Novartis Patient Support™

Prior Authorization and Appeals Guide

Information and sample letters to help you navigate coverage for your patients on VANRAFIA® (atrasentan)

Not an actual patient.

Phone:
844-4VANRAF (844-482-6723)

Fax:
877-6VANRAF (877-682-6723)

Online:
www.vanrafia.com

For questions or support, reach out to your dedicated Access and Reimbursement Team or contact Novartis Patient Support.

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Please see full Important Safety Information on pages 13-15 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Table of Contents

This guide intends to be a resource for you to use if your patient is faced with common insurance restrictions like a prior authorization (PA), step edit, or a plan not having a policy in place for VANRAFIA® (atrasentan). Whether using an electronic PA form or submitting requests manually, the tips, checklists, and sample letters included in this guide are designed to help you and your patients gather relevant documentation for complete communications with your patient's health plan.

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The information herein is provided for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.

Select a tab on the bottom of each page to go to the section that interests you. Press the home icon button to return to this page. This guide is interactive—keep an eye out for callouts to see where you can click.

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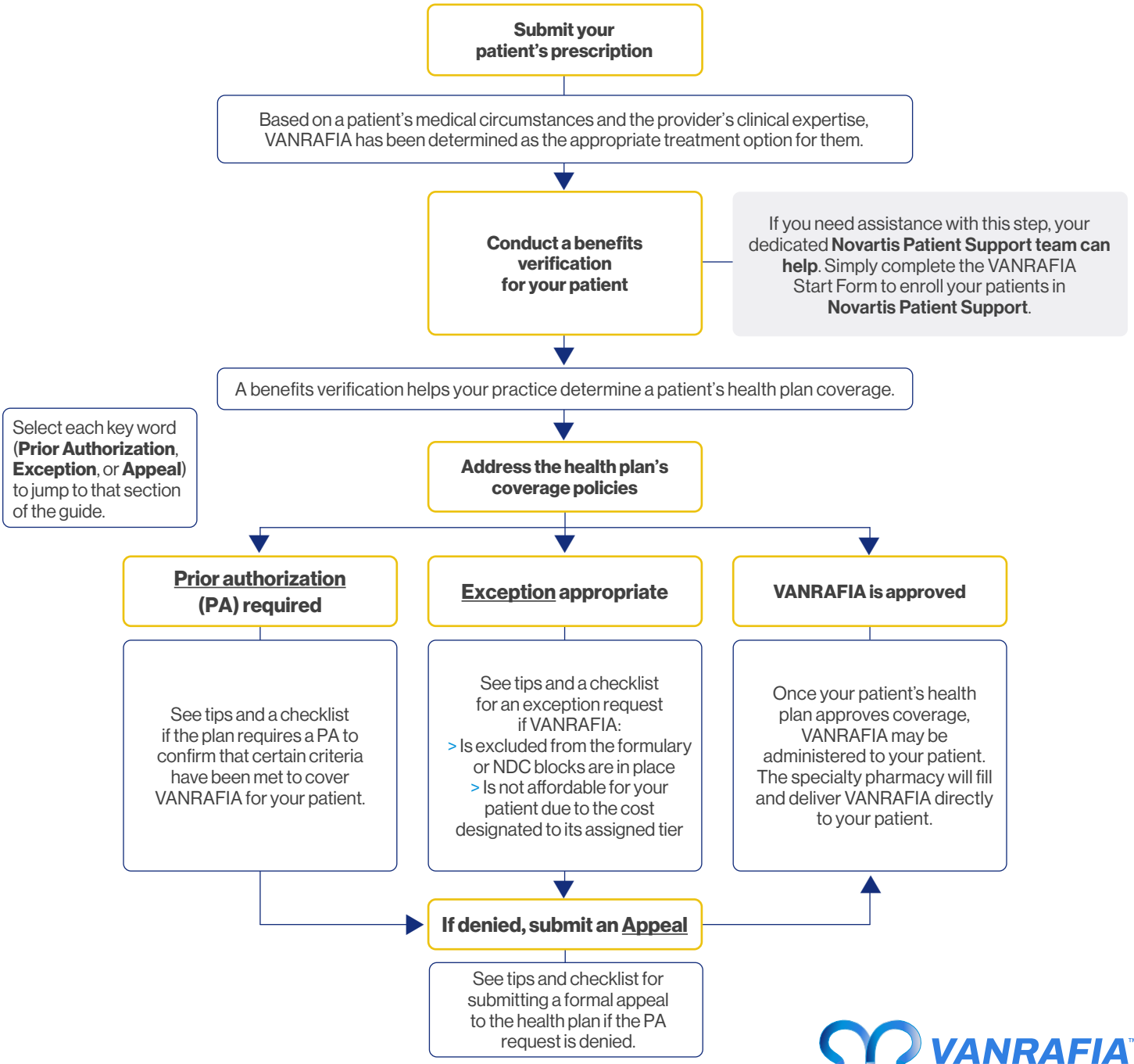
Overview of the Reimbursement Process

Various health insurance providers may manage access to VANRAFIA differently. Use this page to review the coverage process and identify which steps apply to your patient.



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Tips for Completing a PA Request

If a patient's health plan requires a PA for VANRAFIA, review the specific forms and information required by the health plan to ensure that the PA request is as complete as possible.

Tips

- **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for VANRAFIA

- **Ensure** that you understand and satisfy all plan-specific requirements
  - The patient's health plan may have a unique PA form that can be located on their website or by contacting their customer service
  - In certain states, a standardized PA form may be required for submission to a health plan along with clinical documentation
  - Some health plans encourage the use of electronic PA submission platforms (eg, CoverMyMeds®)

Start a request

Visit covermymeds.com
Log in to your account
Select "New Request" for HCP-initiated requests or "Enter Key" for pharmacy-initiated requests

CoverMyMeds: Automating part of the prior authorization (PA) process

CoverMyMeds' nationwide pharmacy integrations support the start of a prior authorization (PA) request that is sent to the provider for completion – which may help patients access their medications faster*. *Compared to phone and fax

- **Consider** including a personalized letter with PA documentation; you may prefer/your patient's health plan may require you to submit a Letter of Medical Necessity to explain your rationale supporting your patient's clinical need for VANRAFIA

Click here to download sample **Letter(s) of Medical Necessity** for your office:

A PA may be denied for VANRAFIA based on various reasons. Common causes of a PA denial are shown below.

Medical Necessity	Health plans may deny access if the proposed treatment does not meet the threshold for being medically necessary or clinically appropriate.
Administrative Errors	An incorrect billing code, spelling errors, insufficient information, or other administrative inaccuracies can result in a denied PA request.
Step Therapy	Depending on a health plan's formulary, patients are often required to receive a less expensive drug before a more expensive treatment can be prescribed.

Health plans take time to formulate their PA policies and coverage decisions. If a drug is not listed on formulary or is NDC blocked, you may be able to submit an exception for these scenarios.

See the following page for a helpful PA request checklist.

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Preparing a PA Submission

Submission checklist

Consider the following points when preparing to submit a PA for your patient. The checklist below is provided to help ensure your PA Request Letter is as complete as possible when communicating with health plans. The following page contains a sample letter that you may reference when crafting your own letter to the patient's health plan. The list below is intended to provide examples of what information is usually required.

- **Fill out the plan- and/or state-specific PA form**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements for VANRAFIA
- **Check that the following information is accurate and complete:**
  - Patient and insurance information (name, address, DOB, insurance information, etc)
  - Prescriber information (name, address, specialty, office contact, NPI, etc)
- **Document the treatment strength, frequency, quantity, and estimated length of therapy, including the appropriate NDC code**
- **Attach relevant clinical documentation supporting treatment with VANRAFIA, such as:**
  - Relevant medical records and clinical notes that support treatment with VANRAFIA
    - Diagnosis including the appropriate ICD-10-CM code and date of diagnosis
  - Appropriate clinical information from the Prescribing Information for VANRAFIA
    - Additional clinical data that may support the prescriber's recommendation
  - Disease-specific criteria, including information such as the following:
    - Confirm patient is 18 years or older
    - Record of diagnosis by kidney biopsy
    - Indicator of rapid kidney function loss
    - Recent urine protein excretion (g/d) or urine- protein-to-creatinine ratio (UPCR) (g/g) value
    - Recent assessment of patient renal function, including eGFR
  - 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
    - ACE inhibitor 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

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Preparing a PA Submission (cont)

Click here to download a customizable PA letter for your office in Word doc format.

Click here for a list of ICD-10 codes.

▶ **Reach out** to your dedicated Access and Reimbursement Team—they can help you understand plan requirements and coverage criteria

▶ **For support** throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

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Submitting an Exception

If the patient's health plan has placed restrictions on VANRAFIA, such as formulary exclusion, higher tier placement, or step therapy requirements, you will need to submit an exception request to ensure coverage.

Step Therapy Exception Request

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

Tiering Exception Request

Use this type of exception request to support patients seeking approval for VANRAFIA as a preferred drug that has a lower co-payment than its assigned tier.

Formulary Exception Request

Use this type of exception request to support patients seeking approval for VANRAFIA or to remove any applicable National Drug Code (NDC) blocks if VANRAFIA is excluded from the formulary of your patient's health plan.

Tips

- **Conduct** a benefits verification of your patient's health plan to help determine the specific coverage criteria for VANRAFIA
- **Check** to see if the patient's health plan has its own **Exception Request Form**—it can be located on their website or by contacting their customer service
- **You may also submit** a **Step Therapy Exception Request/Tiering Exception Request** or **Formulary Exception Request** if your patient's health plan previously approved VANRAFIA but has since changed its formulary to exclude or move VANRAFIA to a higher tier without grandfathering in current patients
- **Consider** asking your patient to write their own exception request letter that is signed by the physician
- **Click here** to view a checklist with helpful tips for your patient when writing to their health plan
- If your office uses an **electronic PA submission site**, check to see if you can submit an exception via the platform

See the following page for a helpful exception request checklist.

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Exception Request Checklist

Consider the following points when preparing to submit an exception request. The checklist below is provided to help ensure your exception request is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- **Fill out the health plan's exception request form, if required**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
- **Complete a Letter of Medical Necessity with relevant patient information and clinical support, which can include information such as:**
  - Patient's name, date of birth, health plan information (policy number)
  - A statement of the exception you are requesting for the patient and the reason for the request
  - Diagnosis and corresponding ICD-10 code(s)
    - **Click here** for a list of ICD-10 codes
  - Rationale for choosing VANRAFIA
  - Summary of the patient's current condition and relevant treatment history
  - If appropriate, a statement of the patient's financial hardship
- **Disease-specific criteria, which can include information such as the following:**
  - Relevant medical records and clinical notes that support treatment with VANRAFIA
  - Appropriate clinical information from the Prescribing Information for VANRAFIA
  - Disease-specific criteria, including information such as the following:
    - Confirm patient is 18 years or older
    - Record of diagnosis by kidney biopsy
    - Indicator of rapid kidney function loss
    - Recent urine protein excretion (g/d) or urine- protein-to-creatinine ratio (UPCR) (g/g) value
    - Recent assessment of patient renal function, including eGFR
  - 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
    - ACE inhibitor 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

Click here to download sample **Letter(s) of Medical Necessity** for your office.

- Reach out to your dedicated Novartis Access and Reimbursement Team—they can help you identify and understand plan requirements and coverage criteria

- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

Please see full Important Safety Information on pages 13-15 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Submitting an Appeal

If the patient's PA or exception request for VANRAFIA has been denied, you can consider an appeal. Your patient's health plan will provide a written explanation 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.

Tips

- **Conduct a benefits verification** of your patient's health plan to help determine the specific coverage criteria for VANRAFIA
- **Promptly submit the appeal** upon receipt of the denial before the health plan's deadline
- **Clearly address the plan's specific reason(s)** for denial when writing the appeal letter
- **Review the appeals process** for your patient's health plan
- **Always refer to the health plan's website** to locate their appeal form or information for submitting your own document
  - Many health plans will allow **up to 3 levels of appeal of PA denials**; the third level of appeal may include a review by an independent, non–insurance-affiliated external review board or hearing
  - Your patient's appeals rights and the appeals process are covered in health plan documents and on each Explanation of Benefits (EOB) form
- If your office uses an **electronic PA submission site**, check to see if you can submit an appeal via the platform

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Appeal Submission Checklist

Consider the following points when preparing to submit an appeal. The checklist below is provided to help ensure your appeal submission is as complete as possible when communicating with health plans. The checklist is intended to provide examples of what information is usually required.

- **Fill out an Appeal Form in response to the denial, if required by the health plan**
  - Conduct a benefits verification to ensure that you satisfy all of the health plan's requirements
  - Make sure that you review and attach the denial letter
- **Complete an Appeal Letter with relevant patient information and clinical support, such as:**
  - Patient's name, date of birth, health plan information (policy number)
  - Denial date and denial reference number
  - Summary of patient's diagnosis and corresponding ICD-10 code(s)
    - **Click here** for a list of ICD-10 codes
  - Summary of patient's treatment history
  - Detail why each of the health plan's suggested alternative therapies are not appropriate for your patient
  - Rationale for choosing VANRAFIA
- **Disease-specific criteria, which can include information such as the following:**
  - Relevant medical records and clinical notes that support treatment with VANRAFIA
  - Appropriate clinical information from the Prescribing Information for VANRAFIA
  - Disease-specific criteria, including information such as the following:
    - Confirm patient is 18 years or older
    - Record of diagnosis by kidney biopsy
    - Indicator of rapid kidney function loss
    - Recent urine protein excretion (g/d) or urine- protein-to-creatinine ratio (UPCR) (g/g) value
    - Recent assessment of patient renal function, including eGFR
  - 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
    - ACE inhibitor 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

- Reach out to your dedicated Novartis Access and Reimbursement Team—they can help you identify and understand plan requirements and coverage criteria

- For support throughout the coverage process and additional resources for your patient, submit the Start Form to enroll your patient in Novartis Patient Support

Click here to download sample **Letter(s) of Appeal** for your office.

Please see full Important Safety Information on pages 13-15 and full Prescribing Information, including Boxed WARNING and Medication Guide.

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Sample Letters

The sample letter links below are available for you to reference when crafting your own letter to the patient's health plan. The sample letters are intended to provide examples of the types of information that are often required.

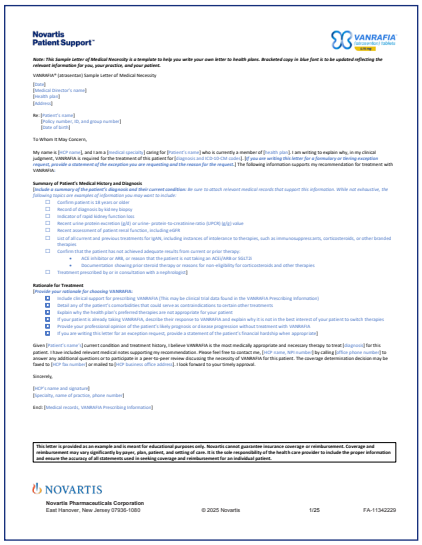
Click the links below to download sample letters for your office:

Sample Letters

Sample PA Request Letter

Sample Letter of Medical Necessity (IgA Nephropathy)

Sample Appeal Letter (IgA Nephropathy)



Example of Letter of Medical Necessity (IgA Nephropathy)

Click the links below to download patient resources for your office:

Patient Resources

Patient Letter Checklist

Example of Patient Letter Checklist

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Glossary

- **Appeal:** A request to a patient's health plan to reconsider their decision to deny coverage
- **Co-payment:** A cost-sharing arrangement in which a covered person pays a specified charge when they receive a covered service—like doctor visits, prescription medications, and other health care services
- **Exception:** A coverage request made to a patient's health plan to remove a plan restriction placed on a treatment
- **Explanation of benefits (EOB):** A statement from the health plan sent to members to track the use of medications and/or health care services, and the associated costs and payments
- **Formulary:** A list of prescription medications covered by an insurer/health plan
- **National Drug Code (NDC):** Universal product identifier with a unique set of numbers used for human drugs in the US
- **Preferred drug:** A medication designated as a valuable, cost-effective treatment option. In a multi-tier plan, preferred drugs are assigned to a lower tier than non-preferred drugs
- **Prior authorization (PA):** Also called preauthorization, an administrative tool used by health plans to determine if they will cover a prescribed procedure, service, or medication based on the patient's medical necessity
- **Step therapy:** A health plan policy requiring patients to follow a stepwise approach to trying (and failing) a medication before the plan will cover any alternative medications
- **Tiers:** Most health plans' formularies are divided into different categories, called tiers, with increasingly scaled co-payments. Tiers are commonly based on brand or generic medications, preferred or non-preferred medications, and traditional or specialty medications

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Indication and Important Safety Information for VANRAFIA™ (atrasentan) tablets, for oral use

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.

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WARNINGS AND PRECAUTIONS (CONTINUED)

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 × upper limit of normal [ULN]), consider periodic liver test monitoring. Do not initiate VANRAFIA in patients with severe hepatic impairment.

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 × 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 ≥5%) with VANRAFIA were peripheral edema and anemia.

WARNINGS AND PRECAUTIONS (CONTINUED)

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.

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

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Not an actual Novartis Patient Support team member.

Click here for full Prescribing Information including Boxed WARNING and Medication Guide on www.vanrafia.com.

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

4/25

FA-11297632

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Note: This Sample Letter of Medical Necessity is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting the relevant information for you, your practice, and your patient.

VANRAFIA® (atrasentan) Sample Letter of Medical Necessity

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of birth]

To Whom It May Concern,

My name is [HCP name], and I am a [medical specialty] caring for [Patient's name] who is currently a member of [health plan]. I am writing to explain why, in my clinical judgment, VANRAFIA is required for the treatment of this patient for [diagnosis and ICD-10-CM codes]. [***If you are writing this letter for a formulary or tiering exception request, provide a statement of the exception you are requesting and the reason for the request***.] The following information supports my recommendation for treatment with VANRAFIA:

Summary of Patient's Medical History and Diagnosis
[***Include a summary of the patient's diagnosis and their current condition:*** *Be sure to attach relevant medical records that support this information. While not exhaustive, the following topics are examples of information you may want to include:*

- ☐ Confirm patient is 18 years or older
- ☐ Record of diagnosis by kidney biopsy
- ☐ Indicator of rapid kidney function loss
- ☐ Recent urine protein excretion (g/d) or urine- protein-to-creatinine ratio (UPCR) (g/g) value
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ 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:
  - ACE inhibitor 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]

Rationale for Treatment
[***Provide your rationale for choosing* VANRAFIA:**

- ☐ Include clinical support for prescribing VANRAFIA (This may be clinical trial data found in the VANRAFIA Prescribing Information)
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Explain why the health plan's preferred therapies are not appropriate for your patient
- ☐ If your patient is already taking VANRAFIA, describe their response to VANRAFIA and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with VANRAFIA
- ☐ If you are writing this letter for an exception request, provide a statement of the patient's financial hardship when appropriate]

Given [Patient's name's] current condition and treatment history, I believe VANRAFIA is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient. I have included relevant medical notes supporting my recommendation. Please feel free to contact me, [HCP name, NPI number] by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of VANRAFIA for this patient. The coverage determination decision may be faxed to [HCP fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

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

Encl: [Medical records, VANRAFIA Prescribing Information]

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Note: This Sample Letter of Appeal is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting relevant information for you, your practice, and your patient.

VANRAFIA® (atrasentan) Sample Letter of Appeal

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name], and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I prescribed VANRAFIA for this patient to treat [diagnosis and ICD-10-CM codes] and submitted a [Prior Authorization/Formulary Exception Request/Tiering Exception Request] on [date of submission]. The request was denied on [date of denial and reference number] and the reason given was [reason from the health plan's denial letter]. I request a formal appeal of your denial for VANRAFIA, based on my review of the patient's diagnosis, care plan, and clinical guidelines for treatment. I maintain that VANRAFIA is the appropriate therapy for [Patient's name]. The following information supports my recommendation for treatment with VANRAFIA:

Summary of Patient's Medical History and Diagnosis
[***Include a summary of the patient's diagnosis and current condition:*** *Be sure to attach relevant medical records that support this information.*
The following topics are examples of information you may want to include:

- ☐ Confirm patient is 18 years or older
- ☐ Record of diagnosis by kidney biopsy
- ☐ Indicator of rapid kidney function loss
- ☐ Recent urine protein excretion (g/d) or urine- protein-to-creatinine ratio (UPCR) (g/g) value
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ 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:
  - ACE inhibitor 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]

Rationale for Treatment
[***Provide your rationale for choosing VANRAFIA:***

- ☐ Include clinical support for prescribing VANRAFIA (*This may be clinical trial data found in the VANRAFIA Prescribing Information*)
- ☐ Detail any of the patient's comorbidities that could serve as contraindications to certain other treatments
- ☐ Ensure that you clearly address the health plan's reason(s) for denial. If the plan requires step therapy, provide an explanation indicating why the treatments specified are not appropriate for your patient
- ☐ If your patient is already taking VANRAFIA, describe their response to VANRAFIA and explain why it is not in the best interest of your patient to switch therapies
- ☐ Provide your professional opinion of the patient's likely prognosis or disease progression without treatment with VANRAFIA]

Given [Patient's name's] current condition and treatment history, I believe VANRAFIA is the most medically appropriate and necessary therapy to treat [diagnosis] for this patient and would appreciate your prompt reconsideration of this denial.

I have included a copy of the denial letter along with relevant medical notes in response to the denial. Please feel free to contact me, [HCP's name, NPI number], by calling [office phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of VANRAFIA for this patient. The appeal decision may be faxed to [fax number] or mailed to [HCP business office address]. I look forward to your timely approval.

Sincerely,

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

Encl: Denial letter, Medical records, VANRAFIA Prescribing Information

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Note: This Sample Prior Authorization Request Letter is a template to help you write your own letter to health plans. Bracketed copy in blue font is to be updated reflecting the relevant information for you, your practice, and your patient.

VANRAFIA® (atrasentan) Sample Prior Authorization Request Letter

[Date]
[Medical Director's name]
[Health plan]
[Address]

Re: [Patient's name]
[Policy number, ID, and group number]
[Date of Birth]

To Whom It May Concern,

My name is [HCP's name] and I am a [medical specialty] caring for [Patient's name], who is currently a member of [health plan]. I am writing to request prior authorization of VANRAFIA [dose/frequency] for the treatment of this patient for [diagnosis and ICD-10-CM codes] As per the requirements of the plan, I have tried [required step-therapies] for my patient before prescribing VANRAFIA. Included please find a statement explaining why these preferred therapies are not appropriate for my patient. The following information supports my recommendation for treatment with VANRAFIA:

I have attached relevant medical records, including the patient's diagnosis, test results, and treatment history.
[***Include a summary of the patient's treatment history:***

- ☐ Confirm patient is 18 years or older
- ☐ Record of diagnosis by kidney biopsy
- ☐ Indicator of rapid kidney function loss
- ☐ Recent urine protein excretion (g/d) or urine- protein-to-creatinine ratio (UPCR) (g/g) value
- ☐ Recent assessment of patient renal function, including eGFR
- ☐ 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:
  - ACE inhibitor 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]

Given [Patient's name's] current condition and treatment history, I believe VANRAFIA should be authorized to treat [diagnosis] for this patient. Please do not hesitate to contact me by calling [office phone number] if you require additional information or would like to discuss this case further.

The prior authorization decision may be faxed to [fax number] or mailed to [HCP business office address]. Thank you for your prompt attention to this matter.

Sincerely,

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

Encl: Medical records, VANRAFIA Prescribing Information