myRARE™ for Evkeeza (evinacumab-dgnb)

ENROLLMENT GUIDE

FOR THE myRARE™ PATIENT SUPPORT PROGRAM

A resource for completing the myRARE Start Form for patients who are prescribed EVKEEZA for treatment of homozygous familial hypercholesterolemia (HoFH).

This guide is not intended as clinical guidance. Healthcare providers should complete the myRARE Start Form according to their own professional medical judgment.

Scan the QR code or visit **EVKEEZAhcp.com** and click the Support & Resources tab to view the myRARE enrollment video which details the enrollment process.

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 on page 2 and full Prescribing Information, including Patient Information.

Evkeeza® (evinacumab-dgnb) Injection

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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.

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 (≥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 additional Important Safety Information on page 1 and full Prescribing Information, including Patient Information.

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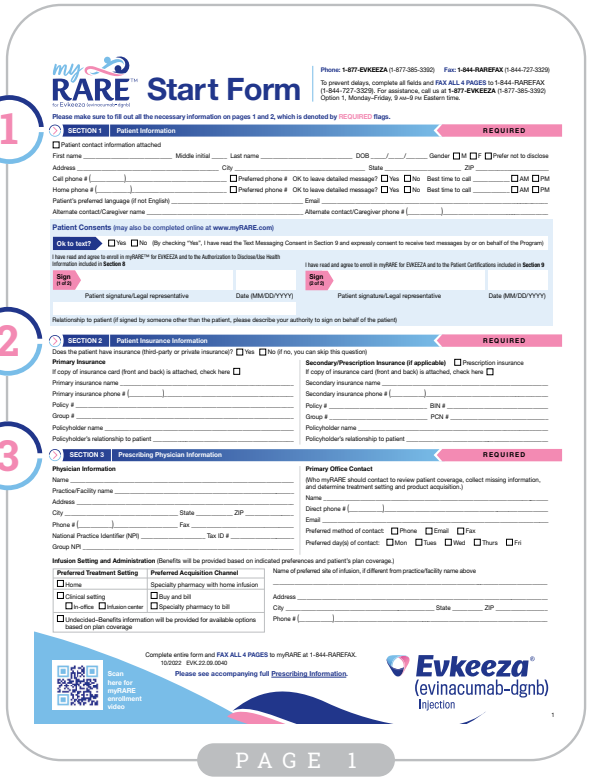
Key steps for enrolling patients in the myRARE™ Patient Support Program

All **REQUIRED** sections of this Enrollment Form should be completed, including specific information about the patient's condition for treatment with EVKEEZA. Frequently missed required information is denoted with **PINK** flags throughout the form. The guidance provided on each page can help ensure this form is fully completed and processed in a timely manner.

1 Patient information

- This section needs to be completed by the patient. However, if the patient needs help or has questions, use the following information to guide them in completing this form
- Encourage the patient to **provide cell and home phone numbers**, choose a preferred phone number, and allow the myRARE Patient Support Program to leave a voicemail message
- Ask the patient to check the **best time of the day to be contacted**
- Inform patients of the option to consent to receive text messages from myRARE
- Make sure the patient signs where indicated to confirm the patient has **read and agreed to the Authorization to Disclose/Use Health Information in Section 8 and the Patient Certifications in Section 9**
- The patient can provide consent to enroll in the myRARE Patient Support Program online at **www.myRARE.com**



2 Insurance information

- Provide the **patient's insurance** information; the left side is for primary insurance, and the right side is for secondary or prescription drug insurance
- **If you check the boxes for attaching the patient's insurance cards, attach copies** of the front and back of the cards, including prescription drug cards
- Ask the patient to complete Section 7 **if the patient wants to request financial assistance for EVKEEZA from the Patient Assistance Program**. You or the patient can contact the program for eligibility information

3 Prescriber information

- Provide all relevant information, including name, practice, contact information, preferred method of contact, and identification numbers
- Provide the name, phone number, and email of the primary point of contact at the provider's office
- Choose the preferred treatment setting and address if different from practice/facility
- Select the preferred acquisition channel (buy and bill or specialty pharmacy)
- If "undecided" is selected, myRARE will research benefits information for available options based on the patient's coverage

Please see Important Safety Information on pages 1-2 and full Prescribing Information, including Patient Information.

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Key steps for enrolling patients in the myRARE™ Patient Support Program (cont'd)

4 Diagnosis/prescription

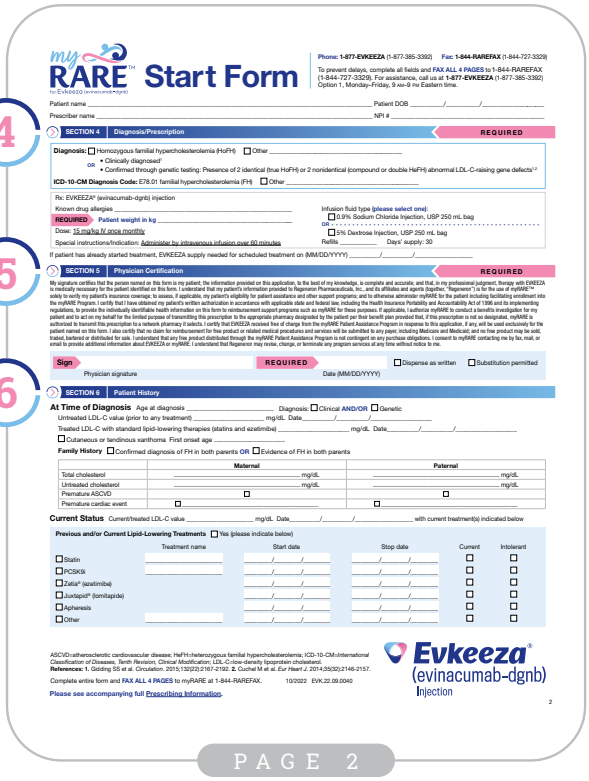
- HoFH must be clinically diagnosed or confirmed by genetic testing
- Include all **applicable information for the prescription and administration of EVKEEZA**, including known drug allergies, the patient's weight, type of infusion fluid, refills requested, and scheduled treatment date

5 Physician certification

- Certify the information provided and the terms and conditions of the myRARE Patient Support Program by **signing and dating the form**
- Indicate selection by **checking Dispense as written or Substitution permitted**

6 Patient history

- Include **all applicable information**, including the patient's status, diagnosis and the ICD-10-CM diagnosis code, medical history, and family history of HoFH
- Providers should follow **payer-specific coding requirements and exercise independent clinical judgment** when selecting codes and submitting claims to accurately reflect the diagnosis of the patient



myRARE Start Form

Phone: 1-877-EVKEEZA (1-877-385-3392) Fax: 1-844-RAREFAX (1-844-727-3329)

To prevent delays, complete all fields and FAX ALL 4 PAGES to 1-844-RAREFAX (1-844-727-3329). For assistance, call us at 1-877-EVKEEZA (1-877-385-3392) Option 1, Monday–Friday, 9 AM–9 PM Eastern time.

Patient name _____ Patient DOB ____/____/____

Prescriber name _____ NPI # _____

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SECTION 4 | Diagnosis/Prescription — REQUIRED

Diagnosis: ☐ Homozygous familial hypercholesterolemia (HoFH) ☐ Other _____

OR
- Clinically diagnosed[1]
- Confirmed through genetic testing: Presence of 2 identical (true HoFH) or 2 nonidentical (compound or double HoFH) abnormal LDL-C-raising gene defects[1,2]

ICD-10-CM Diagnosis Code: E78.01 familial hypercholesterolemia (FH) ☐ Other _____

Rx: EVKEEZA® (evinacumab-dgnb) injection

Known drug allergies _____

REQUIRED Patient weight in kg _____

Dose: 15 mg/kg IV once monthly

Special instructions/Indication: Administer by intravenous infusion over 60 minutes

Infusion fluid type (please select one):
☐ 0.9% Sodium Chloride Injection, USP 250 mL bag
OR
☐ 5% Dextrose Injection, USP 250 mL bag

Refills _____ Days' supply: 30

5

If patient has already started treatment, EVKEEZA supply needed for scheduled treatment on (MM/DD/YYYY) ____/____/____

SECTION 5 | Physician Certification — REQUIRED

My signature certifies that the person named on this form is my patient, the information provided on this application, to the best of my knowledge, is complete and accurate, and that, in my professional judgment, therapy with EVKEEZA is medically necessary for the patient identified on this form. I understand that my patient's information provided to Regeneron Pharmaceuticals, Inc., and its affiliates and agents (together, "Regeneron") is for the use of myRARE™ solely to verify my patient's insurance coverage, to assess, if applicable, my patient's eligibility for patient assistance and other support programs, and to otherwise administer myRARE for the patient including facilitating enrollment into the myRARE Program. I certify that I have obtained my patient's written authorization in accordance with applicable state and federal law, including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, to provide the individually identifiable health information on this form to reimbursement support programs such as myRARE for those purposes. If applicable, I authorize myRARE to conduct a benefits investigation for my patient and to act on my behalf for the limited purpose of transmitting this prescription to the appropriate pharmacy designated by the patient per their benefit plan provided that, if this prescription is not so designated, myRARE is authorized to transmit this prescription to a network pharmacy it selects. I certify that EVKEEZA received free of charge from the myRARE Patient Assistance Program in response to this application. If any, will be used exclusively for the patient named on this form. I also certify that no claim for reimbursement for free product or related medical procedures and services will be submitted to any payer, including Medicare and Medicaid, and no free product may be sold, traded, bartered or distributed for sale. I understand that any free product distributed through the myRARE Patient Assistance Program is not contingent on any purchase obligations. I consent to myRARE contacting me by fax, mail, or email to provide additional information about EVKEEZA or myRARE. I understand that Regeneron may revise, change, or terminate any program services at any time without notice to me.

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Sign REQUIRED ☐ Dispense as written ☐ Substitution permitted

Physician signature Date (MM/DD/YYYY)

SECTION 6 | Patient History

At Time of Diagnosis Age at diagnosis _____ Diagnosis: ☐ Clinical AND/OR ☐ Genetic

Untreated LDL-C value (prior to any treatment) _____ mg/dL Date ____/____/____

Treated LDL-C with standard lipid-lowering therapies (statins and ezetimibe) _____ mg/dL Date ____/____/____

☐ Cutaneous or tendinous xanthoma First onset age _____

Family History ☐ Confirmed diagnosis of FH in both parents OR ☐ Evidence of FH in both parents

	Maternal	Paternal
Total cholesterol	_____ mg/dL	_____ mg/dL
Untreated cholesterol	_____ mg/dL	_____ mg/dL
Premature ASCVD	☐	☐
Premature cardiac event	☐	☐

Current Status Current/treated LDL-C value _____ mg/dL Date ____/____/____ with current treatment(s) indicated below

Previous and/or Current Lipid-Lowering Treatments ☐ Yes (please indicate below)

Treatment name	Start date	Stop date	Current	Intolerant
☐ Statin	____/____/____	____/____/____	☐	☐
☐ PCSK9i	____/____/____	____/____/____	☐	☐
☐ Zetia® (ezetimibe)	____/____/____	____/____/____	☐	☐
☐ Juxtapid® (lomitapide)	____/____/____	____/____/____	☐	☐
☐ Apharesis	____/____/____	____/____/____	☐	☐
☐ Other _____	____/____/____	____/____/____	☐	☐

ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; LDL-C=low-density lipoprotein cholesterol.

References: 1. Gidding SS et al. *Circulation*. 2015;132(22):2167-2192. 2. Cuchel M et al. *Eur Heart J*. 2014;35(32):2146-2157.

Complete entire form and FAX ALL 4 PAGES to myRARE at 1-844-RAREFAX. 10/2022 EVK.22.09.0040

Please see accompanying full Prescribing Information.

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PAGE 2

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

Please see Important Safety Information on pages 1-2 and full Prescribing Information, including Patient Information.

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Completing and submitting the myRARE™ Start Form

7 Financial information

- Ask the patient to complete this section **if they want to request financial assistance for EVKEEZA** from the myRARE Patient Assistance Program
- Include the **size of the household and total household income.** The patient may qualify for financial assistance from the myRARE Patient Assistance Program if they meet all of the eligibility criteria, including total household income

8 Patient authorization

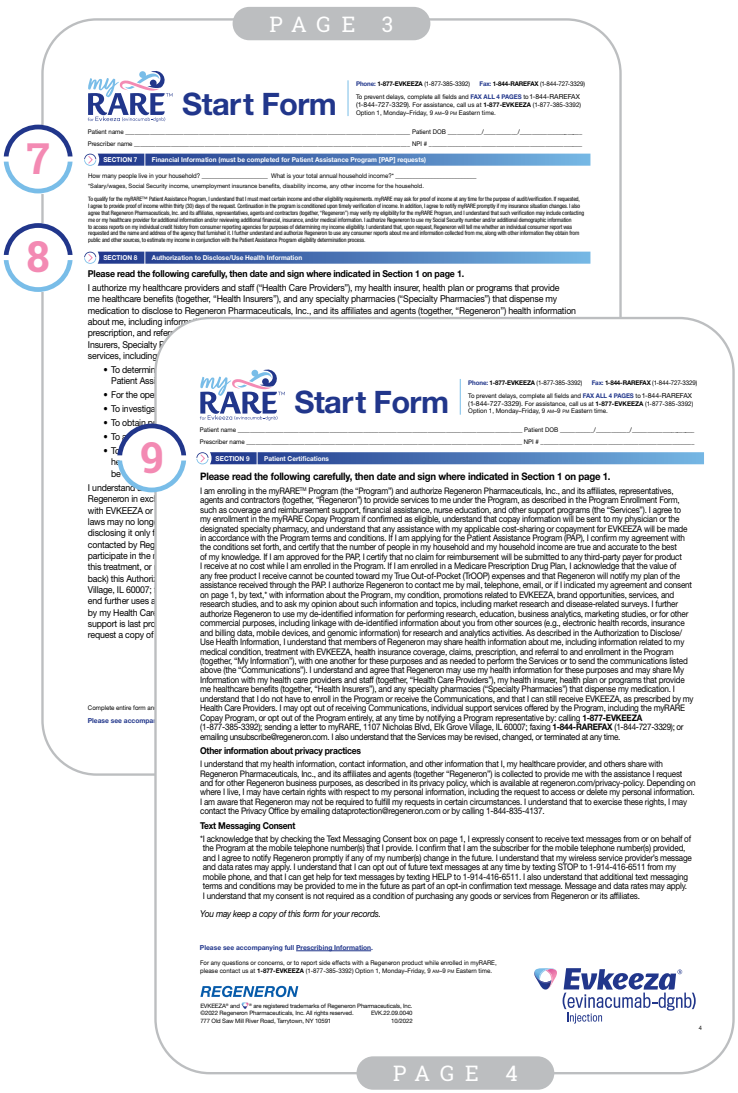
- The patient has to authorize the disclosure of personal health information **by signing and dating the form on page 1**

9 Patient certification

- The patient has to read and certify the information in the Patient Certifications section **by signing and dating the form on page 1**

To submit the myRARE Start Form, complete all fields and FAX ALL 4 PAGES to **1-844-RAREFAX** (1-844-727-3329).

For assistance, call **1-877-EVKEEZA** (1-877-385-3392) Option 1, Monday–Friday, 9 AM–9 PM Eastern time.



Please see full Prescribing Information, including Patient Information.

For any questions or concerns, or to report side effects with a Regeneron product while enrolled in the myRARE Patient Support Program, please contact us at **1-877-EVKEEZA** (1-877-385-3392) Option 1, Monday–Friday, 9 AM–9 PM Eastern time.

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