



Renal Specialty Pharmacy 3-Step Guide

Considerations for submitting prescriptions to
specialty pharmacies for Novartis renal products



1 Submitting
prescriptions

2 Benefits verification and
coverage determination

3 Patient cost and
affordability

Novartis is dedicated to advancing rare kidney disease treatments and helping eligible patients start and stay on the products they need

Discover Novartis treatment options for certain adult patients with immunoglobulin A nephropathy (IgAN) and complement 3 glomerulopathy (C3G)



IgAN

VANRAFIA is indicated to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio ≥ 1.5 g/g.¹

This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether VANRAFIA 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.



IgAN

FABHALTA is indicated to slow kidney function decline in adults with primary IgAN at risk of disease progression.²

C3G

FABHALTA is indicated for the treatment of adults with C3G, to reduce proteinuria.²

FABHALTA and VANRAFIA are two different drugs and were not studied for combination use. The Prescribing Information for each drug does not mention the other drug, nor that the drugs can be used together.

Click [here](#) for full Prescribing Information for VANRAFIA, including Boxed WARNING and Medication Guide. Click [here](#) for full Prescribing Information for FABHALTA, including Boxed WARNING and Medication Guide.

This guide contains information and resources for starting appropriate patients on Novartis rare renal treatments through a specialty pharmacy (SP)

This process can be summarized in 3 steps:

1	Submit your patient’s prescription	
	• Choosing where to send the prescription	4
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	• Explore local coverage	6
2	The SP will complete a benefits verification and determine patient coverage needs	
	• The benefits verification process	7
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3	The SP will confirm patient cost, identify/offer affordability programs, and coordinate shipment	
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ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.



Be prepared to work with the SP directly when prescribing VANRAFIA or FABHALTA. Novartis Access & Reimbursement Managers (ARMs) are also available to provide additional information throughout the coverage process.



Submit your Rx directly to a participating SP*

If e-prescribing, you can send prescriptions to any Biologics by McKesson or CareMed location.

Biologics by McKesson

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

OR

CareMed†

Website: caremed.com
Phone: 1-877-227-3405
Fax: 1-877-542-2731

For patients in Puerto Rico: Medplus Solutions

Website:
medpluspr.com

Phone:
1-787-523-3888

Fax:
1-888-855-8865

Email:
sprx@medpluspr.com



You can also choose to submit a prescription through Novartis Patient Support™ by completing a Start Form. Contact a Novartis representative or visit the brand's HCP website for more information.

Working with an SP

Unlike a traditional retail pharmacy, the SP will ship the product directly to your patient. Ensure that your patient is aware of which SP will deliver their medication.

Typical support offered by SPs can include the following:

- ✓ Assistance navigating insurance coverage
- ✓ Affordability support
- ✓ Refill reminders
- ✓ Clinical and educational support
- ✓ Ongoing communication



For FABHALTA patients needing help with vaccinations, the SP can connect them with Novartis Patient Support.

Please reach out to the SP to learn more about the support that may be available. Inform your patient that the SP will contact them directly, and a confirmation of scheduling between patient and the SP is required before the product can be delivered.



Regardless of how you choose to submit an Rx, any of the participating SPs or Novartis Patient Support can help determine eligibility for financial support for your patients, such as the Co-Pay Plus offer or the Bridge Program.‡§

HCP, health care professional.

*Novartis does not recommend or require the use of any particular pharmacy.

†CareMed is a subsidiary of Onco360®.

‡**FABHALTA: Limitations apply.** Up to a \$20,000 annual co-pay benefit limit for the cost of FABHALTA and up to \$1,000 for qualifying vaccination costs. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with private insurance and a prior authorization requirement or an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this Program without notice. Additional limitations may apply. See complete Terms & Conditions at www.FABHALTA.com for details.

§**VANRAFIA: Limitations apply.** Up to a \$15,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with private insurance and a prior authorization requirement or an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at www.VANRAFIA.com for details.

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Prepare to send your Rx to your chosen SP

Prescription checklist

You will need to gather the appropriate information and materials when preparing to submit a prescription to your chosen SP. The checklist below is intended to help you understand the kind of information that is usually required when submitting a prescription. Please note that this is only an example, and it's important to check your chosen SP's specific requirements prior to submitting the Rx.

- ☐ The prescription and explicit start date
- ☐ A written diagnosis, primary diagnosis code (ICD-10-CM), and stage of disease for the prescribed medication
[See page 12 for a list of ICD-10-CM code examples ▶](#)
- ☐ Clear dosing instructions such as total dose, quantity, frequency (qd, bid), and refills
- ☐ A description of the patient (eg, height, weight, date of birth)
- ☐ Mobile phone and caregiver contact information
- ☐ Copies of the front and back of all insurance cards, including prescription and medical, and demographic fact sheet, including the patient email
- ☐ Clinical information that supports the treatment decision, including pathology or laboratory reports, treatment history, and a description of the treatment plan
- ☐ For nurse practitioners or physician assistants, please include the name, NPI#, and DEA# of the supervising physician
- ☐ Patient navigator/office contact(s) information



Contact the SP directly to clarify exact materials that need to be submitted.

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The Coverage Lookup Tool

Explore coverage for your patients with this easy-to-use resource

The Coverage Lookup Tool makes understanding coverage easy for you and your patients so that you can get them on treatment as quickly as possible.

To access the **VANRAFIA** Coverage Lookup Tool, visit VANRAFIA-hcp.com/local-insurance-coverage

To access the **FABHALTA** Coverage Lookup Tool, visit FABHALTA-hcp.com/coverage

Simply enter your ZIP Code or NPI number to quickly view coverage information based on channel and/or plan name.

Showing results for 07936. [Edit results](#)

78% of patients in your area have coverage for FABHALTA® (iptacopan).

2

Search By Plan Name

3

FAVORABLE COVERAGE

Channel	Plan Name	FABHALTA Status	Coverage Details
Commercial	State of New Jersey (OptumRx)	Covered	Details
Managed Medicaid	Horizon Blue Cross Blue Shield of New Jersey	Covered	Details
Commercial	UnitedHealthcare	Covered	Details
Commercial	Cigna National Formularies	Covered	Details
Managed Medicaid	UnitedHealthcare Community Plan (NJ)	Covered	
HIX	Horizon Blue Cross Blue Shield of New Jersey - HIX	Covered - SSE	Details
Commercial	Aetna	Covered	
Commercial	Express Scripts National Formularies	Covered	
Commercial	Oxford Health Plans	Covered	Details
Managed Medicaid	Wellpoint (NJ)	Covered	Details

4

[Show all results](#)

1

Search by Zip Code

Search by NPI Number

or

Search

Search

Covered: Brand-name drugs that are reimbursed through the plan but may have additional restrictions. SSE (Single-step edit): trial of 1 other therapy where consistent with prescribing information. The information provided is not a guarantee of coverage. Actual benefits are determined by each plan administrator in accordance with its policies and procedures. Because formularies change and many health plans offer more than one formulary, please check with the health plan to confirm coverage for individual patients. Source: Formulary data are provided by Managed Markets Insight & Technology, LLC and are current as of May 2025.

1

You have 2 options to get started:

A. Allow your device to share location:

This will automatically generate coverage information based on your ZIP Code

B. Manually enter your ZIP Code or NPI number within the appropriate search bar

2

Use the search bar to find a specific plan

3

Filter your results by the following options:

• Insurance type

• Plan name

• Coverage status

• Additional coverage details

4

View additional coverage details (when applicable), such as:

• Prior authorization requirements

• Inclusion criteria

• Required lab tests

• Reauthorization information



If you can't find the plan you are looking for, there still may be coverage. Please work with the SP directly to determine exact coverage for your patients.

Click [here](#) for full Prescribing Information for VANRAFIA, including Boxed WARNING and Medication Guide. Click [here](#) for full Prescribing Information for FABHALTA, including Boxed WARNING and Medication Guide.

6

1

Submitting prescriptions

2

Benefits verification and coverage determination

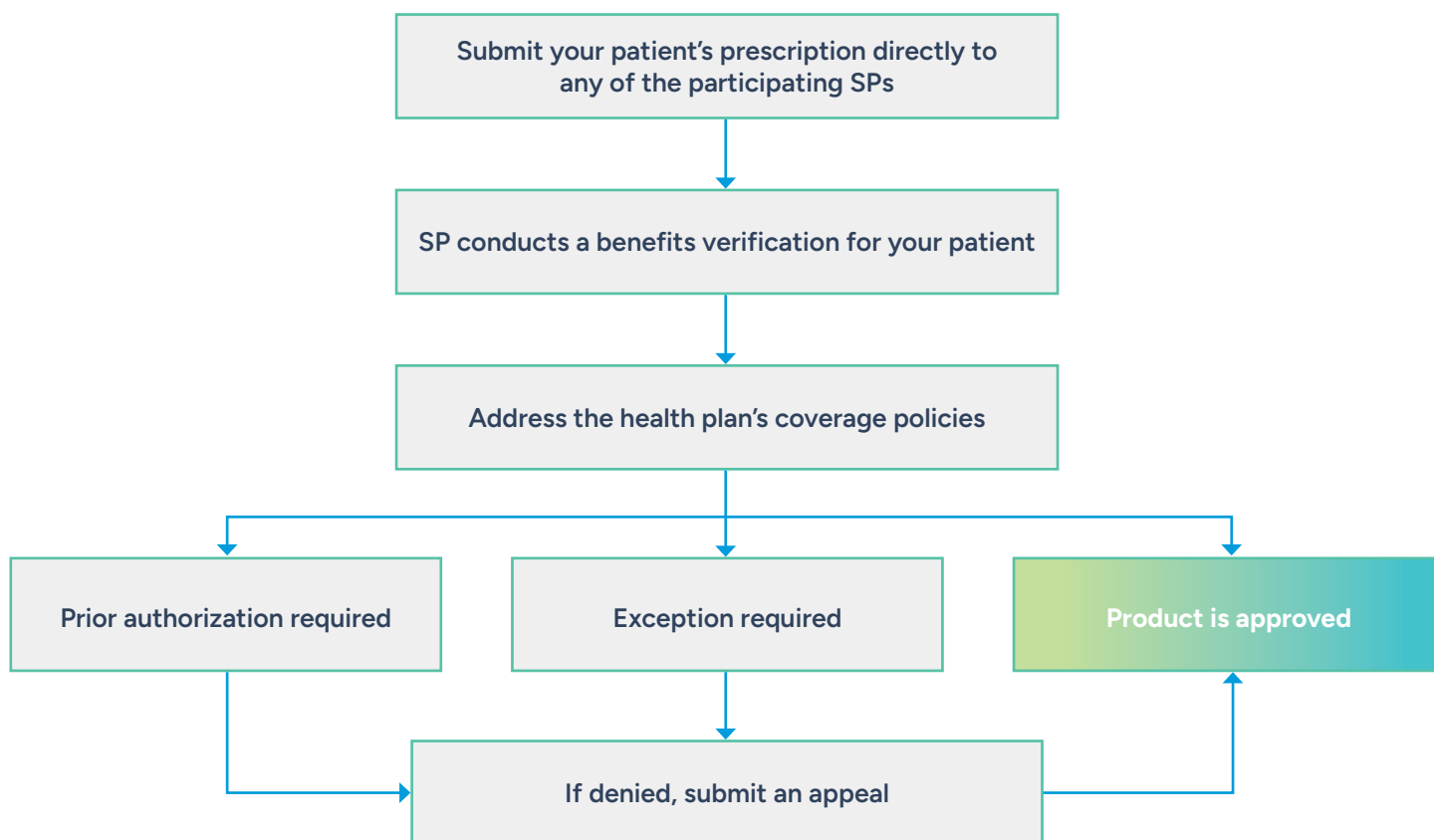
3

Patient cost and affordability



Benefits verifications (BVs)

BVs determine a patient's health plan coverage and potential next steps that may be necessary to acquire coverage for a product. Once the BV has been conducted, there are a few potential outcomes



IgAN	IgAN	C3G
For more information about prior authorizations, exceptions, and appeals (including sample letters) for VANRAFIA, see the Prior Authorization and Appeals Guide at VANRAFIA-hcp.com/resources	For more information about prior authorizations, exceptions, and appeals (including sample letters) for FABHALTA, see the Prior Authorization and Appeals Guide at FABHALTA-hcp.com/igan/resources	For more information about prior authorizations, exceptions, and appeals (including sample letters) for FABHALTA, see the Prior Authorization and Appeals Guide at FABHALTA-hcp.com/c3g/resources

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Preparing prior authorizations for VANRAFIA



Prior authorization checklist

The checklist below is intended to help you understand the kind of information that is usually required when submitting a prior authorization for VANRAFIA (the information below can also be used when submitting a letter of medical exception).

Please note that this is only an example, and it's important to check the payer's specific requirements prior to submission. Your chosen SP can also guide you through this process and gathering the appropriate content for coverage requests.

VANRAFIA prior authorization checklist

- ☐ Relevant medical records and clinical notes that support treatment
- ☐ Appropriate clinical information from the **Prescribing Information**
- ☐ Disease-specific criteria, which can include information such as the following:
 - ☐ Confirm patient is **18 years or older**
 - ☐ Record of diagnosis by **kidney biopsy**
 - ☐ Recent **urine protein excretion** (g/d) or **urine protein-to-creatinine ratio** (UPCR) (g/g) value
 - ☐ Recent and prior assessment of patient renal function, including **eGFR**
 - ☐ Indicator of risk of rapid disease progression/kidney function loss
 - ☐ List of all current and **previous treatments** for IgAN, including instances of intolerance to therapies such as immunosuppressants, corticosteroids, or other branded therapies. Confirm that the patient has not achieved adequate results from current or prior therapy
 - ☐ **ACEi** or **ARB**, or reason that the patient is not taking an ACEi/ARB or **SGLT2i**
 - ☐ Documentation showing prior steroid therapy or reasons for non-eligibility for **corticosteroids** and other therapies
- ☐ Treatment prescribed by or in consultation with a **nephrologist**



Download the VANRAFIA Prior Authorization and Appeals Kit, Sample Letter of Appeal, and/or Sample Letter of Medical Necessity to support the PA and appeals process for VANRAFIA patients.



82% of all prior authorizations are approved for VANRAFIA^{3,*†}

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; SGLT2i, sodium-glucose cotransporter-2 inhibitor.

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

†Between April 2024 and March 2026.

Click [here](#) for full Prescribing Information for VANRAFIA, including Boxed WARNING and Medication Guide. Click [here](#) for full Prescribing Information for FABHALTA, including Boxed WARNING and Medication Guide.



Preparing prior authorizations for FABHALTA IgAN



Prior authorization checklist

The checklist below is intended to help you understand the kind of information that is usually required when submitting a prior authorization for FABHALTA IgAN (the information below can also be used when submitting a letter of medical exception).

Please note that this is only an example, and it's important to check the payer's specific requirements prior to submission. Your chosen SP can also guide you through this process and gathering the appropriate content for coverage requests.

FABHALTA IgAN prior authorization checklist

- ☐ Relevant medical records and clinical notes that support treatment
- ☐ Appropriate clinical information from the **Prescribing Information**
- ☐ Disease-specific criteria, which can include information such as the following:
 - ☐ Confirm patient is **18 years or older**
 - ☐ Record of diagnosis by **kidney biopsy**, including MEST-C scoring if available
 - ☐ Recent **urine protein excretion (g/d)** or **urine protein-to-creatinine ratio (UPCR) (g/g)** value
 - ☐ Recent and prior assessment of patient renal function, including **eGFR**
 - ☐ Indicator of inflammatory lesions and persistent hematuria
 - ☐ Indicator of risk of rapid disease progression/kidney function loss
 - ☐ List of all current and **previous treatments** for IgAN, including instances of intolerance to therapies such as immunosuppressants, corticosteroids, or other branded therapies. Confirm that the patient has not achieved adequate results from current or prior therapy
 - ☐ **ACEi** or **ARB**, or reason that the patient is not taking an ACEi/ARB or **SGLT2i**
 - ☐ Documentation showing prior steroid therapy or reasons for non-eligibility for **corticosteroids** and other therapies
- ☐ Treatment prescribed by or in consultation with a **nephrologist**



Download the FABHALTA IgAN Prior Authorization and Appeals Kit, [Sample Letter of Appeal](#), and/or [Sample Letter of Medical Necessity](#) to support the PA and appeals process for FABHALTA patients.



90% of all prior authorizations are approved for FABHALTA IgAN^{4,*†}

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; eGFR, estimated glomerular filtration rate; MEST-C, mesangial hypercellularity (M), endocapillary hypercellularity (E), segmental glomerular sclerosis (S), tubular atrophy and interstitial fibrosis (T), and crescents (C); SGLT2i, sodium-glucose cotransporter-2 inhibitor.

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

†Between August 2023 and March 2026.

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Preparing prior authorizations for FABHALTA C3G



Prior authorization checklist

The checklist below is intended to help you understand the kind of information that is usually required when submitting a prior authorization for FABHALTA C3G (the information below can also be used when submitting a letter of medical exception).

Please note that this is only an example, and it's important to check the payer's specific requirements prior to submission. Your chosen SP can also guide you through this process and gathering the appropriate content for coverage requests.

FABHALTA C3G prior authorization checklist

- ☐ Relevant medical records and clinical notes that support treatment
- ☐ Appropriate clinical information from the **Prescribing Information**
- ☐ Disease-specific criteria, which can include information such as the following:
 - ☐ Confirm that patient is **18 years or older**
 - ☐ Record of **biopsy** confirmed C3G (C3GN or DDD)
 - ☐ Recent **urine protein-to-creatinine ratio (UPCR)** lab results
 - ☐ Recent and prior assessment of patient renal function, including **eGFR**
 - ☐ Recent **serum C3 level**
 - ☐ Indicator of risk of rapid disease progression/kidney function loss
 - ☐ List of all current and **previous treatments** for C3G, including instances of intolerance to therapies such as immunosuppressants, corticosteroids, mycophenolate mofetil, or other branded therapies. Confirm that the patient has not achieved adequate results from current or prior therapy
 - ☐ **ACEi or ARB**, or reason that the patient is not taking an ACEi/ARB or SGLT2i
 - ☐ Documentation showing prior steroid therapy or reasons for ineligibility for **corticosteroids** and other therapies
 - ☐ Documentation showing **prior mycophenolate mofetil therapy** or reasons for **ineligibility for mycophenolate mofetil** and other therapies
- ☐ Treatment prescribed by or in consultation with a **nephrologist**



Download the FABHALTA C3G [Prior Authorization and Appeals Kit](#), [Sample Letter of Appeal](#), and/or [Sample Letter of Medical Necessity](#) to support the PA and appeals process for FABHALTA patients.



90% of all prior authorizations are approved for FABHALTA C3G^{5,*†}

ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; C3, complement 3; C3GN, C3 glomerulonephritis; DDD, dense deposit disease; eGFR, estimated glomerular filtration rate; SGLT2i, sodium-glucose cotransporter-2 inhibitor.

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

†Between August 2023 and March 2026.

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Preparing exceptions and appeals

Exception requests

Exception requests are needed if a patient's health plan has placed certain restrictions, such as formulary exclusions and step therapy requirements. You will need to submit an exception request to ensure coverage.

There are 2 types of exception requests:



Formulary Exception Request

Use this type of exception request to support patients seeking approval for VANRAFIA/FABHALTA or to remove any applicable coverage blocks if VANRAFIA/FABHALTA is excluded from the formulary of your patient's health plan.



Step Therapy Exception Request

Use this type of exception request to support patients seeking approval for VANRAFIA/FABHALTA without having to try other health plan preferred alternatives first.

When submitting an exception request, you will need similar clinical documentation as you would need for a prior authorization (refer to [pages 8-10](#) for more information).

Appeals

If the patient's prior authorization or exception request has been denied, you should consider an appeal. Your patient's health plan will provide a written explanation of the denial and include information about how to request an appeal. Review the health plan's guidelines on the appeals process to ensure the appeal is as complete as possible.



The **majority of appeals are approved** for Novartis renal products⁶



Denials can happen for a number of reasons, but you and your patient always have the option to submit an appeal. Your chosen SP may be able to assist you with this process.

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Accurate classification and coding of IgAN and C3G is important

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

Indication	ICD-10-CM Code	Description
IgAN ⁷	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
C3G ⁷	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

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.

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Out-of-pocket costs and affordability options

Once the patient has been approved to begin VANRAFIA/FABHALTA, determine patient out-of-pocket costs and affordability options, which will vary by plan.

Percentage of patients who paid \$10 or less per month ^{8,9,*}			
	 Commercial/private	 Medicare [†]	 Medicaid
VANRAFIA [‡]	95%	83%	100%
FABHALTA IgAN [§]	96%	87%	100%
FABHALTA C3G	93%	66%	100%

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

[†]In 2026, the out-of-pocket maximum for Medicare Part D is \$2100.

Any of the participating SPs can help determine financial support options for your patients, such as the Co-Pay Plus offer or the Bridge Program.^{1,‡} SPs can also help determine eligibility for other relevant savings options.

[‡]Specialty pharmacy data from April 2025 to March 2026 for 2469 prescriptions, which represents approximately 99% of total prescriptions. For the remaining patients, the out-of-pocket cost for the product varies and may be as high as the total cost of the product.

[§]Specialty pharmacy data from April 2025 to March 2026 for 3019 prescriptions, which represents approximately 99% of total prescriptions. For the remaining patients, the out-of-pocket cost for the product varies and may be as high as the total cost of the product.

^{||}Specialty pharmacy data from August 2025 to July 2026 for 1396 prescriptions, which represents approximately 99% of total prescriptions. For the remaining patients, the out-of-pocket cost for the product varies and may be as high as the total cost of the product.

[¶]FABHALTA: Limitations apply. Up to a \$20,000 annual co-pay benefit limit for the cost of FABHALTA and up to \$1,000 for qualifying vaccination costs. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with private insurance and a prior authorization requirement or an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this Program without notice. Additional limitations may apply. See complete Terms & Conditions at www.FABHALTA.com for details.

[¶]VANRAFIA: Limitations apply. Up to a \$15,000 annual limit. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with private insurance and a prior authorization requirement or an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at www.VANRAFIA.com for details.

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VANRAFIA Indication and Important Safety Information



1 Submitting prescriptions

INDICATION

VANRAFIA is indicated to reduce 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 a reduction of proteinuria. It has not been established whether VANRAFIA 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.

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY

VANRAFIA is contraindicated for use in pregnant patients; it may cause major birth defects, based on animal data. Exclude pregnancy prior to initiation of treatment with VANRAFIA. Advise use of effective contraception before the initiation of treatment, during treatment, and for 2 weeks after discontinuation of treatment with VANRAFIA. Stop VANRAFIA as soon as possible if the patient becomes pregnant.

CONTRAINDICATIONS

Pregnancy

Use of VANRAFIA is contraindicated in patients who are pregnant.

Hypersensitivity

VANRAFIA is contraindicated in patients with a history of a hypersensitivity reaction to atrasentan or any component of the product.

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity

Based on data from animal reproduction studies, VANRAFIA may cause fetal harm when administered to a pregnant patient and is contraindicated during pregnancy. The available human data for endothelin receptor antagonists (ERAs) do not establish the presence or absence of major birth defects related to the use of VANRAFIA. Counsel patients who can become pregnant of the potential risk to a fetus. Exclude pregnancy prior to initiation of treatment with VANRAFIA. Advise patients to use effective contraception prior to initiation of treatment, during treatment, and for 2 weeks after discontinuation of treatment with VANRAFIA. When pregnancy is detected, discontinue VANRAFIA as soon as possible.

Hepatotoxicity

Some ERAs have caused elevations of aminotransferases, hepatotoxicity, and liver failure. Asymptomatic and transient transaminase elevations have been observed with VANRAFIA. Obtain liver enzyme testing before initiating VANRAFIA, and repeat during treatment as clinically indicated. In patients with elevated aminotransferases at baseline ($>3 \times$ upper limit of normal [ULN]), consider periodic liver test monitoring. Do not initiate VANRAFIA in patients with severe hepatic impairment.

2 Benefits verification and coverage determination

3 Patient cost and affordability



VANRAFIA Important Safety Information (continued)



1 Submitting prescriptions

Hepatotoxicity (continued)

Advise patients to report symptoms suggesting hepatic injury (eg, nausea, vomiting, right upper quadrant pain, fatigue, anorexia, jaundice, dark urine, fever, or itching). If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin $>2 \times$ ULN, or by clinical symptoms of hepatotoxicity, discontinue VANRAFIA. Consider reinitiation of VANRAFIA when hepatic enzyme levels normalize in patients who have not experienced clinical symptoms of hepatotoxicity or jaundice.

Fluid Retention

Fluid retention may occur with ERAs and has been observed in clinical studies with VANRAFIA. VANRAFIA has not been evaluated in IgAN patients with heart failure. If clinically significant fluid retention develops, consider initiating or increasing diuretic treatment and interrupting VANRAFIA treatment.

Decreased Sperm Counts

VANRAFIA, similar to other ERAs, may have an adverse effect on spermatogenesis. Counsel men about the potential effects on fertility.

ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 5\%$) with VANRAFIA were peripheral edema and anemia.

EFFECT OF OTHER DRUGS ON VANRAFIA

Strong or Moderate CYP3A Inducers: Avoid concomitant use with a strong or moderate CYP3A inducer. Atrasentan is a CYP3A substrate. Concomitant use with a strong and moderate CYP3A inducer is expected to decrease atrasentan exposure, which may reduce VANRAFIA efficacy.

OATP1B1/1B3 Inhibitors: Avoid concomitant use with organic anion transporting polypeptides (OATP) 1B1/1B3 (OATP1B1/1B3) inhibitors. Atrasentan is an OATP1B1/1B3 substrate. Concomitant use with an OATP1B1/1B3 inhibitor increases atrasentan exposure, which may increase the risk of VANRAFIA adverse reactions.

Click [here](#) for full Prescribing Information, including Boxed WARNING and [Medication Guide](#).

2 Benefits verification and coverage determination

3 Patient cost and affordability



FABHALTA Indications and Important Safety Information



1 Submitting prescriptions

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.

2 Benefits verification and coverage determination

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

3 Patient cost and affordability



FABHALTA Important Safety Information (continued)



1 Submitting prescriptions

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 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.

2 Benefits verification and coverage determination

3 Patient cost and affordability



FABHALTA Important Safety Information (continued)



1 Submitting prescriptions

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 ($\geq 10\%$) 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.

Click [here](#) for full Prescribing Information, including Boxed WARNING and Medication Guide.

2 Benefits verification and coverage determination

3 Patient cost and affordability



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Submitting
prescriptions

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Benefits verification and
coverage determination

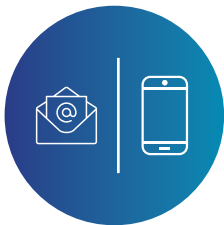
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Patient cost and
affordability

Click [here](#) for full Prescribing Information for VANRAFIA, including Boxed WARNING and [Medication Guide](#). Click [here](#) for full Prescribing Information for FABHALTA, including Boxed WARNING and [Medication Guide](#).



For questions about your patient's coverage or where they are in the access process, contact your preferred SP for clarification.



If your office needs information about coverage, services, and offerings, contact a Novartis representative.