VANRAFIA™
(atrasentan) tablets
0.75 mg

EHR Considerations Checklist

Ensure drug routing and administration records are correct

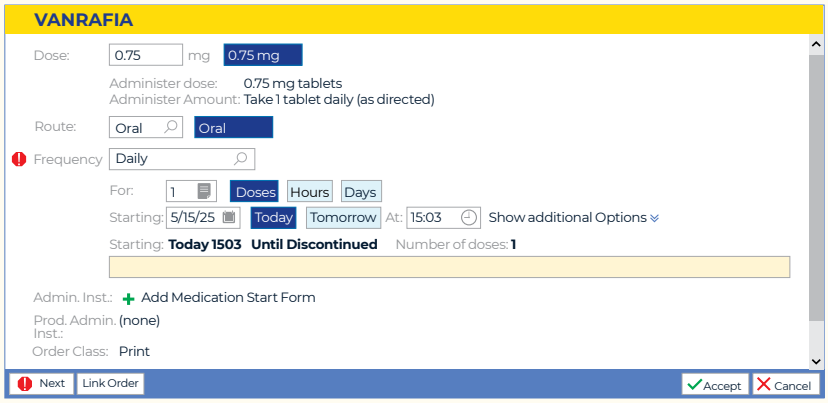
For example:

- NDC: 0078-1420-15
- Dosage
- Route of Administration: Oral
- Order Class: Specialty pharmacies
  - When configuring VANRAFIA® (atrasentan) in your electronic health record (EHR), ensure the routing is correctly configured, because this medication should not be e-prescribed
- Configure VANRAFIA to be distributed via specialty pharmacies (select pharmacies as noted below)
  - Configure the medication record on the specific drug itself to restrict available pharmacies to the 2 specialty pharmacies that are able to dispense the medication

Specialty Pharmacies		
	CareMed®*	**Biologics by McKesson**
Business Hours	24 hours a day, 7 days a week	24 hours a day, 7 days a week
Website	caremedsp.com	biologics.mckesson.com
Phone Number	1-877-227-3405	1-800-850-4306
Fax Number	1-877-542-2731	1-800-823-4506

*CareMed is a subsidiary of Onco360®

Hypothetical Drug Routing and Administration Record



This image is intended for illustrative purposes only.

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

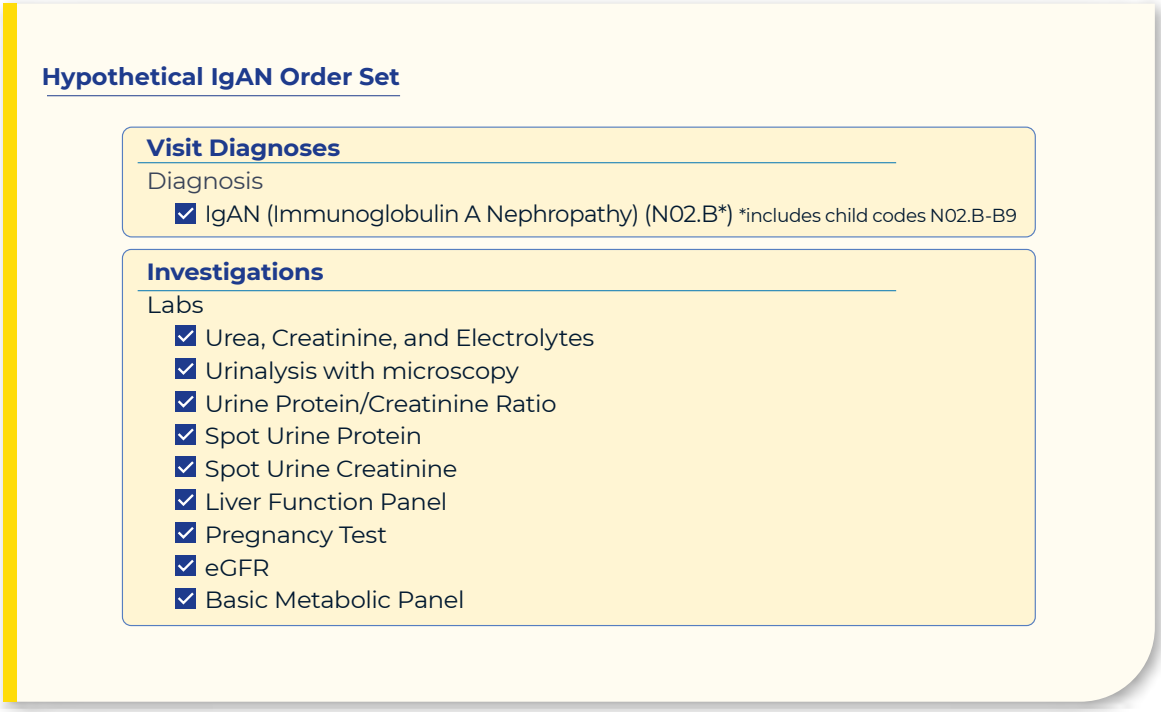
WARNING: EMBRYO-FETAL TOXICITY

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.

Please see additional Important Safety Information throughout and full Prescribing Information, including Boxed WARNING and Medication Guide.

Considerations for creation of a VANRAFIA specific order set

- Consider configuring labs and follow-up visits to evaluate for proteinuria



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IMPORTANT SAFETY INFORMATION (continued)

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 × 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.

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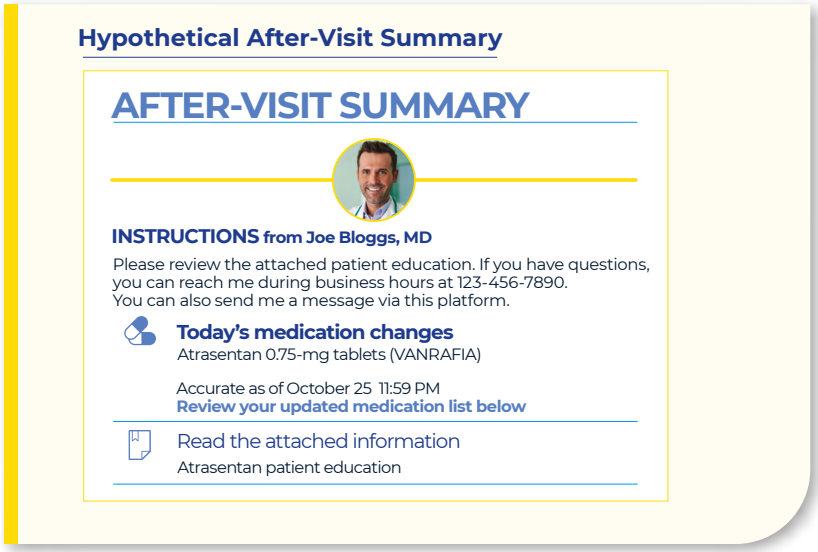
Embedding patient education within the After-Visit Summary

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

Hypothetical After-Visit Summary



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IMPORTANT SAFETY INFORMATION (continued)

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.

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Leverage templates to account for documentation requirements

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

Hypothetical Template

Previous History
@PMH@
@PSH@
@SOCH@
@FAMHX@
@ALLERGY@
@MEDSCONDENSED@

Physical Exam
@VSHOSP@

Results
@EDLABS@
@EDRADIOLOGY@
The laboratory results, imaging results and other diagnostic exam results were reviewed in the EHR.

ED Course & Medical Decision Making
@EDMEDS@
@EDCOURSE@

Procedures
@PROCDOC@

Diagnosis
@DIAGX@

Disposition
***Discharged
@EDDISCHARGERX@

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IMPORTANT SAFETY INFORMATION (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.

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

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

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Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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