

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

We know that navigating insurance and reimbursement can be a challenge. Novartis Patient Support is by your side to help throughout the process.

This guide provides an overview of International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes for FABHALTA.

When considering ICD-10-CM codes for FABHALTA:

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

Examples of potential codes that may be relevant for FABHALTA include:

Primary Diagnosis Codes¹

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

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

HCP, health care provider.

Please see Important Safety Information on pages 3-5 and full Prescribing Information, including Boxed WARNING and Medication Guide.



Not an actual
health care provider.

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

Primary Diagnosis Codes¹

Indication	ICD-10-CM Code	Description
Complement 3 Glomerulopathy (C3G)	N00.A	Acute nephritic syndrome with C3GN
	N01.A	Rapidly progressive nephritic syndrome with C3GN
	N02.A	Recurrent and persistent hematuria with C3GN
	N03.A	Chronic nephritic syndrome with C3GN
	N04.A	Nephrotic syndrome with C3GN
	N05.A	Unspecified nephritic syndrome with C3GN
	N06.A	Isolated proteinuria with C3GN
	N07.A	Hereditary nephropathy, not elsewhere classified with C3GN
	N00.6	Acute nephritic syndrome with DDD
	N01.6	Rapidly progressive nephritic syndrome with DDD
	N02.6	Recurrent and persistent hematuria with DDD
	N03.6	Chronic nephritic syndrome with DDD
	N04.6	Nephrotic syndrome with DDD
	N05.6	Unspecified nephritic syndrome with DDD
	N06.6	Isolated proteinuria with DDD
	N07.6	Hereditary nephropathy, not elsewhere classified with DDD

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

Indication	ICD-10-CM Code	Description
Paroxysmal Nocturnal Hemoglobinuria (PNH)	D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]

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C3GN, C3 glomerulonephritis; DDD, dense deposit disease.

Please see Important Safety Information on pages 3-5 and full Prescribing Information, including Boxed WARNING and Medication Guide.



Questions?

Reach out to your **FABHALTA Access and Reimbursement team** or call **Novartis Patient Support** at **833-99FABHA (833-993-2242)**, Monday-Friday, 8:00 AM-8:00 PM ET, excluding holidays.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

FABHALTA is indicated for:

- The treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).
- Slowing kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk of disease progression.
- The treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS CAUSED BY ENCAPSULATED BACTERIA

FABHALTA, a complement inhibitor, increases the risk of serious infections, especially those caused by encapsulated bacteria, such as *Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae* type b. Life-threatening and fatal infections with encapsulated bacteria have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccinations for encapsulated bacteria at least 2 weeks prior to the first dose of FABHALTA, unless the risks of delaying therapy with FABHALTA outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccinations against encapsulated bacteria in patients receiving a complement inhibitor.**
- **Patients receiving FABHALTA are at increased risk for invasive disease caused by encapsulated bacteria, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious infections and evaluate immediately if infection is suspected.**

Because of the risk of serious infections caused by encapsulated bacteria, FABHALTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the FABHALTA REMS.

CONTRAINDICATIONS

- In patients with serious hypersensitivity to FABHALTA or any of the excipients.
- For initiation in patients with unresolved serious infection caused by encapsulated bacteria, including *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae* type b.

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

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Serious Infections Caused by Encapsulated Bacteria (continued)

unvaccinated patients treated with complement inhibitors. The initiation of FABHALTA is contraindicated in patients with unresolved serious infections caused by encapsulated bacteria.

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

FABHALTA REMS

- FABHALTA is available only through a restricted program under a REMS called FABHALTA REMS because of the risk of serious infections caused by encapsulated bacteria.
- Under the FABHALTA REMS, prescribers must enroll in the program; counsel patients about the risks, signs, and symptoms of serious infections caused by encapsulated bacteria; provide patients with the REMS educational materials; ensure patients are vaccinated against encapsulated bacteria; prescribe antibacterial drug prophylaxis if patients' vaccination status is not up-to-date and treatment must be started urgently; and provide instructions to always carry the Patient Safety Card during treatment and for 2 weeks following the last dose of FABHALTA.
- Further information is available by telephone: 1-833-993-2242 or online at www.FABHALTA-REMS.com.

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.

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (CONTINUED)

Hyperlipidemia (continued)

- 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 ($\geq 10\%$) in adults with PNH receiving FABHALTA were headache, nasopharyngitis, diarrhea, abdominal pain, bacterial infection, viral infection, nausea, and rash.
- The most common adverse reactions ($\geq 5\%$) in adults with IgAN receiving FABHALTA were abdominal pain and dizziness.
- The most common adverse reactions ($\geq 10\%$) in adults with C3G receiving FABHALTA were nasopharyngitis and viral infection.

DRUG INTERACTIONS

- Concomitant use of CYP2C8 inducers (eg, rifampin) may decrease iptacopan exposure, which may result in loss of or reduced efficacy of FABHALTA. Monitor the clinical response and discontinue use of the CYP2C8 inducer if loss of efficacy of FABHALTA is evident.
- Concomitant use of strong CYP2C8 inhibitors (eg, gemfibrozil) may increase iptacopan exposure, which may result in an increased risk for adverse reactions with FABHALTA. Coadministration with a strong CYP2C8 inhibitor is not recommended.

USE IN SPECIFIC POPULATIONS

- Because of the potential for serious adverse reactions in a breastfed child, breastfeeding should be discontinued during treatment and for 5 days after the final dose.
- FABHALTA is not recommended in patients with severe hepatic impairment (Child-Pugh class C). No dose adjustment is required for patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

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

Reference: Centers for Disease Control and Prevention. ICD-10-CM. July 2, 2026. Accessed July 20, 2026.

https://www.cdc.gov/nchs/icd/icd-10-cm/index.html#cdc_generic_section_4-find-icd-10-cm-codes