



PATIENT ACCESS PLANNING

with myRARE® for EVKEEZA

This guide outlines **the recommended process your practice can follow to support your patients** living with the rare disease homozygous familial hypercholesterolemia (HoFH) who will be treated with EVKEEZA.

INDICATION

EVKEEZA is an angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to diet and exercise and other low-density lipoprotein-cholesterol (LDL-C) lowering therapies to reduce LDL-C in adults and pediatric patients, aged 1 year and older, with homozygous familial hypercholesterolemia (HoFH).

IMPORTANT SAFETY INFORMATION

Contraindication

EVKEEZA is contraindicated in patients with a history of serious hypersensitivity reaction to evinacumab-dqnb or to any of the excipients in EVKEEZA. Serious hypersensitivity reactions, including anaphylaxis, have occurred.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#).



Evkeeza[®]
(evinacumab-dqnb)
Injection


EVKEEZA approval checklist



Refer to this checklist to become familiar with the steps that may be required for your patient to receive treatment with EVKEEZA. Implementing it in your practice will help you track each step as it takes place and effectively communicate the approval process with your patient to keep them informed. This checklist may also be a helpful tool when consulting with the EVKEEZA support team.

- Discuss why you have prescribed EVKEEZA** with your patient and the approval process for the drug
 - Explain why EVKEEZA is the appropriate treatment option for your patient, using available discussion resources:
 - EVKEEZA Pre-Start Form Checklist
 - EVKEEZA Patient Discussion Guide Flip Chart
 - Outline expectations around the approval process
- Submit the fully completed EVKEEZA Start Form** and fax it to myRARE® at **1-844-RAREFAX** (1-844-727-3329) or upload to Docu-Send at [DocuSend.org](https://www.docusend.org)
 - Obtain the patient's signature in both locations in Section 1 on the Start Form or patients can provide consent electronically by visiting [myRARE.com](https://myrare.com) and clicking the "Enroll" button
 - Patient consent is required for the Field Reimbursement Manager (FRM) team to support your patient's case
 - After myRARE receives your patient's complete enrollment information, they will contact your office for confirmation that it's OK to reach out to your patient
- An EVKEEZA team introduction session** is available for you to meet the FRM and myRARE Patient Navigator and learn more about their roles and how they will support your office and patient throughout the EVKEEZA access and reimbursement process
 - This is recommended for your first patient on EVKEEZA and/or your first time through the EVKEEZA onboarding process
- Your FRM will reach out** to you to review your patient's coverage and benefits
 - Be prepared with the faxed Summary of Benefits from myRARE for your conversation with your FRM
- Decide on the site of care** for EVKEEZA treatment in consultation with your patient
 - There are many different types of infusion settings, including home infusion, physician office infusion, independent infusion center, or hospital outpatient department*
 - The site of care will depend on your patient's coverage and the site of care's network status with the insurance company, along with any formulary review process. Please reach out to your FRM if you have any questions
- Gather the necessary documentation** for the prior authorization (PA) submission and discuss the next steps for PA submission with your FRM as needed
 - Your FRM can provide you with checklists and letter templates for additional support, which are also available at [EVKEEZAhcp.com](https://www.evkeeza.com) under the *Support and Resources* tab

Once the PA is approved, **determine the next steps** based on the site-of-care selection.

- If the initial PA is denied**, you can choose to speak with your FRM to review the denial, and consider additional steps available to help obtain approval for treatment  [Click here for steps to appeal the decision.](#)
- Stay in touch with your FRM and Patient Navigator** about your patient's status and schedule for the first medication shipment and infusion date
- Follow up with your patient** periodically and plan out a schedule for reviewing lab values to track the progress of their treatment

*Regeneron does not recommend the use of any particular site of care.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

Serious Hypersensitivity Reactions: Serious hypersensitivity reactions, including anaphylaxis, have occurred with EVKEEZA. If signs or symptoms of serious hypersensitivity reactions occur, discontinue EVKEEZA infusion, treat according to the standard-of-care, and monitor until signs and symptoms resolve.

Please see Important Safety Information throughout and accompanying full [Prescribing Information](#).

EVKEEZA approval checklist



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 - EVKEEZA Patient Discussion Guide Flip Chart
 - Outline expectations around the approval process



If the request is denied, consider appealing the decision

- **Understand** the reason for denial
- **Submit** an appeal letter: ensure that all new documentation is complete with the necessary details and Healthcare Common Procedure Coding System (HCPCS) codes and that any required payer appeal form is completed and included in your appeal package
- **Some payers** will require a signed attestation form from the patient authorizing you as the prescriber to appeal the denial on the patient's behalf
- **Consider** a peer-to-peer review, consisting of a conversation with the health plan's medical director
- **Request** an external review, consisting of an independent, third-party evaluation of the coverage denial (if applicable) after a denial of a formal written appeal
- **Follow up** on the status of the decision and be sure to request all payer decisions and information provided be sent to you in a written format
- **For your patients prescribed EVKEEZA® (evinacumab-dgnb)**, your FRM will work with you regarding interim access options while the appeals process is ongoing

available to help obtain approval for treatment [Click here for steps to appeal the decision.](#)

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IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

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Your EVKEEZA support team



Regeneron is committed to helping patients and their caregivers

Starting a patient on a new treatment can be challenging. Regeneron and myRARE® **can work with you** throughout the acquisition, treatment, and reimbursement process for EVKEEZA.

Regeneron Field Reimbursement Managers (FRMs)

Your Regeneron FRM is your field-based point of contact who can provide access and reimbursement education and support to you, including benefits investigations, prior authorizations (PA), appeals, and claims assistance.

myRARE for EVKEEZA

myRARE is the **Patient Support Program for EVKEEZA** that may be able to provide your patients with:

- Financial support that facilitates access to EVKEEZA when eligible patients need assistance with out-of-pocket costs
 - myRARE will help investigate your patients' eligibility for financial assistance programs
- Access and reimbursement support to help your patients receive EVKEEZA as quickly as possible
- Additional support to help navigate through the insurance and treatment coordination challenges that patients may face

After submitting the myRARE for EVKEEZA Start Form, the myRARE team will research your patient's insurance coverage for EVKEEZA.

A myRARE Patient Navigator will be your patient's primary point of contact and can provide the following:

- Explain the patient's insurance benefits for treatment with EVKEEZA
- Help to identify financial assistance programs that may be able to assist with the cost of EVKEEZA, if your patient is eligible
- Provide information on PA status and/or appeal options that may be available

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Embryo-Fetal Toxicity: EVKEEZA may cause fetal harm when administered to pregnant patients. Advise patients who may become pregnant of the risk to a fetus. Consider obtaining a pregnancy test prior to initiating treatment with EVKEEZA. Advise patients who may become pregnant to use effective contraception during treatment and for at least 5 months following the last dosage.

Adverse Reactions

Adults and Pediatric Patients (12 to 17 years): Common adverse reactions ($\geq 5\%$) were nasopharyngitis (16%), influenza-like illness (7%), dizziness (6%), rhinorrhea (5%), and nausea (5%).

Please see Important Safety Information throughout and accompanying full **Prescribing Information**.



If you have any questions, or for additional assistance, please contact myRARE® at **1-877-EVKEEZA (1-877-385-3392) Option 1, Monday–Friday, 9 AM–9 PM Eastern time**

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

Pediatric Patients (5 to 11 years): The safety profile was consistent with that observed in adults and pediatric patients aged 12 and older, with the additional adverse reaction of fatigue in 3 (15%) patients.

Use in Specific Populations

Pregnancy: EVKEEZA may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. If a patient becomes pregnant while receiving EVKEEZA, healthcare providers should report EVKEEZA exposure by calling 1-833-385-3392.


Lactation: There are no data on the presence of evinacumab-dqnb in human milk or animal milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EVKEEZA and any potential adverse effects on the breastfed infant from EVKEEZA or from the underlying maternal condition.


Females and Males of Reproductive Potential: Consider pregnancy testing in patients who may become pregnant prior to starting treatment with EVKEEZA. EVKEEZA may cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use effective contraception during treatment with EVKEEZA and for at least 5 months following the last dosage of EVKEEZA.

Pediatrics: The safety profile of EVKEEZA in pediatric patients aged 1 to 11 years was similar to the safety profile in adults and pediatric patients aged 12 years and older, with the additional adverse reaction of fatigue in patients aged 5 to 11 years. The safety and effectiveness of EVKEEZA have not been established in pediatric patients younger than 1 year of age.

Please see accompanying full [Prescribing Information](#).

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 **Evkeeza®**
(evinacumab-dqnb)
Injection