings and Precautions, Section 5.1.

Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy **have not been studied** in unvaccinated or vaccinated patients receiving complement inhibitors, including FABHALTA.[1]

Commonly used antibiotics for meningococcal prophylaxis for patients on complement inhibitors can include **penicillin** or, in the presence of penicillin allergy, **azithromycin**.[2]

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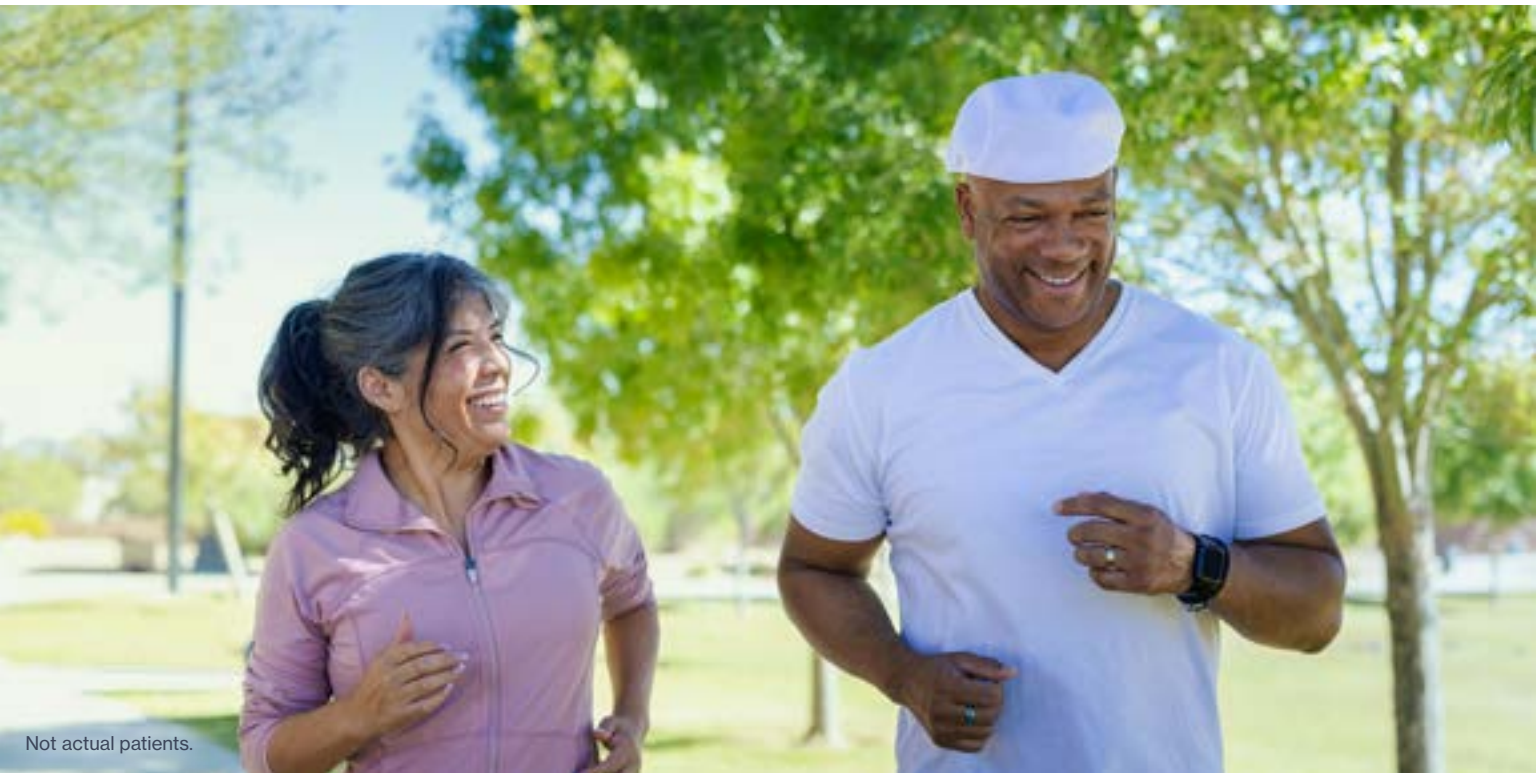
During treatment with FABHALTA

As vaccination does not eliminate the risk of serious encapsulated bacterial infections, closely monitor patients for early signs and symptoms. Inform patients of these signs and symptoms, and instruct patients to seek immediate medical care if they occur.

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

Consider interruption of FABHALTA in patients who are receiving 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.



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Advisory Committee on Immunization Practices (ACIP) vaccination recommendations

ACIP recommendations and dosing schedule for patients receiving complement inhibition therapy may differ from commercial product indications and usage. Please see individual product Prescribing Information for more information.

ACIP Recommendation: *Streptococcus pneumoniae* (required)[3,4,a]

Prior vaccines	Aged 19-49 years with an immunocompromised condition	Aged ≥50 years
None or PCV7 only at any age	PCV20 or PCV21 or PCV15 → PPSV23 (≥8 weeks[f])	PCV20 or PCV21 or PCV15 → PPSV23 (≥8 weeks[f])
PPSV23 only[b]	≥1 year, PCV20 or PCV21 or PCV15	≥1 year, PCV20 or PCV21 or PCV15
PCV13 only[b]	≥1 year, PCV20 or PCV21	≥1 year, PCV20 or PCV21
PCV13[b] and 1 dose PPSV23[c]	≥5 years, PCV20[g] or PCV21[g]	If PPSV23 received at age <65 years and ≥5 years, PCV20 or PCV21
PCV13[b] and 2 doses PPSV23[d]	Review pneumococcal vaccine recommendations again when patient turns 50 years of age ≥5 years, PCV20[g] or PCV21[g]	Use shared clinical decision-making,[h] If PPSV23 received at age ≥65 years and ≥5 years, PCV20 or PCV21

Pregnancy: No vaccination recommendation due to limited data. Refer to ACIP recommendations for additional information.[4]

PCV13 Prevnar 13® PCV15 Vaxneuvance® PCV20 Prevnar 20® PCV21 Capvaxive® PPSV23[e] Pneumovax 23®

PCV, pneumococcal conjugate vaccine; PPSV, pneumococcal polysaccharide vaccine.

[a]One dose of PCV13, PCV15, PCV20, PCV21, or PPSV23 should be administered as indicated in the table. [b]At any age. [c]Given at <65 years for individuals aged ≥50 years, or 1 dose of PPSV23 for individuals aged 19 to 49 years. [d]Given at ≥65 years for individuals aged ≥65 years, or 2 doses of PPSV23 for individuals aged 19 to 49 years. [e]If PPSV23 is not available, one dose of PCV20 or PCV21 may be used. [f]Considered minimum interval for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak. [g]If PCV21 or PCV20 is used, the series is complete, and it need not be followed by additional pneumococcal vaccine doses. [h]Together with the patient, vaccine providers may choose to administer PCV20 or PCV21 to individuals aged ≥65 years who have already received PCV13 (but not PCV15, PCV20, or PCV21) at any age and PPSV23 at age ≥65 years.

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ACIP vaccination recommendations (continued)

ACIP Recommendations: *Neisseria meningitidis* serogroups A, C, W, Y, and B (required)[4,5,a]

MenACWY (Menveo® or MenQuadfi®)	+	MenB-4C (Bexsero®) or MenB-FHbp (Trumenba®)[b]	OR	MenACWY-TT/ MenB-FHbp (Penbraya®)[6,e]
2 doses ≥8 weeks apart		**3 doses** At 0, 1-2, and 6 months after first dose[c]		**2 doses** 6 months apart[f]
1 booster every **5 years** while taking FABHALTA		Administer 1 dose of MenB booster 1 year after primary series. Revaccinate every 2-3 years while taking FABHALTA[d]		Administer 1 dose of MenB booster 1 year after primary series. Revaccinate every 2-3 years while taking FABHALTA

Pregnancy: ACIP recommends delaying MenB until after pregnancy due to lack of safety data in pregnant women. MenB may be administered if the patient is at increased risk and vaccination benefits outweigh potential risks. Refer to ACIP recommendations for additional information.[4]

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. Various durations and regimens of antibacterial drug prophylaxis have been considered, but the optimal durations and drug regimens for prophylaxis and their efficacy have not been studied in unvaccinated or vaccinated patients receiving complement inhibitors, including FABHALTA. 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.[1]

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 these signs and symptoms 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.[1]

The brand names mentioned in this document are the property of their respective trademark owners. Reference to specific commercial products, manufacturers, companies, or trademarks does not constitute its endorsement or recommendation by the US government, Department of Health and Human Services, or Centers for Disease Control and Prevention (CDC). Dosing schedules were developed by the CDC and are freely available on the agency website for no charge (https://www.cdc.gov/vaccines/hcp/imz-schedules/adult-notes.html).

FHbp, factor H binding protein; Men, *Neisseria meningitidis* serogroup; TT, tetanus toxoid.

[a]Recommended in high risk patients aged ≥2 months for MenACWY and aged ≥10 years for MenB. [b]MenB-4C and MenB-FHbp are not interchangeable (use the same product for all doses in series). [c]If dose 2 is administered ≥6 months after dose 1, a third dose should not be administered; if dose 3 is administered ≤4 months after dose 2, a fourth dose should be administered ≥4 months after dose 3. [d]MenACWY-TT/MenB-FHbp may be used for booster doses in patients receiving FABHALTA if booster doses of both MenACWY and MenB are indicated at the same visit. [e]Recommended for individuals aged ≥10 years receiving FABHALTA when both MenACWY and MenB vaccines are indicated at the same visit. [f]People receiving FABHALTA who are given a dose of MenACWY-TT/MenB-FHbp and who are recommended to receive additional doses of MenACWY and MenB <6 months after a dose of pentavalent meningococcal vaccine should receive separate MenACWY and MenB-FHbp vaccines. MenACWY-TT/MenB-FHbp doses deviating from the licensed 6-month interval can be considered valid for MenACWY or MenB if the timing would otherwise have been valid for that component.

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Vaccination process and counseling tips

Once you have identified that your patient is eligible for FABHALTA, follow these steps to get them started:

Step 1

Confirm your patient is up to date on vaccinations

- If your patient cannot find their vaccination records, refer to the **Vaccination FAQs** for support
- Review patient medical records for any allergies/contraindications to vaccinations

Step 2

Counsel your patient on the importance of vaccination and risks associated with therapy

- Remind your patient about the risk of developing serious infection and provide the signs and symptoms of infection
- During treatment, provide your patient with the FABHALTA Patient Safety Card, which includes information on the risk of serious infections, so they can show it to any health care provider who treats them

Step 3

Ensure your patient completes required vaccinations or receives antibiotic prophylaxis if they cannot delay treatment initiation and administer required vaccinations as soon as possible

- Provide your patient with a prescription for each of the vaccines that are required
- Encourage your patient to **sign up for Novartis Patient Support** to receive vaccination support, including scheduling an in-home vaccination appointment or finding a location near them
- Provide your patient with the **Patient Tips and Checklist for Getting Your Vaccines** and the **Patient Vaccinations: What to Expect and How to Prepare Flashcard** to help prepare them for their vaccination appointment
- Complete the **Sample Letter of Medical Necessity for Vaccinations** to proactively help mitigate issues at the pharmacy. Fax the letter directly to the pharmacy and/or provide a copy of the letter to your patient to bring with them to their vaccination appointment

Step 4

Begin Treatment/Ongoing Monitoring

- Educate patients on any booster vaccinations needed during therapy
- Monitor patients for infections

Novartis
Patient Support

A dedicated team for you and your patients

Novartis Patient Support is a comprehensive program that offers assistance to health care professionals and eligible patients who are getting started on FABHALTA.

Novartis Patient Support can help support your patients every step of the way

Insurance Support

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

Financial Support

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

Vaccination Support

Our vaccination support program provides in-home vaccination and guided navigation to help simplify the process for eligible patients, regardless of insurance.

- With in-home vaccination, a licensed clinician will administer all required vaccines in the patient's home at no cost
- With guided navigation support, a list of available vaccination providers near the patient's address will be provided. A copy of the list is sent to both you and the patient
- You can opt into vaccination support† on the FABHALTA Start Form to further understand what your patient may be eligible for with a dedicated Novartis Patient Support team

Ongoing Support

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

Start FABHALTA at no cost for 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.‡

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Novartis
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3 steps for getting patients started with Novartis Patient Support

1 **Fill out the electronic Start Form on the CoverMyMeds® portal by visiting covermymeds.health**

2 **Complete Start Form, capture consent, and submit**

- Fill out all required sections of the Start Form with the patient. Ensure both you and the patient sign the form to capture enrollment consent
- Complete the Start Form and send to Novartis Patient Support or a FABHALTA specialty pharmacy
- Please fill out the form completely, as missing information may result in treatment delays. You will be contacted to request any incomplete information

3 **Connect with us**

A dedicated Novartis Patient Support team is available to support you and your patients every step of the way. Call us at **833-99FABHA (833-993-2242)**.

4 **Patients can also sign up at support.fabhalta.com**

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Novartis
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Frequently asked questions (FAQs)

Frequently asked questions and answers to help you and your patients through the vaccination process for FABHALTA

Q: What assistance can Novartis Patient Support provide to help my patients get vaccinated?

A: Before patients start treatment with FABHALTA, there are some vaccinations they will likely need based on the Risk Evaluation and Mitigation Strategy (REMS) program requirements. Our dedicated Novartis Patient Support team offers support to schedule appointments for in-home vaccination and help them locate vaccines locally.

- Novartis Patient Support can help eligible patients find a site where they can receive the vaccination(s) they need
- Novartis Patient Support team members can help facilitate in-home vaccinations and share a list of vaccine providers near the patient. This can help make it easier for patients to set up their appointments

In-Home Vaccine Administration

Q: How can I sign up my patients for in-home vaccine administration?

A: You can enroll your patients using the FABHALTA® (iptacopan) Start Form to further understand the vaccination offerings that may be available to them. Novartis Patient Support will connect your eligible patients with their preferred vaccination services.

Q: Who is eligible for in-home vaccination support?

A: To be eligible for in-home vaccination, patients:

- Must be 18 years of age or older
- Must be enrolled via FABHALTA Start Form with HCP's selection of Vaccination Support
- Must have an on-label indication and prescription for FABHALTA
- Eligibility is not limited to any insurance type, including Medicare, Medicaid, and uninsured patients, across all approved FABHALTA indications

Q: What vaccines are offered?

A: All required meningococcal and pneumococcal vaccinations needed prior to starting FABHALTA will be available to be administered through in-home vaccination services.

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Frequently asked questions (FAQs) (continued)

Q: How much will in-home vaccine administration cost?

A: Eligible patients can receive in-home vaccine administration at no cost.

Q: Is the support available in all states?

A: In-home administration is not available in Arkansas, Oregon, Guam, Northern Mariana Islands, and the US Virgin Islands.

Guided Navigation

Q: What types of vaccine providers does Novartis Patient Support identify for my patients?

A: Many pharmacies, retail clinics, health care providers, government sites (like your local health department), and travel clinics may provide the vaccinations for FABHALTA. As part of Novartis Patient Support, our Novartis Patient Support team members can help connect patients to vaccination locations that are convenient for them.

Q: Will the required vaccinations be covered by my patient's health plan?

A: Most private health plans cover certain vaccinations at no cost to the patient, including meningococcal and pneumococcal vaccines. Medicare patients may be covered at no out-of-pocket cost.[7,8]

We recommend that patients bring both their medical and pharmacy insurance cards with them when receiving their vaccinations to help ensure coverage.

Q: Does Novartis Patient Support offer vaccination co-pay support?

A: Yes, Novartis Patient Support Co-Pay Plus* offer can help eligible, privately insured patients with up to $1,000 for qualifying vaccination costs (excluding administration fees). For further assistance on vaccinations, you can reach out to a Novartis Patient Support team member.

*See page 22 for Co-Pay Plus terms and conditions.

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Frequently asked questions (FAQs) (continued)

Q: Will a prescription be needed to receive the vaccinations?

A: It is helpful, and often required by the vaccine provider, to bring a prescription for the requested vaccinations to appointments. There may be state requirements for such prescriptions. Having a prescription helps the vaccine provider understand why these vaccinations are needed, and it may also avoid delays.

To further support patients, we provide a Sample Letter of Medical Necessity for Vaccinations that they can share with the pharmacist or HCP that explains their need for certain vaccinations before starting FABHALTA. You can download the Sample Letter at **fabhalta-hcp.com**.

Q: What should my patient bring to their vaccination appointment?

A: Patients should make sure to bring their medical and pharmacy insurance cards, vaccination prescription(s), FABHALTA Vaccination Card, and Sample Letter of Medical Necessity for Vaccinations. If they are eligible, they can also bring their FABHALTA Co-Pay Plus* offer to help cover out-of-pocket expenses for the vaccinations. Be sure to remind your patients that the FABHALTA Co-Pay Plus offer excludes administration costs, should the vaccination provider charge for these additional costs.

Q: What is the FABHALTA Vaccination Card?

A: The FABHALTA Vaccination Card is a document that helps patients, health care providers and staff, as well as vaccine providers, keep track of vaccinations and boosters. Your patients will receive a Vaccination Card with their Novartis Patient Support Welcome Kit. It is also accessible at **fabhalta-hcp.com**.

Pharmacy Support

Q: What should my patients expect when they get their vaccinations at a pharmacy?

A: When patients get vaccinations at a pharmacy, typically, a trained pharmacist will administer the vaccination and be able to answer questions that they might have. Each pharmacy location may have a different set of vaccinations available. While patients can ask a pharmacy if they can order a vaccine, not all pharmacies are able to do so on demand. Therefore, encourage patients to call ahead and make an appointment before going to the pharmacy.

Be sure to let patients know to inform the pharmacy if they are allergic to any vaccines. Patients should also let the pharmacy know if they are feeling sick on the day of their scheduled vaccination visit.

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Frequently asked questions (FAQs) for vaccinations (continued)

Q: What should my patients expect when they get their vaccinations at a travel clinic?

A: When patients get vaccinations at a travel clinic, a trained health care professional will administer the vaccination and be able to answer questions they might have about the vaccines.

Travel clinics may not accept insurance coverage and may charge patients the full cost of the vaccination. This and the costs of the vaccinations vary from site to site. For the most up-to-date information, patients can ask for cost estimates from the travel clinic directly. For privately insured patients, please note that the patient's Co-Pay Plus* offer cannot be used if the provider is not accepting their insurance. It's only intended to cover out-of-pocket expenses after insurance.

Be sure to let patients know to inform the travel clinic if they are allergic to any vaccines. Patients should also let the travel clinic know if they are feeling sick on the day of their scheduled vaccine visit.

For the Novartis Patient Support team to check eligibility, the health care provider would need to submit the FABHALTA Start Form. Patients can ask their provider to submit the Start Form.

Q: What should my patients expect when they get their vaccines through in-home administration?

A: Once your patient is enrolled in Vaccination Support through Novartis Patient Support, their dedicated Novartis Patient Support team member will confirm eligibility and then contact our 3rd party partners to coordinate the shipment and in-home administration of the required vaccines with a licensed clinician. Once administered, the clinician will share vaccination records with you and your patient.

Q: What should patients say if there is pushback at the pharmacy or from another health care professional?

A: To help mitigate these types of situations, we provide a Sample Letter of Medical Necessity for Vaccinations that patients can share with the pharmacist explaining their need for certain vaccinations before starting FABHALTA, or you can send the letter directly to the pharmacy. You can download the Sample Letter at **fabhalta-hcp.com**. This letter reiterates the necessity of certain vaccinations for patients of any age who are on a complement inhibitor like FABHALTA that has a REMS requirement for vaccination.

Q: Why would my patient need a Sample Letter of Medical Necessity to be vaccinated?

A: There may be an age restriction for your patient that requires a letter of medical necessity.

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Frequently asked questions (FAQs) (continued)

Vaccination History

Q: What if my patient is already vaccinated?

A: If your patient is up to date on the required vaccinations against encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, you can safely administer FABHALTA.

Q: What if my patient is not up to date on their vaccinations?

A: FABHALTA therapy may be indicated in a patient who is not up to date with vaccinations against encapsulated bacteria, according to Advisory Committee on Immunization Practices (ACIP) recommendations. In this scenario, complete or update vaccines at least 2 weeks before starting FABHALTA, unless the risks of delaying FABHALTA outweigh the risk of developing a serious infection.

If urgent FABHALTA therapy is indicated in a patient that is not up to date with these vaccines, provide the patient with antibacterial drug prophylaxis and administer the vaccines as soon as possible.

Q: What if my patient cannot find their immunization records?

A: You can provide the following suggestions to your patient to help them find their immunization records. Patients may want to check[9]:

- Previous health care providers
- Their home
- State or local Immunization Information Systems (IIS)
- Schools and colleges
- Former employers
- Their local health department by calling the CDC Information Contact Center at 800-CDC-INFO (800-232-4636)

If your patient cannot find their personal records, they may need to get some of the vaccinations again.

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 **fabhalta-hcp.com**.

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Sample Letter Of Medical Necessity
For Vaccinations

A resource to help you complete the letter of medical necessity

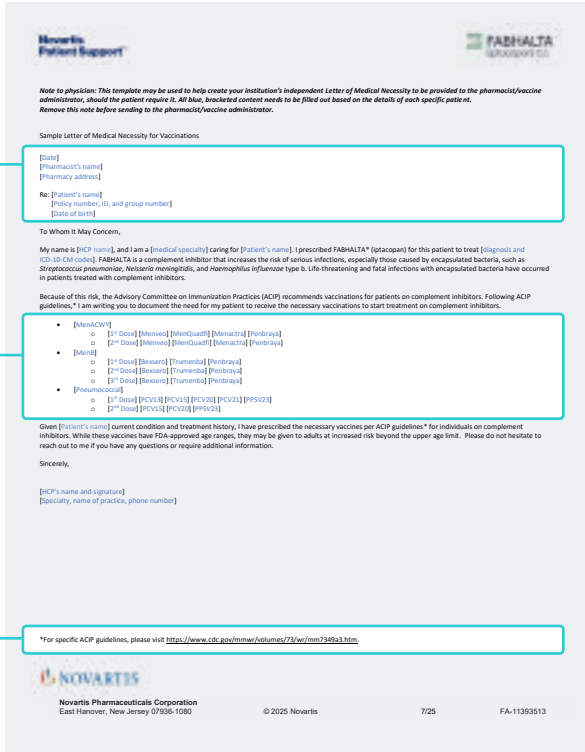
Novartis Patient Support will work with your practice to help eligible patients start on FABHALTA, including navigating the vaccination process. We created the Sample Letter below in case more support is needed at the pharmacy when patients visit to receive the required vaccination(s). Instructions for the letter include:

1. Download the Sample Letter **here**
2. See key information called out below to help you fill out the letter
3. After filling out the letter, fax it directly to your patient's pharmacy and/or provide a copy of the letter to your patient for them to bring to their vaccination appointment

All blue, bracketed content needs to be filled out based on your information and the details of each specific patient.

Fill out the appropriate vaccination information for your patient here, including the dose number and vaccine brand. Only include necessary vaccinations. Delete any bracketed content that is not relevant.

To further support you and your patient's need for vaccinations, we've included a link to the current Advisory Committee on Immunization Practices (ACIP) guidelines: **https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a3.htm**.



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FABHALTA (iptacopan)

Note to physician: This template may be used to help create your institution's independent Letter of Medical Necessity to be provided to the pharmacist/vaccine administrator, should the patient require it. All blue, bracketed content needs to be filled out based on the details of each specific patient. Remove this note before sending to the pharmacist/vaccine administrator.

Sample Letter of Medical Necessity for Vaccinations

[Date]
[Pharmacist's name]
[Pharmacy 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]. I prescribed FABHALTA® (iptacopan) for this patient to treat [diagnosis and ICD-10-CM codes]. FABHALTA is a complement inhibitor that 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.

Because of this risk, the Advisory Committee on Immunization Practices (ACIP) recommends vaccinations for patients on complement inhibitors. Following ACIP guidelines,* I am writing you to document the need for my patient to receive the necessary vaccinations to start treatment on complement inhibitors.

- [MenACWY]
  - [1st Dose] [Menveo] [MenQuadfi] [Menactra] [Penbraya]
  - [2nd Dose] [Menveo] [MenQuadfi] [Menactra] [Penbraya]
- [MenB]
  - [1st Dose] [Bexsero] [Trumenba] [Penbraya]
  - [2nd Dose] [Bexsero] [Trumenba] [Penbraya]
  - [3rd Dose] [Bexsero] [Trumenba] [Penbraya]
- [Pneumococcal]
  - [1st Dose] [PCV13] [PCV15] [PCV20] [PCV21] [PPSV23]
  - [2nd Dose] [PCV15] [PCV20] [PPSV23]

Given [Patient's name] current condition and treatment history, I have prescribed the necessary vaccines per ACIP guidelines* for individuals on complement inhibitors. While these vaccines have FDA-approved age ranges, they may be given to adults at increased risk beyond the upper age limit. Please do not hesitate to reach out to me if you have any questions or require additional information.

Sincerely,

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

*For specific ACIP guidelines, please visit https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a3.htm.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

7/25 FA-11393513

For questions or support, reach out to your dedicated **Novartis Access and Reimbursement team** or contact **Novartis Patient Support**, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays.

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Sample Letter Of Medical Necessity
For Vaccinations (continued)

Novartis Patient Support™

FABHALTA (iptacopan)

Note to physician: This template may be used to help create your institution's independent Letter of Medical Necessity to be provided to the pharmacist/vaccine administrator, should the patient require it. All blue, bracketed content needs to be filled out based on the details of each specific patient.
Remove this note before sending to the pharmacist/vaccine administrator.

Sample Letter of Medical Necessity for Vaccinations

[Date]
[Pharmacist's name]
[Pharmacy 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]. I prescribed FABHALTA® (iptacopan) for this patient to treat [diagnosis and ICD-10-CM codes]. FABHALTA is a complement inhibitor that 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.

Because of this risk, the Advisory Committee on Immunization Practices (ACIP) recommends vaccinations for patients on complement inhibitors. Following ACIP guidelines,* I am writing you to document the need for my patient to receive the necessary vaccinations to start treatment on complement inhibitors.

- [MenACWY]
  - [1st Dose] [Menveo] [MenQuadfi] [Menactra] [Penbraya]
  - [2nd Dose] [Menveo] [MenQuadfi] [Menactra] [Penbraya]
- [MenB]
  - [1st Dose] [Bexsero] [Trumenba] [Penbraya]
  - [2nd Dose] [Bexsero] [Trumenba] [Penbraya]
  - [3rd Dose] [Bexsero] [Trumenba] [Penbraya]
- [Pneumococcal]
  - [1st Dose] [PCV13] [PCV15] [PCV20] [PCV21] [PPSV23]
  - [2nd Dose] [PCV15] [PCV20] [PPSV23]

Given [Patient's name] current condition and treatment history, I have prescribed the necessary vaccines per ACIP guidelines* for individuals on complement inhibitors. While these vaccines have FDA-approved age ranges, they may be given to adults at increased risk beyond the upper age limit. Please do not hesitate to reach out to me if you have any questions or require additional information.

Sincerely,

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

*For specific ACIP guidelines, please visit https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a3.htm.

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

7/25 FA-11393513

Please see Important Safety Information on pages 18-21 and full Prescribing Information, including Boxed WARNING and Medication Guide.

FABHALTA® (iptacopan) 200 mg capsules

Novartis
Patient Support

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

FABHALTA is indicated for:

- The treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- The reduction of 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.
- 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.

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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: 833-993-2242 or online at www.FABHALTA-REMS.com.

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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 upper respiratory tract infection, lipid disorder, and abdominal pain.
- The most common adverse reactions (≥10%) in adults with C3G receiving FABHALTA were nasopharyngitis and viral infection.

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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.

Novartis Patient Support™

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 **fabhalta-hcp.com**.

***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.

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

‡**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.

References: 1. Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp. **2.** UpToDate. Treatment and prevention of meningococcal infection. Updated January 31, 2025. Accessed March 7, 2025. https://www.uptodate.com/contents/treatment-and-prevention-of-meningococcal-infection **3.** Kobayashi M, Leidner AJ, Gierke R, et al. Expanded recommendations for use of pneumococcal conjugate vaccines among adults aged ≥50 years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2024. *MMWR Morbidity and Mortality Weekly Report*. 2025;74(1):1-8. **4.** Centers for Disease Control and Prevention. Adult immunization schedule by age. November 21, 2024. Accessed July 1, 2025. https://www.cdc.gov/vaccines/hcp/imzschedules/adult-notes.html **5.** Centers for Disease Control and Prevention. Clinical guidance for managing meningococcal disease risk in patients receiving complement inhibitor therapy. November 26, 2024. Accessed April 28, 2025. https://www.cdc.gov/meningococcal/hcp/clinical-guidance/complement-inhibitor.html **6.** Collins JP, Crowe SJ, Ortega-Sanchez IR, et al. Use of the Pfizer pentavalent meningococcal vaccine among persons aged≥10 Years: recommendations of the Advisory Committee on Immunization Practices — United States, 2023. *MMWR Morb Mortal Wkly Rep*. 2024;73(15):345-350. **7.** Centers for Disease Control and Prevention. Vaccine information for adults: how to pay for vaccines. Updated July 10, 2024. Accessed February 27, 2025. https://www.cdc.gov/vaccines-adults/recommended-vaccines/how-to-pay-adult-vaccines.html **8.** Medicare Learning Network. Medicare Part D vaccines. Published June 2024. Accessed February 27, 2025. https://www.cms.gov/files/document/mln908764-medicare-part-d-vaccines.pdf **9.** Immunize.org. Tips for locating old immunization records. Published April 27, 2023. Accessed February 27, 2025. https://www.immunize.org/wp-content/uploads/catg.d/p3065.pdf

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East Hanover, New Jersey 07936-1080

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