FABHALTA®
(iptacopan) 200 mg capsules

# *FOR UNDIAGNOSED PATIENTS,*
# *YOUR DIAGNOSIS OF PNH CAN MAKE A DIFFERENCE*

Patients may wait years for a PNH diagnosis,
**BUT A SINGLE TEST CAN PUT THEM ON THE PATH TO TREATMENT.**[1,2]

## In this diagnostic guide:



**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 on pages 6 and 7, and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.**

# Could patients in your care have undiagnosed PNH?

## Paroxysmal nocturnal hemoglobinuria (PNH) is a rare, acquired clonal disorder characterized by hemolysis, thrombosis, and bone marrow failure (BMF)[2,3]


The estimated global prevalence of PNH is 10 to 20 cases per million[3]

PNH can affect both males and females equally, with a median age of 36 years at disease onset[3,4]

## Those living with PNH can struggle with the effects of uncontrolled or poorly controlled hemolysis[3]

Patients with PNH face intravascular hemolysis (IVH) and may develop extravascular hemolysis (EVH).

**IVH occurs inside the blood vessels** when PNH RBCs are destroyed by the membrane attack complex (MAC) in the terminal complement pathway[5-7]

**EVH occurs in the liver and spleen, and it can emerge in a proportion of patients** treated with terminal complement inhibitors due to unchecked C3 opsonization[5,6,8-13,*]

## Variable clinical presentation of PNH may contribute to diagnostic delays[1,2]

**Patients reported significant diagnostic delays in one study that surveyed 163 adults with PNH[1]:**

**24%** of patients were diagnosed after ≥5 years

**~38%** of patients saw **≥5 HCPs** prior to PNH diagnosis

**Patients living with undiagnosed PNH may face RBC transfusions, thrombosis, and other major vascular events[1,4]**

> ***Early recognition to diagnosis is going to be critical...recognizing it [and] keeping it in your differential.***
>
> **BHUMIKA PATEL, MD,** HEMATOLOGIST/ONCOLOGIST
>
> Compensated for her time by Novartis.

*Based on preliminary studies in patients treated with eculizumab suggesting terminal complement inhibition induces C3 fragment deposition on PNH RBCs. The C3 fragments trigger destruction of the RBCs by macrophages, making EVH a potential consequence of terminal complement inhibition. Additional studies are needed to further understand the impact of terminal complement inhibition on EVH.[5,6,8-13]
C3, complement 3; HCP, health care professional; RBC, red blood cell.



# Once PNH is suspected, one test can help with a definitive diagnosis

## When clinical evaluation leads to suspicion of PNH, diagnosis can be confirmed using the gold standard flow cytometry test[2,3]

**C.H.E.C.K. Th.A.T.**

If your patient has some or all of these signs and symptoms, remember to **CHECK ThAT** and consider a flow cytometry test[3,4,†]

**C** oombs-negative hemolytic anemia

**H** emoglobinuria

**E** rectile dysfunction

**C** ytopenias

**K** idney disease

**Th** rombosis at unusual sites

**A** nemia/aplastic anemia

**T** iredness

## Your diagnosis is essential because similar symptoms can require vastly different treatments[2,14,15]

- PNH symptoms often overlap with those of AA and MDS, as these diseases can be associated with each other
- PNH is not mutually exclusive to BMF disorders

**NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) Recommendation**

**NCCN Guidelines® recommends consideration of flow cytometry to evaluate for PNH clone in patients with MDS and recommends peripheral blood flow cytometry for PNH for newly diagnosed AA in patients with suspected hereditary myeloid malignancy predisposition syndromes[16]**

†This list does not include all possible symptoms associated with PNH.
The NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.
AA, aplastic anemia; MDS, myelodysplastic syndrome; NCCN, National Comprehensive Cancer Network.

# Could patients with certain acute, severe symptoms benefit from a flow cytometry test for PNH?

## Rebecca, age 47

**Rebecca is presenting with acute, severe symptomatic anemia and a history of thrombosis.**

Hypothetical patient case and portrayal.

### Clinical history[4,8,17,18]:

- Presented to ER with **symptomatic anemia (shortness of breath and sallow skin);** lab work identified low hemoglobin and laboratory evidence of hemolysis (elevated LDH and ARC)
- Had **deep veinous thrombosis** in right lower leg in the past year

### Diagnosis:

- ER refers Rebecca to a hematologist, who **suspects PNH and orders a flow cytometry test; PNH is definitively diagnosed**[2,3]

### Treatment considerations:

- Rebecca shares her concern that her symptoms led to an ER visit; she is very interested in learning about the full range of treatment options available

ARC, absolute reticulocyte count; ER, emergency room; LDH, lactate dehydrogenase.

**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 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.



# Could patients with certain chronic symptoms benefit from a flow cytometry test for PNH?

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## Tim, age 35

**Tim is presenting with chronic anemia over the last 2 years.**

Hypothetical patient case and portrayal.

### Clinical history[17]:

- **Chronic anemia (fatigue, abdominal pain, and shortness of breath)** for the last 2 years

### Diagnosis[1-5,18-21]:

- HCP identifies normal iron levels and rules out GI blood loss; refers Tim to a hematologist
- Hematologist suspects BMF and orders bone marrow study, which is not definitive
- Hematologist confirms laboratory evidence of hemolysis such as elevated LDH and ARC and **suspects PNH; orders flow cytometry; PNH is definitively diagnosed**

### Treatment considerations:

- Tim travels frequently for work and expresses concern about treatment with scheduled infusions

**Rebecca and Tim are both eligible for treatment with FABHALTA, the first and only oral monotherapy approved for adults with PNH[22]**

GI, gastrointestinal.

**IMPORTANT SAFETY INFORMATION (continued)**

**WARNINGS AND PRECAUTIONS (continued)**

**Serious Infections Caused by Encapsulated Bacteria (continued)**

- 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.

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# Indication and Important Safety Information

## INDICATION

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

## IMPORTANT SAFETY INFORMATION

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- **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.**

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- Complete or update vaccination against encapsulated bacteria at least 2 weeks prior to the start of FABHALTA, according to the current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of therapy with FABHALTA. Note that ACIP recommends an administration schedule in patients receiving complement inhibitors that differs from the administration schedule in the vaccine prescribing information. If urgent FABHALTA therapy is indicated in a patient who is not up to date with vaccines against encapsulated bacteria according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer these vaccines as soon as possible. The benefits and risks of treatment with FABHALTA, as well as the benefits and risks of antibacterial drug prophylaxis in unvaccinated or vaccinated patients, must be considered against the known risks for serious infections caused by encapsulated bacteria.
- Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination. Closely monitor patients for early signs and symptoms of serious infection and evaluate patients immediately if an infection is suspected. Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if they occur. Promptly treat known infections. Serious infection may become rapidly life-threatening or fatal if not recognized and treated early. Consider interruption of FABHALTA in patients who are undergoing treatment for serious infections, depending on the risks of interrupting treatment in the disease being treated.

### FABHALTA REMS

- FABHALTA is available only through a restricted program under a REMS called FABHALTA REMS, because of the risk of serious infections caused by encapsulated bacteria.
- 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.



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### Monitoring of PNH Manifestations After FABHALTA Discontinuation (continued)

- 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 see accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.**

**References: 1.** Bektas M, Copley-Merriman C, Khan S, Sarda SP, Shammo JM. Paroxysmal nocturnal hemoglobinuria: patient journey and burden of disease. *J Manag Care Spec Pharm*. 2020;26(12)(suppl b):S8-S14. doi:10.18553/jmcp.2020.26.12-b.s8 **2.** Shah N, Bhatt H. Paroxysmal nocturnal hemoglobinuria. In: *StatPearls*. StatPearls Publishing; 2023. Accessed August 15, 2024. https://www.ncbi.nlm.nih.gov/books/NBK562292 **3.** Cançado RD, Araújo ADS, Sandes AF, et al. Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria. *Hematol Transfus Cell Ther*. 2021;43(3):341-348. doi:10.1016/j.htct.2020.06.006 **4.** Schrezenmeier H, Röth A, Araten DJ, et al. Baseline clinical characteristics and disease burden in patients with paroxysmal nocturnal hemoglobinuria (PNH): updated analysis from the International PNH Registry. *Ann Hematol*. 2020;99(7):1505-1514. doi:10.1007/s00277-020-04052-z **5.** Brodsky RA. Paroxysmal nocturnal hemoglobinuria. *Blood*. 2014;124(18):2804-2811. doi:10.1182/blood-2014-02-522128 **6.** Notaro R, Luzzatto L. Breakthrough hemolysis in PNH with proximal or terminal complement inhibition. *N Engl J Med*. 2022;387(2):160-166. doi:10.1056/NEJMra2201664 **7.** Risitano AM, Frieri C, Urciuoli E, Marano L. The complement alternative pathway in paroxysmal nocturnal hemoglobinuria: from a pathogenic mechanism to a therapeutic target. *Immunol Rev*. 2023;313(1):262-278. doi:10.1111/imr.1313710.1111/imr.13137 **8.** Dingli D, Matos JE, Lehrhaupt K, et al. The burden of illness in patients with paroxysmal nocturnal hemoglobinuria receiving treatment with the C5-inhibitors eculizumab or ravulizumab: results from a US patient survey. *Ann Hematol*. 2022;101:251-263. doi:10.1007/s00277-021-04715-5 **9.** Risitano AM, Marotta S, Ricci P, et al. Anti-complement treatment for paroxysmal nocturnal hemoglobinuria: time for proximal complement inhibition? A position paper from the SAAWP of the EBMT. *Front Immunol*. 2019;10(1157):1-24. doi:10.3389/fimmu.2019.01157 **10.** Risitano AM, Notaro R, Marando L, et al. Complement fraction 3 binding on erythrocytes as additional mechanism of disease in paroxysmal nocturnal hemoglobinuria patients treated by eculizumab. *Blood*. 2009;113(17):4094-4100. doi:10.1182/blood-2008-11-189944 **11.** Versmold K, Alashkar F, Raiser C, et al. Long-term outcomes of patients with paroxysmal nocturnal hemoglobinuria treated with eculizumab in a real-world setting. *Eur J Haematol*. 2023;111(1):84-95. doi:10.1111/ejh.1397010 **12.** Hill A, Rother RP, Arnold L, et al. Eculizumab prevents intravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria and unmasks low-level extravascular hemolysis occurring through C3 opsonization. *Haematologica*. 2010;95(4):567-573. doi:10.3324/haematol.2009.007229 **13.** Shammo J, Kim J, Georget M, Pattipaka T, Fermont JM. P796: Hospitalization in patients with paroxysmal nocturnal hemoglobinuria: a retrospective analysis of observational study data from the United States. *Hemasphere*. 2023;7(suppl):e22585a2. doi:10.1097/01.HS9.0000970088.22585.a2 **14.** Moore CA, Krishnan K. Aplastic anemia. In: *StatPearls*. StatPearls Publishing; 2023. Accessed August 15, 2024. https://www.ncbi.nlm.nih.gov/books/NBK534212 **15.** Dotson JL, Lebowicz Y. Myelodysplastic syndrome. In: *StatPearls*. StatPearls Publishing; 2022. Accessed August 15, 2024. https://www.ncbi.nlm.nih.gov/books/NBK534126 **16.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myelodysplastic Syndromes V3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed August 15, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org. **17.** Mayo Clinic Staff. Anemia. May 11, 2023. Accessed September 4, 2024. https://www.mayoclinic.org/diseases-conditions/anemia/symptoms-causes/syc-20351360 **18.** Shammo J, Gajra A, Patel Y, et al. Low rate of clinically evident extravascular hemolysis in patients with paroxysmal nocturnal hemoglobinuria treated with a complement C5i: results from a large, multicenter, US real-world study. *J Blood Med*. 2022;13:425-437. doi:10.2147/JBM.S361863 **19.** Cotter J, Baldaia C, Ferreira M, Macedo G, Pedroto I. Diagnosis and treatment of iron-deficiency anemia in gastrointestinal bleeding: a systematic review. *World J Gastroenterol*. 2020;26(45):7242-7257. doi:10.3748/wjg.v26.i45.7242 **20.** Stein J, Connor S, Virgin G, Ong DE, Pereyra L. Anemia and iron deficiency in gastrointestinal and liver conditions. *World J Gastroenterol*. 2016;22(35):7908-7925. doi:10.3748/wjg.v22.i35.7908 **21.** Mayo Clinic Staff. Aplastic anemia – diagnosis & treatment. February 11, 2022. Accessed September 4, 2024. https://www.mayoclinic.org/diseases-conditions/aplastic-anemia/diagnosis-treatment/drc-20355020 **22.** Fabhalta. Prescribing information. Novartis Pharmaceuticals Corp.

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# FOLLOWING A DIAGNOSIS OF PNH,
# START THEIR TREATMENT JOURNEY WITH FABHALTA

**Discover the only FDA-approved oral monotherapy for adults with PNH that can help deliver comprehensive hemolysis control (both IVH and EVH)[22]**

Working proximally in the alternative complement pathway to inhibit Factor B, FABHALTA controls both drivers of hemolysis

Scan to learn more

Scanning the QR code takes the user to https://www.fabhalta-hcp.com

**INDICATION**

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# LAYOUT INDICATOR

## FA-11251793_FABHALTA BRANDED DIAGNOSTIC TOOL_10.24

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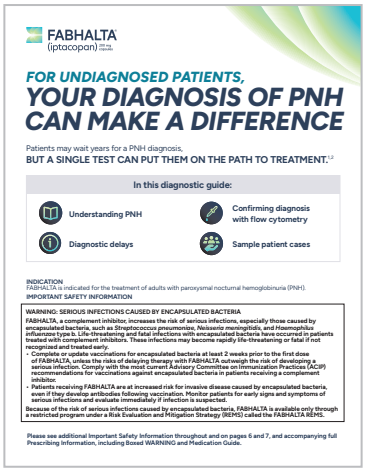

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Patients may wait years for a PNH diagnosis,
**BUT A SINGLE TEST CAN PUT THEM ON THE PATH TO TREATMENT.**[1,2]

**In this diagnostic guide:**

- Understanding PNH
- Confirming diagnosis with flow cytometry
- Diagnostic delays
- Sample patient cases

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### SPREAD (PAGE 2-3)

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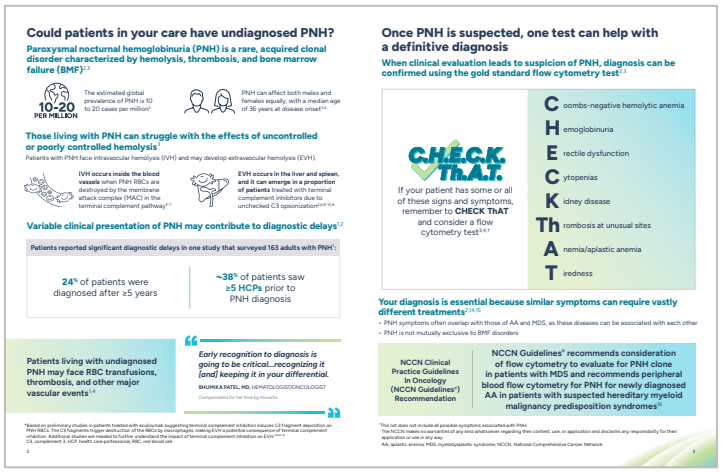

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10-20 PER MILLION — The estimated global prevalence of PNH is 10 to 20 cases per million[3]

PNH can affect both males and females equally, with a median age of 36 years at disease onset[4-6]

**Those living with PNH can struggle with the effects of uncontrolled or poorly controlled hemolysis**[2]

Patients with PNH face intravascular hemolysis (IVH) and may develop extravascular hemolysis (EVH).

**IVH occurs inside the blood vessels** when PNH RBCs are destroyed by the membrane attack complex (MAC) in the terminal complement pathway[6,7]

**EVH occurs in the liver and spleen, and it can emerge in a proportion of patients** treated with terminal complement inhibitors due to unchecked C3 opsonization[6,8-10,a]

**Variable clinical presentation of PNH may contribute to diagnostic delays**[1,2]

**Patients reported significant diagnostic delays in one study that surveyed 163 adults with PNH[1]:**

- **24%** of patients were diagnosed after ≥5 years
- **~38%** of patients saw **≥5 HCPs** prior to PNH diagnosis

**Patients living with undiagnosed PNH may face RBC transfusions, thrombosis, and other major vascular events**[1,4]

*"Early recognition to diagnosis is going to be critical...recognizing it [and] keeping it in your differential."*

**BHUMIKA PATEL, MD,** HEMATOLOGISTONCOLOGIST

Compensated for her time by Novartis.

[a]Based on preliminary studies in patients treated with eculizumab suggesting terminal complement inhibition induces C3 fragment deposition on PNH RBCs. The C3 fragments trigger destruction of the RBCs by macrophages, making EVH a potential consequence of terminal complement inhibition. Additional studies are needed to further understand the impact of terminal complement inhibition on EVH.[6,8-10]

C3, complement 3; HCP, health care professional; RBC, red blood cell.

2

**Once PNH is suspected, one test can help with a definitive diagnosis**

**When clinical evaluation leads to suspicion of PNH, diagnosis can be confirmed using the gold standard flow cytometry test**[2,3]

**CHECK THAT**

If your patient has some or all of these signs and symptoms, remember to **CHECK THAT** and consider a flow cytometry test[3,4,7]

- **C** oombs-negative hemolytic anemia
- **H** emoglobinuria
- **E** rectile dysfunction
- **C** ytopenias
- **K** idney disease
- **Th** rombosis at unusual sites
- **A** nemia/aplastic anemia
- **T** iredness

**Your diagnosis is essential because similar symptoms can require vastly different treatments**[2,4,11]

- PNH symptoms often overlap with those of AA and MDS, as these diseases can be associated with each other
- PNH is not mutually exclusive to BMF disorders

**NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Recommendation**

**NCCN Guidelines® recommends consideration of flow cytometry to evaluate for PNH clone in patients with MDS and recommends peripheral blood flow cytometry for PNH for newly diagnosed AA in patients with suspected hereditary myeloid malignancy predisposition syndromes[b]**

[b]This list does not include all possible symptoms associated with PNH.
The NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.
AA, aplastic anemia; MDS, myelodysplastic syndrome; NCCN, National Comprehensive Cancer Network.

3

### BACK COVER (PAGE 8)

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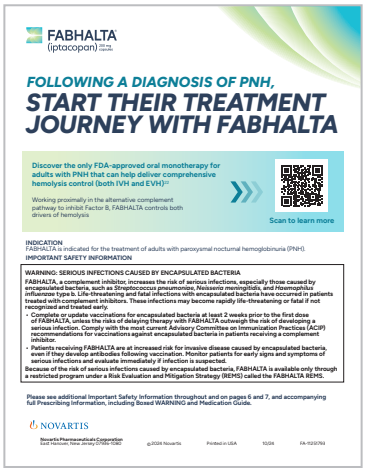

FABHALTA (iptacopan)

*FOLLOWING A DIAGNOSIS OF PNH,*

***START THEIR TREATMENT JOURNEY WITH FABHALTA***

**Discover the only FDA-approved oral monotherapy for adults with PNH that can help deliver comprehensive hemolysis control (both IVH and EVH)**[12]

Working proximally in the alternative complement pathway to inhibit Factor B, FABHALTA controls both drivers of hemolysis

Scan to learn more

**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 on pages 6 and 7, and accompanying full Prescribing Information, including Boxed WARNING and Medication Guide.**

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