my RARE™ for Evkeeza (evinacumab-dgnb)

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.

INDICATIONS AND USAGE

EVKEEZA is an angiopoietin-like 3 (ANGPTL3) inhibitor indicated as an adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, aged 5 years and older, with homozygous familial hypercholesterolemia (HoFH).

Limitations of Use:

- The safety and effectiveness of EVKEEZA have not been established in patients with other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH).
- The effects of EVKEEZA on cardiovascular morbidity and mortality have not been determined.

IMPORTANT SAFETY INFORMATION

Contraindication

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

Please see additional Important Safety Information throughout and full Prescribing Information, including Patient Information.

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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.

- ☐ **Submit the fully completed EVKEEZA Start Form** and fax it to myRARE™ at 1-844-RAREFAX (1-844-727-3329)
  - 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**
  - Patient consent is required for the Reimbursement Business Manager (RBM) 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
- ☐ **A support team introduction session** is available for you to meet the RBM and myRARE Patient Navigator after the Start Form has been submitted to 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 RBM 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 RBM
- ☐ **Discuss why you have prescribed EVKEEZA** with your patient and the approval process for the drug
  - Explain why EVKEEZA is the right treatment option for your patient and outline expectations around the approval process
- ☐ **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 RBM 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 RBM as needed
  - Your RBM can provide you with checklists and letter templates for additional support, which are also available at **www.EVKEEZAhcp.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 RBM to review the denial, and consider additional steps available to obtain approval for treatment. **Click here for steps to appeal the decision.**
- ☐ **Stay in touch with your RBM and Patient Navigator** about your patient's status, as needed, 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

Contact your RBM at any point during this process if you have questions. If you are unsure who your RBM is, call **1-877-EVKEEZA** (1-877-385-3392) and select Option 5

*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 allergic reactions occur, discontinue EVKEEZA infusion, treat according to the standard-of-care, and monitor until signs and symptoms resolve.

Please see additional Important Safety Information throughout and full Prescribing Information, including Patient Information.

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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 partner with you** throughout the acquisition, treatment, and reimbursement process for EVKEEZA.

Regeneron Reimbursement Business Managers (RBMs)

Your Regeneron RBM is your field-based point of contact who can provide education and support for the access and reimbursement of EVKEEZA. RBMs can help identify the most common reasons for claim denials. Contact your RBM for claim support. If you are unsure who your RBM is, call **1-877-EVKEEZA** (1-877-385-3392) and select **Option 5**.

myRARE for EVKEEZA

myRARE for EVKEEZA is a **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

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)

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.

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IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

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

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-dgnb 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 and efficacy of EVKEEZA have not been established in pediatric patients with HoFH who are younger than 5 years old.

Please see full Prescribing Information, including Patient Information.

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