FABHALTA®
iptacopan 200 mg capsules

EHR Considerations Checklist

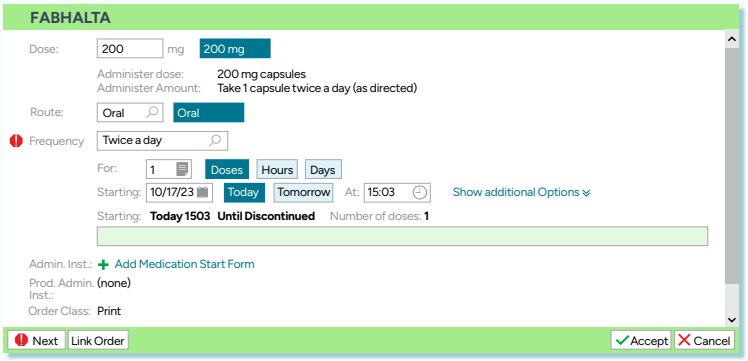
Ensure drug routing and administration records are correct

For example:

- NDC: 0078-1189-20
- Dosage
- Route of Administration: Oral
- Order Class: Specialty pharmacies
  - When configuring FABHALTA® in your electronic health record (EHR), ensure the routing is correctly configured, as this medication should not be e-prescribed.
- Configure FABHALTA to be distributed via specialty pharmacies (select pharmacies as noted below)
  - Configure the medication record on the specific drug itself to restrict available pharmacies to the 2 specialty pharmacies that are able to dispense the medication.
- Risk Evaluation and Mitigation Strategy (REMS) requirements

	Specialty Pharmacies	
	Onco360®	**Biologics by McKesson**
Business Hours	24 hours a day, 7 days a week	24 hours a day, 7 days a week
Website	www.onco360.com	biologics.mckesson.com
Phone Number	1-877-662-6633	1-800-850-4306

Hypothetical Drug Routing and Administration Record



This image is intended for illustrative purposes only.

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.

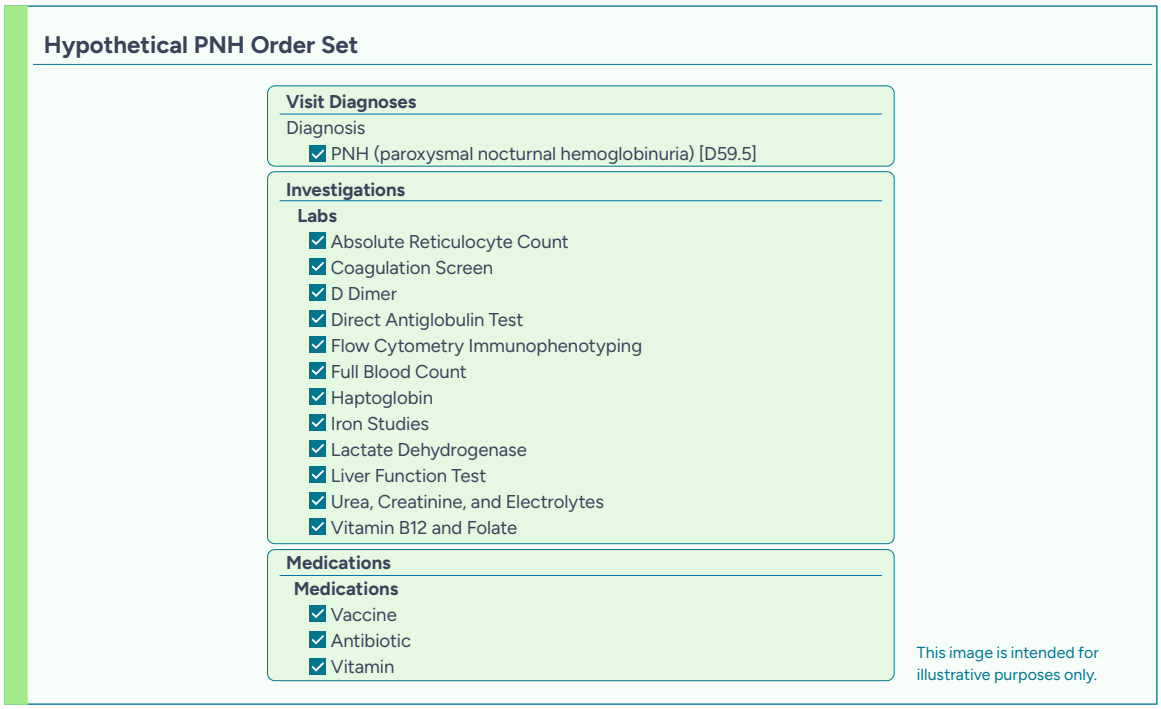
- **Complete or update vaccinations for encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, unless the risks of delaying therapy with FABHALTA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) 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 see additional Important Safety Information throughout and full Prescribing Information, including Boxed WARNING and Medication Guide.

Considerations for creation of a FABHALTA specific order set

- To account for REMS requirements, configure vaccinations and/or prophylactic antibiotics in the order set
- Consider configuring labs and follow-up visits to evaluate for hemolysis (standing labs), lactate dehydrogenase (LDH), hemoglobin, and flow cytometry



IMPORTANT SAFETY INFORMATION (continued)

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 non-groupable 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.

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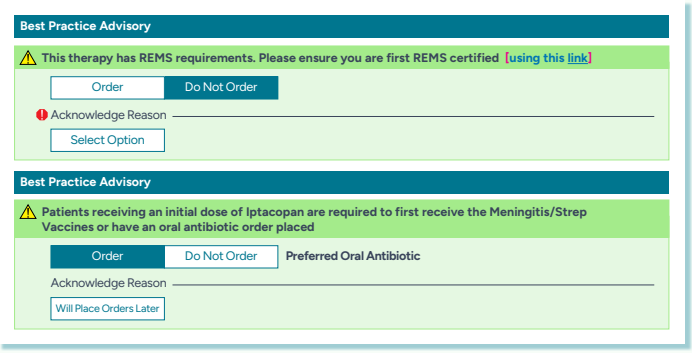
Integration of Clinical Decision Support (CDS) tools to ensure REMS requirements are considered and addressed

For example:

- Pop-up decision support like a best practice advisory with a larger block of text explaining REMS or a link to the FABHALTA REMS FDA website, etc
  - Alternatively, the REMS website hyperlink can be included within the order itself as part of the order composer; however, this option may not be as obvious and may have space limitations for text

Hypothetical Best Practice Alert



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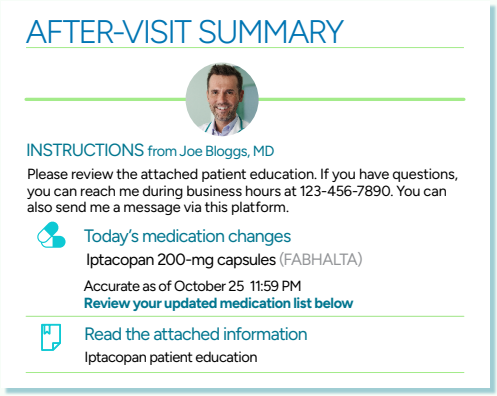
Embedding patient education within the After-Visit Summary

- Consider embedding patient education within the patients after-visit summary or discharge notes

Hypothetical After-Visit Summary



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IMPORTANT SAFETY INFORMATION (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, 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.

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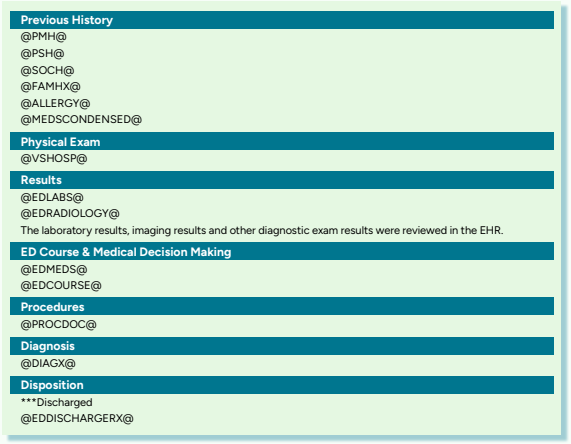
Leverage templates to account for documentation requirements

- Templates can be used to standardize documention, eg, prior authorization, reauthorization, REMs, etc

Hypothetical Template



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IMPORTANT SAFETY INFORMATION (continued)

Hyperlipidemia

- FABHALTA increases total cholesterol, LDL-cholesterol, and serum triglycerides during PNH clinical trials. Some patients required cholesterol lowering medications.
- 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 ≤ 130mg/dL at baseline during the randomization or core treatment period, 14 patients developed LDL-cholesterol > 130-160mg /dL, 6 patients developed LDL-cholesterol > 160-190mg /dL and 4 patients developed LDL-cholesterol >190mg /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.
- 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 renal impairment (eGFR < 30 mL/min/1.73 m^2) with or without hemodialysis. No dose adjustment is required in patients with mild (eGFR 60 to < 90 mL/min/1.73 m^2) or moderate (eGFR 30 to < 60 mL/min/1.73 m^2) renal impairment.
- FABHALTA is not recommended in patients with severe hepatic impairment (Child-Pugh class C). No dose adjustment is required for patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

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For more information on how the Novartis Health Information Technology Team can collaborate with your organization to identify shared priorities please email: HIT.Novartis@novartis.com

Novartis is not responsible for the implementation, testing, and ongoing operation of any electronic health record (EHR) tools. If you have any questions pertaining to the use of these guides, please refer to your internal IT/IS department. These tools are not designed for, and have not been demonstrated to meet, any accreditation requirements.

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