

# EVKEEZA ACCESS AND REIMBURSEMENT — G U I D E —

A resource guide to help your patients access EVKEEZA  
and the myRARE<sup>®</sup> Patient Support Program

Please see Important Safety Information  
on pages 3 and 4 and full [Prescribing  
Information](#).





**Evkeeza**<sup>®</sup>  
(evinacumab-dgnb)  
Injection

# Introduction

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

# > EVKEEZA

## INDICATION

EVKEEZA is an angiotensin-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-dgnb or to any of the excipients in EVKEEZA. Serious hypersensitivity reactions, including anaphylaxis, have occurred.

### 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.

**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%).

**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.

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



## > EVKEEZA (cont'd)

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Use in Specific Populations (cont'd)

**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 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 Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

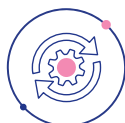


## > About this guide

This guide offers resources for healthcare providers treating patients living with the rare disease, homozygous familial hypercholesterolemia (HoFH), who will be treated with EVKEEZA. Each section provides information on the steps required to obtain access, reimbursement, and ongoing support for your patient including:



Coverage support



Access and  
reimbursement support



Product support



Financial support



Patient education from  
a nurse or pharmacist  
on how your patient  
will receive EVKEEZA



Personal support for your  
patients from a Patient  
Navigator (PN) throughout  
their EVKEEZA journey

Review this comprehensive guide sequentially to learn the required administrative steps for your patient's access to EVKEEZA, or click on the tabs at the right of each page to jump to a specific resource section.

Regeneron is committed to helping patients and their caregivers. Regeneron and myRARE® can partner with you throughout the acquisition, treatment, and reimbursement process. An assigned myRARE Coordinator will be the point of contact for your office. Patients can have a PN as a single point of contact. The myRARE PN will work with patients throughout their EVKEEZA journey.

Phone: **1-877-EVKEEZA** (1-877-385-3392) **Option 1**

Hours of operation: **Monday–Friday, 9 AM–9 PM** Eastern time

Fax: **1-844-RAREFAX** (1-844-727-3329)

Website: [www.EVKEEZAhcp.com](http://www.EVKEEZAhcp.com)

Upload: [www.DocuSend.org](http://www.DocuSend.org)

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# Patient access planning

with myRARE®

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

# > Steps to patient access for EVKEEZA with myRARE®

myRARE can support your patient throughout the treatment process

	Steps to patient access	myRARE support along the way
Prescription	<p><b>STEP 1 Start Form</b> &gt;</p> <ul style="list-style-type: none"> <li>• Complete myRARE Start Form to start the process—physician signature is required to process enrollment</li> <li>• Fax Start Form to <b>1-844-RAREFAX</b> (1-844-727-3329) or upload to Docu-Send at <a href="http://DocuSend.org">DocuSend.org</a></li> <li>• If patient is not in the office, they can complete signatures online at <a href="http://www.myRARE.com">www.myRARE.com</a></li> </ul>	<ul style="list-style-type: none"> <li>• myRARE confirms receipt and will let you know if any additional information is immediately needed</li> </ul>
Before infusion	<p><b>STEP 2 Understanding coverage</b> &gt;</p> <ul style="list-style-type: none"> <li>• Benefits verification completed to understand coverage options for EVKEEZA</li> <li>• Review the available benefits, prior authorization (PA) requirements, and additional notes from Summary of Benefits</li> </ul>	<ul style="list-style-type: none"> <li>• myRARE will contact you to review benefit information faxed to you and answer any questions you may have</li> </ul>
	<p><b>STEP 3 Determine access plan</b> &gt;</p> <p><b>Decide on product acquisition and site of care for patient</b></p> <ul style="list-style-type: none"> <li>• If you have additional questions, reach out to your Field Reimbursement Manager (FRM)</li> </ul>	<ul style="list-style-type: none"> <li>• myRARE will confirm with you how you want to move forward based on patient's coverage and your access plan for the patient</li> </ul>
	<p><b>STEP 4 Pursue coverage</b> &gt;</p> <ul style="list-style-type: none"> <li>• Pursue coverage:               <ul style="list-style-type: none"> <li>– PA will be required by plans that have an established policy for EVKEEZA or those that require PA for categories of medications such as specialty drugs or biologics</li> <li>– <b>Medical exception</b> will be required for plans that have not yet established coverage criteria</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• myRARE can help research authorization requirements, provide sample letters, and track authorization status</li> </ul>
	<p><b>STEP 5 Appeal (if necessary)</b> &gt;</p> <ul style="list-style-type: none"> <li>• Appeal, if necessary. Given the rare disease designation of HoFH, an appeal may be required to get coverage approved</li> <li>• Please share any payer response from the plan with myRARE</li> <li>• Understand what appeal options are available and the timeline to complete your appeal</li> </ul>	<ul style="list-style-type: none"> <li>• myRARE can review the denial to help outline information that may be required by the patient's health plan</li> </ul>

Continued on next page

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## > Steps to patient access for EVKEEZA with myRARE® (cont'd)

	Steps to patient access	myRARE support along the way
Before infusion (cont'd)	<p>STEP 6 <b>Financial support</b></p> <ul style="list-style-type: none"> <li>Assess patient's support needs. Whether their insurance has approved or denied coverage, this is a good time to review options</li> <li><b>If approved:</b> Confirm patient's out-of-pocket costs and see whether patient is eligible for assistance</li> <li><b>If denied:</b> Determine whether patient is eligible for the Patient Assistance Program, see page 41 for details</li> </ul>	<ul style="list-style-type: none"> <li>myRARE will identify support available based on patient insurance type, coverage status, and income (if applicable) and verify patient eligibility</li> </ul>
Infusion	<p>STEP 7 <b>Product acquisition</b></p> <ul style="list-style-type: none"> <li><b>Acquire EVKEEZA through Specialty Pharmacy or Specialty Distributor</b></li> <li>See <a href="#">page 29</a> for contact information</li> </ul>	
After infusion	<p>STEP 8 <b>Seek reimbursement (if buy and bill)</b></p> <ul style="list-style-type: none"> <li>Determine any payer-specific requirements for the claims submission</li> <li>Submit the claim in a timely fashion after double-checking to ensure that codes are accurate and appropriate documentation is included</li> <li>Submit a claim for reimbursement</li> <li>Track payer remittance</li> <li>If claim is denied, review response to determine appeal options</li> </ul>	<ul style="list-style-type: none"> <li>myRARE can provide information on billing, claims processing, and claims status tracking assistance</li> </ul>
Monthly	<p>STEP 9 <b>Coordinate ongoing treatment</b></p> <ul style="list-style-type: none"> <li>Schedule next infusion per EVKEEZA Prescribing Information, monthly dosing</li> <li>Verify no change in patient insurance or coverage</li> </ul>	<ul style="list-style-type: none"> <li>myRARE can assist with ongoing coverage confirmation</li> </ul>

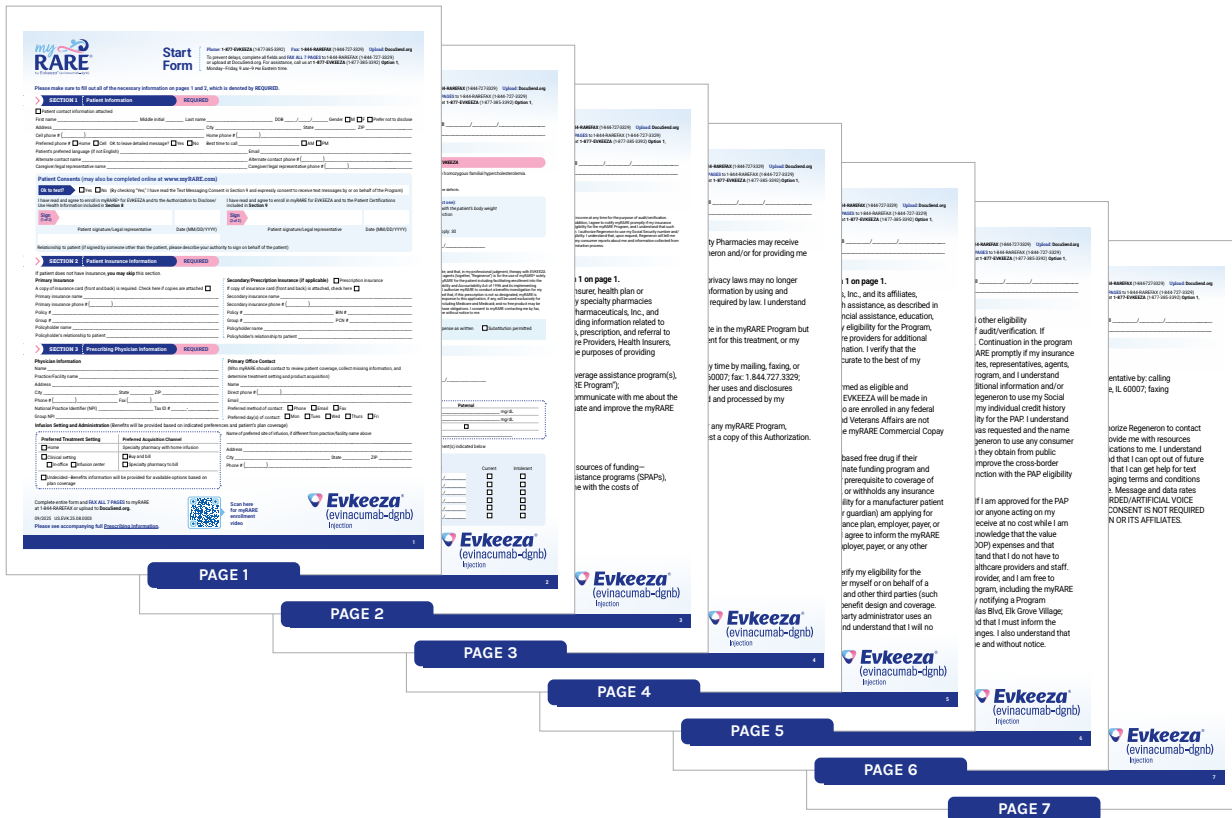
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# Submitting the myRARE® Start Form for EVKEEZA

Once you have determined that EVKEEZA is a medically appropriate treatment for your patient living with HoFH, begin by submitting a prescription using the myRARE Start Form.



Complete all sections of this Enrollment Form, including specific information about the patient's condition for treatment with EVKEEZA. Completing and submitting the Start Form will begin the benefits verification process for your patient.

> The guidance provided for each page can help ensure this form is fully completed and processed in a timely manner

Visit <https://EVKEEZAhcp.com/s/support-resources> to access a video that details the myRARE enrollment process and how myRARE can help your patients

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



# Submitting the myRARE® Start Form for EVKEEZA (cont'd)

## 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
- Inform patient of the options to **provide cell and home phone numbers**, choose a preferred phone number, and allow the myRARE Patient Support Program (PSP) to leave a detailed 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**
- Patients can provide consent by:
  - Signing a paper copy of the Start Form
  - Visiting [myRARE.com](http://myRARE.com) and clicking the blue enroll button
  - Receiving an email from their Patient Navigator and filling out the Patient Consent Form (available in English and Spanish)

The screenshot shows the 'myRARE Start Form' for EVKEEZA. It is divided into three main sections, each with a pink 'REQUIRED' flag:

- SECTION 1: Patient Information** (REQUIRED): Includes fields for patient name, address, city, state, ZIP, phone numbers, and preferred language. It also has checkboxes for 'I agree to be contacted' and 'I agree to be contacted by text message'.
- SECTION 2: Insurance Information** (REQUIRED): Includes fields for primary and secondary insurance names, policy numbers, and group numbers. It also has checkboxes for 'I have read and agree to attach my insurance information' and 'I have read and agree to attach my insurance information'.
- SECTION 3: Prescribing Physician Information** (REQUIRED): Includes fields for physician name, address, city, state, ZIP, phone numbers, and preferred method of contact. It also has checkboxes for 'I have read and agree to attach my insurance information' and 'I have read and agree to attach my insurance information'.

At the bottom of the form, there is a QR code and a 'Scan here for myRARE enrollment video' link. The page number 'PAGE 1' is visible at the bottom.

### 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

### 3 Prescriber information

- Provide all relevant information, including your 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 your practice/facility
- Select the preferred acquisition channel (buy-and-bill or specialty pharmacy)
- If "undecided" is selected, myRARE will receive benefits information for available options based on the patient's plan coverage

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Injection

# Submitting the myRARE® Start Form for EVKEEZA (cont'd)

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

### 4 Diagnosis/prescription

- Check the box to attest that the patient has a confirmed diagnosis of HoFH and to acknowledge that EVKEEZA is indicated solely for patients with this condition
- 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

Click [here](#) to find detailed information about EVKEEZA coding and billing

### 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, medical history, and family history of HoFH

The screenshot shows the 'myRARE Start Form' for EVKEEZA. It is divided into several sections, with three highlighted by red circles and numbers 4, 5, and 6. Section 4, 'Diagnosis/Prescription', contains a checkbox for 'Confirmed diagnosis of HoFH' and fields for 'Infusion fluid from (please select one)', 'Amount (mg/dL)', 'Refills requested', and 'Scheduled treatment date'. Section 5, 'Physician Certification', includes a signature line, date, and checkboxes for 'Dispense as written' and 'Substitution permitted'. Section 6, 'Patient History', contains fields for 'At Time of Diagnosis', 'Diagnosis', 'Age at diagnosis', 'Current Status', and 'Previous and/or Current Lipid-Lowering Treatments'. The form also includes contact information for myRARE and Evkeeza (evinacumab-dgnb) Injection.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



## Submitting the myRARE® Start Form for EVKEEZA (cont'd)

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

#### 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 (PAP)
- 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 certify the financial information provided and agree to the terms and conditions by signing and dating the form on page 1

To submit the myRARE Start Form, complete all fields and FAX ALL 7 PAGES to **1-844-RAREFAX** (1-844-727-3329) or upload to Docu-Send at **DocuSend.org**.

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

- If your patient does not complete the Patient Consent portion of the myRARE for EVKEEZA Start Form in your office, they may do so online at **www.myRARE.com**

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## > Deciding on an infusion setting for your patients

There are many different types of infusion settings. The following guide outlines some of the potential benefits and considerations of each site of care\*

Overview		Benefits	Considerations
<b>Home infusion</b>	> <b>Trained nurses or RNs administer infusions in the patient's home</b>	<ul style="list-style-type: none"> <li>• Patients receive treatment in the comfort of their own home</li> <li>• Convenient for patients with disabilities or those who do not have a local infusion facility</li> <li>• May improve patient adherence due to convenience</li> <li>• Allows patient and caregiver to become familiar with home infusion</li> </ul>	<ul style="list-style-type: none"> <li>• No physician on site</li> <li>• Some insurance plans have restrictions on coverage for home infusion</li> <li>• Patients may have concerns about letting a nurse into their home</li> </ul>
<b>Physician office infusion</b>	> <b>Infusion in the office of the prescribing HCP or another qualified HCP</b>	<ul style="list-style-type: none"> <li>• Physician oversight</li> <li>• Patients are familiar with the office and staff</li> <li>• Staff can confirm that treatment is being given on schedule</li> </ul>	<ul style="list-style-type: none"> <li>• Certain specialist offices may only agree to infuse under a co-management arrangement</li> <li>• HCP review of their contract with patient's insurance to understand payer requirements for coverage and reimbursement</li> </ul>
<b>Independent infusion center</b>	> <b>Stand-alone clinics that administer infusion therapies</b>	<ul style="list-style-type: none"> <li>• Only offer infusion services, so they have more scheduling capacity</li> <li>• Offer comfortable infusion amenities for patients</li> </ul>	<ul style="list-style-type: none"> <li>• Physician may not be on site</li> <li>• Options may be limited by patient's insurance network status</li> <li>• Formulary review of EVKEEZA at infusion center will likely be required and may add time to patient onboarding process</li> </ul>
<b>Hospital outpatient department</b>	> <b>Infusion facility set up as part of a hospital</b>	<ul style="list-style-type: none"> <li>• Often offer longer operating hours for patients to receive treatment</li> <li>• Additional resources may be available from the hospital (billing, scheduling, patient education)</li> </ul>	<ul style="list-style-type: none"> <li>• Payers may set limitations based on this site of care and require less costly options be evaluated before approving hospital outpatient</li> <li>• Large hospitals may be challenging for patients to navigate, but local community satellite locations may be available through some hospitals</li> <li>• Formulary review of EVKEEZA by hospital will likely be required and may add time to patient onboarding process</li> </ul>

HCP=healthcare provider; RNs=registered nurses.

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

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# Benefits verification

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# > Benefits verification

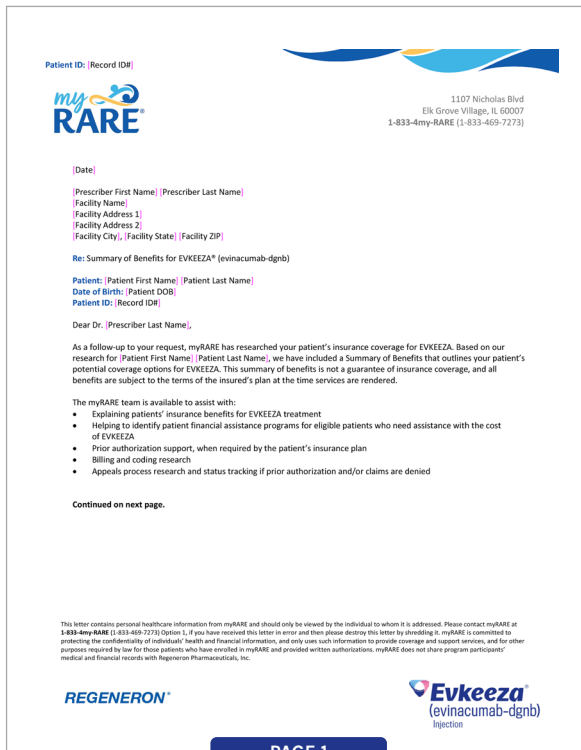
Once you prescribe EVKEEZA for your patient, a **benefits investigation** is an important first step to determining how EVKEEZA will be covered under your patient's health insurance plan.

## myRARE® is available to assist with:

- > **Explaining** patients' insurance benefits for treatment with EVKEEZA
- > Identification of, and referral to, **financial assistance programs for eligible patients** who need assistance with the cost of EVKEEZA
- > **Prior authorization (PA) support** for when a PA is required by your patient's insurance plan
- > **Coding and billing research**
- > **Appeals process** research and tracking the status of claims or a PA

Here is what to expect in a Summary of Benefits:

Page 1 preview



Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



## > Benefits verification (cont'd)

### Summary of Benefits: patient benefit profile

**Note:** A benefits investigation is not a guarantee of insurance coverage. All benefits are subject to the insured's plan at the time services are rendered. Under no circumstances shall the myRARE® Program be held responsible or liable for payment of any claims, benefits, or cost. Any coding information discussed in this document is provided for informational purposes only, is subject to change, and should not be construed as legal advice. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to the specific patient.

### Page 2 preview

The first section of the patient benefit profile includes:

- A** The **ID number assigned to your patient** by the myRARE PSP. Refer to the patient ID when speaking with a program representative
- B** A summary of your patient's **health insurance information**
- C** The **diagnosis code** for treatment with EVKEEZA

Patient ID: [Record ID#]  
Health Plan: [Health Plan Name]  
Coverage: [Primary | Secondary | Tertiary]


**Summary of Benefits for EVKEEZA® (evinacumab-dgnb)**  
Patient benefit profile

This is not a guarantee of insurance coverage. All benefits are subject to the insured's plan at the time services are rendered. Under no circumstances shall the myRARE™ program be held responsible or liable for payment of any claims, benefits, or cost. Any coding information discussed in this document is provided for informational purposes only, is subject to change, and should not be construed as legal advice. Providers should exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to the specific patient.

Plan record ID: \_\_\_\_\_ Patient Name: \_\_\_\_\_  
Date of birth (mm/dd/yyyy): \_\_\_\_\_ Payer name: \_\_\_\_\_ Employer name: \_\_\_\_\_  
Plan name: \_\_\_\_\_ Plan type: \_\_\_\_\_ Policy number: (\_\_\_\_\_) \_\_\_\_\_  
Group number: \_\_\_\_\_ Policy level: \_\_\_\_\_  Primary  Secondary  Tertiary  
Policy effective date: \_\_\_\_\_ Policy end date: \_\_\_\_\_  
Policy effective:  Plan year dates: \_\_\_\_\_  Calendar year (January 1-December 31)  
Payer phone: (\_\_\_\_\_) \_\_\_\_\_ Payer contact: \_\_\_\_\_ Self funded:  Yes  No  
Verified for primary diagnosis: \_\_\_\_\_ Verified for secondary diagnosis: \_\_\_\_\_  
Verified tertiary diagnosis: \_\_\_\_\_

Continued on next page.

This letter contains personal healthcare information from myRARE and should only be viewed by the individual to whom it is addressed. Please contact myRARE at 1-833-4myRARE (1-833-460-7273) Option 1, if you have received this letter in error and then please destroy this letter by shredding it. myRARE is committed to protecting the confidentiality of individuals' health and financial information, and only uses such information to provide coverage and support services, and for other purposes required by law for those patients who have enrolled in myRARE and provided written authorizations. myRARE does not share program participants' medical and financial records with Regeneron Pharmaceuticals, Inc.

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**PAGE 2**

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# > Benefits verification (cont'd)

## Summary of Benefits: patient benefit profile (cont'd)

### Page 3 preview

Detailed benefit information for the cost of EVKEEZA is included under 3 options:

- D Site-of-care purchase option through major medical benefits:** Site of care buys EVKEEZA, bills the health plan, and is reimbursed
- E Specialty pharmacy option through major medical benefits:** Benefits are assigned to a network specialty pharmacy, which bills for the cost of EVKEEZA
- F Specialty pharmacy option through prescription drug benefit:** EVKEEZA is covered under the pharmacy benefit; the specialty pharmacy bills for the cost of EVKEEZA

Additional details include whether your patient's health plan covers the cost of EVKEEZA, your patient's financial responsibility for their deductible and copayment or coinsurance, and specialty pharmacy information, if applicable

- G Administration coverage information:** Whether EVKEEZA is administered at an infusion center or at home, this section indicates whether the administration is covered or not covered by the health plan, and the patient's financial responsibility (coinsurance/copayment)

D
E
F

G

Patient ID: [Record ID#]  
 Health Plan: [Health Plan Name]  
 Coverage: [Primary | Secondary | Tertiary]

This is not a guarantee of insurance coverage. All benefits are subject to the insured's plan at the time services are rendered. Under no circumstances shall the myRARE® program be held responsible for liability for payment of any claims, benefits, or cost.

	Site of care purchase option through major medical benefits (The site of care purchases EVKEEZA® (evinacumab-dgnb) bills for the drug and receives reimbursement from the health plan)	Specialty pharmacy option through major medical benefits (Benefits are assigned to a network specialty pharmacy. The specialty pharmacy bills for EVKEEZA)	Specialty pharmacy option through prescription drug benefit (EVKEEZA is covered under the pharmacy benefit. The specialty pharmacy bills for EVKEEZA)												
<b>EVKEEZA covered</b>	<input type="checkbox"/> Yes - with authorization (see PA requirements on pg. 2) <input type="checkbox"/> No - No authorization required	<input type="checkbox"/> Yes - with authorization (see PA requirements on pg. 2) <input type="checkbox"/> No - No authorization required	<input type="checkbox"/> Yes - with authorization (see PA requirements on pg. 2) <input type="checkbox"/> No - No authorization required												
<b>Deductible</b>	Enter amount: \$	Enter amount: \$	Enter amount: \$												
<b>Deductible met</b>	<input type="checkbox"/> Includes deductible <input type="checkbox"/> Excludes deductible	<input type="checkbox"/> Includes deductible <input type="checkbox"/> Excludes deductible	<input type="checkbox"/> Includes deductible <input type="checkbox"/> Excludes deductible												
<b>Out-of-pocket maximum</b>	Enter amount: \$	Enter amount: \$	Enter amount: \$												
<b>Out-of-pocket maximum met</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No												
<b>Drug copy/coinsurance</b>	Enter % or \$ amount:	Enter % or \$ amount:	Enter % or \$ amount:												
<b>Pharmacy cap</b>	Enter amount: \$	Enter amount: \$	Enter amount: \$												
<b>Pharmacy cap met</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No												
<b>Additional benefit information</b>		Note: Benefits verified for OrsinSP as exclusive SP partner for EVKEEZA.	Note: Benefits verified for OrsinSP as exclusive SP partner for EVKEEZA.												
<b>ADMINISTRATION</b>															
<b>Infusion center:</b>	Covered/Not covered	Covered/Not covered	Covered/Not covered												
<b>Co-insurance/copayment:</b>															
<b>Home infusion:</b>	Covered/Not covered	Covered/Not covered	Covered/Not covered												
<b>Co-insurance/copayment:</b>															
<b>Infusion Centers in network</b>	<table border="1"> <tr> <td>Name:</td> <td>Phone #:</td> </tr> <tr> <td>Street Address:</td> <td>State:</td> </tr> <tr> <td>City:</td> <td>Zip:</td> </tr> <tr> <td>Name:</td> <td>Phone #:</td> </tr> <tr> <td>Street Address:</td> <td>State:</td> </tr> <tr> <td>City:</td> <td>Zip:</td> </tr> </table>			Name:	Phone #:	Street Address:	State:	City:	Zip:	Name:	Phone #:	Street Address:	State:	City:	Zip:
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<b>(Additional in-network options may be available)</b>	<table border="1"> <tr> <td>Name:</td> <td>Phone #:</td> </tr> <tr> <td>Street Address:</td> <td>State:</td> </tr> <tr> <td>City:</td> <td>Zip:</td> </tr> <tr> <td>Name:</td> <td>Phone #:</td> </tr> <tr> <td>Street Address:</td> <td>State:</td> </tr> <tr> <td>City:</td> <td>Zip:</td> </tr> </table>			Name:	Phone #:	Street Address:	State:	City:	Zip:	Name:	Phone #:	Street Address:	State:	City:	Zip:
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Continued on next page.

PAGE 3

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



# > Benefits verification (cont'd)

## Summary of Benefits: patient benefit profile (cont'd)

### Pages 4 and 5 preview

**H** Page 4 lists the **documentation, criteria, and instructions** necessary for submitting a PA (if one is required), and includes **contact information** for the patient's health plan

Patient ID: [Record ID#]  
Health Plan: [Health Plan Name]  
Coverage: [Primary | Secondary | Tertiary]

This is not a guarantee of insurance coverage. All benefits are subject to the insured's plan at the time services are rendered. Under no circumstances shall the myRARE® program be held responsible or liable for payment of any claims, benefits, or cost.

**Prior authorization requirements**

	Infusion administration benefit	Site of care purchase option through major medical benefits (The site of care purchases EVKKEZA® (evinacumab-dgnb) bills for the drug and receives reimbursement from the health plan)	Specialty pharmacy option through major medical benefit (Benefits are assigned to a network specialty pharmacy. The specialty pharmacy bills for EVKKEZA)	Specialty pharmacy option through prescription drug benefit (EVKKEZA is covered under the pharmacy benefit. The specialty pharmacy bills for EVKKEZA)
Prior authorization/Pre-determination required				
Required documentation	--			
Required criteria	--			
To the attention of	--			
Phone	--			
Fax	--			
PA status	--			
PA expiration date	--			
PA instructions	--			

Continued on next page.

**PAGE 4**

**I** Page 5 captures **any additional instructions or notes from the health plan** that may guide your practice in submitting documentation for your patient's treatment with EVKKEZA

Patient ID: [Record ID#]  
Health Plan: [Health Plan Name]  
Coverage: [Primary | Secondary | Tertiary]

Record any special instructions or additional notes within the space below.

[Claims addresses, billing guidelines, benefit summary/additional info (coordination of benefits)]

If you have any questions about this letter or myRARE®, please contact myRARE at 1-833-4my-RARE (1-833-469-7273) Option 1, Monday-Friday, 9 AM-9 PM Eastern time.

Sincerely,

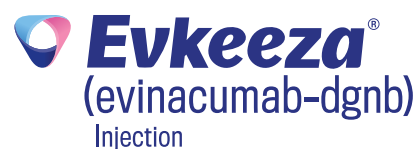
[Signature]  
[Site Coordinator First Name] [Site Coordinator Last Name]  
myRARE Coordinator

**PAGE 5**

**Benefits review**

- myRARE® will schedule time or call to review the coverage information once it is available to confirm the access plan

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.





# Pursuing coverage

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

# > Pursuing coverage

## Prior authorization checklist

Your patient’s health plan will likely require a PA before it approves EVKEEZA. This checklist provides information about the process. When submitting a PA request for EVKEEZA, you can use this checklist to ensure you are providing the essential information requested by the health plan. Keep in mind that PA requirements may vary, so check with your patient’s health plan to ensure you have an accurate list of requirements before you submit.

**Note:** Following a health plan’s guidelines does not guarantee the patient’s health plan will provide reimbursement for EVKEEZA, and the guidelines are not intended to substitute for or influence the physician’s independent medical judgment.

### Tips for submitting a PA for EVKEEZA

- Complete a PA form.** Some plans accept a standardized PA form, while others require you to complete a form they provide. Make sure you include:
  - Patient and provider contact information
  - The provider’s signature to attest to the validity and accuracy of the information provided
  
- Write a Letter of Medical Necessity,** if required. If the PA form does not have fields to sufficiently outline the clinical need, a Letter of Medical Necessity is an option to include additional context to the request for coverage. A sample Letter of Medical Necessity providing general guidelines is available by visiting [www.EVKEEZAhcp.com/s/support-resources](http://www.EVKEEZAhcp.com/s/support-resources) or through your FRM
  
- Attach copies of the front and back of the patient’s health plan card**
  
- Provide additional documentation,** where applicable, that supports your treatment rationale. To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible:
 

<ul style="list-style-type: none"> <li>• Prescribing Information for EVKEEZA</li> <li>• Complete history of patient’s prior and current therapies and their outcomes</li> <li>• Clinical notes outlining your diagnosis for the patient and method of diagnosis</li> <li>• Laboratory results</li> </ul>	<ul style="list-style-type: none"> <li>• Patient’s history and current condition</li> <li>• Associated symptoms</li> <li>• Relevant comorbidities</li> <li>• Summary of your professional opinion of the patient’s likely prognosis or disease progression without treatment</li> </ul>
--	---

> **Tip:** Review the patient’s completed myRARE® Start Form, Section 6, Clinical Status, for any relevant documents on treatment history and family history of familial hypercholesterolemia (FH)

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# > Pursuing coverage (cont'd)

## Prior authorization checklist (cont'd)

### Common causes for coverage denials

Be sure to double-check documentation and paperwork for **errors or incomplete information** that may lead to a denial for EVKEEZA. Reasons for denial may include:

- Lack of documentation supporting appropriate diagnosis for treatment with EVKEEZA
- Outdated lab panels (per health plan time requirement)
- Documentation that was submitted did not support health plan’s criteria for approving EVKEEZA, for example:
  - The patient was not treated with prior therapies required by the health plan without justification (if applicable)
  - Missing data regarding treatment with prior therapies (for example, trial dates or dosage)
  - No reason was given for discontinuing previous therapies

#### To help mitigate PA denials

- Learn about the health plan’s preference for submitting materials (for example, do they prefer email, fax, phone, or via an online portal) and develop a summary sheet of the health plan’s requirements for future use
- Double-check documentation when you submit your PA request
- Follow up with the health plan to ensure all information was received and is clear
- Inquire how long a decision will take once the completed PA is submitted

As a provider, you are solely responsible for billing third-party payers correctly, and you should determine if any payer-specific guidelines apply. The information provided here is general in nature and is not intended to be conclusive or exhaustive, nor is it intended to replace the guidance of a qualified professional advisor.

**For additional assistance** in completing PA forms, please refer to the EVKEEZA Coverage Worksheets, available through your FRM. The worksheets can help you document the medical necessity for EVKEEZA in appropriate patients.

#### Reach us at



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



Visit [www.EVKEEZAhcp.com](http://www.EVKEEZAhcp.com)  
for more information

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



## > Requesting a medical exception

You may consider including a **Letter of Medical Exception** if coverage for EVKEEZA is denied because of the health plan’s policy or if EVKEEZA is subject to a National Drug Code (NDC) block.

> **Tip:** Be sure to populate the appropriate ICD-10-CM code. Ensure the specific diagnosis of HoFH is referenced in a medical exception letter if submitted with the PA.

### Medical exception checklist

Some health plans require a medical exception letter. Regardless, it can be helpful to provide supporting documentation,\* such as:

- ✓ Patient medical records
- ✓ Supporting clinical studies
- ✓ Patient photographs
- ✓ Letter of Medical Necessity

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

\*To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.





# Sample Letter of Medical Exception

> Sample letters may be downloaded at [www.EVKEEZAhcp.com/s/support-resources](http://www.EVKEEZAhcp.com/s/support-resources) or provided by your myRARE® Coordinator upon request

**Sample Letter of Medical Exception**

This letter provides an example of the types of information that may be required when writing a Letter of Medical Exception for EVKEEZA. It is important to note that supplying the information listed in this letter does not guarantee the health plan will provide reimbursement for EVKEEZA, and this information is not intended to be a substitute for or influence the physician's independent medical judgment. The sample letter is provided for your guidance only.

Some key reminders:

- You may consider including a Letter of Medical Exception if coverage for EVKEEZA is denied because of the health plan's policy or if EVKEEZA is subject to a National Drug Code block
- Be sure to populate the appropriate ICD-10-CM code. Ensure the specific diagnosis of HoFH is referenced in the letter

Some health plans require a Letter of Medical Exception along with supporting documentation,\* such as:

- Patient medical records
- Supporting clinical studies
- Patient photographs
- Letter of Medical Necessity

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification.*  
 \*To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible.


**INDICATION**

EVKEEZA is an angiotensin-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.

**IMPORTANT SAFETY INFORMATION**

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

**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 additional Important Safety Information on next page and [click here](#) for full Prescribing Information.

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# > Requesting approval with a Letter of Medical Necessity

You can use a **Letter of Medical Necessity** to provide the reasons that, in your clinical judgment, EVKEEZA is necessary for your patient. The letter should explain **why EVKEEZA is being requested and give health plans additional information** to assess whether the medication can be approved.

### Some key reminders:

- You may consider including a **Letter of Medical Necessity**, like the one on the next page, with your prior authorization request to emphasize the medical necessity for EVKEEZA, or in addition to your appeal letter, as needed
- Letters of Medical Necessity should be signed by the physician only
  - Be sure to populate an appropriate ICD-10-CM code. Ensure the patient’s diagnosis is specified clearly in the letter

### Medical necessity checklist

Some health plans require a Letter of Medical Necessity. Regardless, it can be helpful to provide supporting documentation,\* such as:

- Patient’s medical records
- Peer-reviewed literature
- Supporting clinical studies
- Prescribing Information for EVKEEZA
- Clinical notes and laboratory results

\*To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



# > Sample Letter of Medical Necessity

> Sample letters may be downloaded at [www.EVKEEZAhcp.com/s/support-resources](http://www.EVKEEZAhcp.com/s/support-resources) or provided by your myRARE® Coordinator upon request

**Sample Letter of Medical Necessity**

You can use this sample Letter of Medical Necessity to provide the reasons that, in your clinical judgment, EVKEEZA is necessary for your patient. The letter should explain why EVKEEZA is being requested and give health plans additional information to assess whether the medication can be approved.

Please note that providing such a letter does not guarantee the health plan will offer reimbursement for EVKEEZA, and this information is not intended to be a substitute for or influence the physician's independent medical judgment. The sample letter is provided for your guidance only.

Some key reminders:

- You may consider including a Letter of Medical Necessity, like this one, with your prior authorization request to emphasize the medical necessity for EVKEEZA, or in addition to your appeal letter, as needed
- Letters of Medical Necessity should be signed by the physician only
  - Be sure to populate an appropriate ICD-10-CM code. Ensure the patient's diagnosis is specified clearly in the letter

Some health plans require a Letter of Medical Necessity along with supporting documentation,\* such as:

- Patient's medical records
- Peer-reviewed literature
- Supporting clinical studies
- Prescribing Information for EVKEEZA
- Clinic notes and laboratory results

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification.*  
 \*To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible.

**INDICATION**


EVKEEZA is an angiotensin-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.

**IMPORTANT SAFETY INFORMATION**

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

**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 additional Important Safety Information on next page and [click here](#) for full Prescribing Information.



**Evkeeza**<sup>®</sup>  
(evinacumab-dgnb)  
Injection

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



# > **Appealing PA and medical exception denials**

## Appeal checklist

- ✓ **Double-check** the accuracy of the information provided on the initial PA request
  - Patient information
  - Coding—it is recommended to use the most specific applicable codes. Ensure the specific diagnosis of HoFH is referenced in the Letter of Appeal
- ✓ **Understand** the reason for the denial—it is often included in the denial letter
- ✓ **Review** the plan’s appeal guidelines
  - Deadline to submit appeal
  - Timeline of review by health plan
  - Number of appeals permitted and appeal options (eg, peer-to-peer appeal)
  - Fax number or email address to be used to submit the appeal letter and any additional required information
  - Required additional supporting documentation, such as:
    - Appeal form, if provided by the plan
    - Supporting clinical studies
    - Chart notes
    - Prescribing Information for EVKEEZA
    - Test results
- ✓ **Clarify** any aspect of the appeal process with the health plan’s review department
- ✓ **Prepare** a written appeal. The appeal should be written by the physician (see sample letter on next page). In some cases, the patient can write the appeal
- ✓ **Gather** all required supporting documentation needed to help defend your rationale for coverage for EVKEEZA
- ✓ **Send** the written appeal, along with the supporting documentation, to the health plan for review
- ✓ **Follow up** with the plan on the status of the appeal
- ✓ **Save copies** of all appeal-related documentation, including:
  - Documents submitted with the Letter of Appeal
  - Documents received from the patient’s health plan
  - Health plan representative’s contact information
- ✓ **Contact** myRARE for EVKEEZA with any questions at **1-877-EVKEEZA (1-877-385-3392) Option 1**, Monday–Friday, 9 AM–9 PM Eastern time

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# > Appealing PA and medical exception denials (cont'd)

> Sample letters may be downloaded at [www.EVKEEZAhcp.com/s/support-resources](http://www.EVKEEZAhcp.com/s/support-resources) or provided by your myRARE® Coordinator upon request

### Appeal Checklist and Sample Letter of Appeal

If a health plan receives a prior authorization (PA) request and denies coverage for EVKEEZA for your patient, you may appeal the decision. You can use the checklist on page 3 to help ensure you have taken appropriate steps for a successful appeal, and you can use or adapt the sample Letter of Appeal on page 4 if coverage for EVKEEZA is denied. The sample letter is provided for your guidance only.

Some health plans require a Letter of Appeal along with additional documentation, such as:

- Appeal Form, if provided by the plan
- Chart notes, including clinical cardiac history
- Lipid test results, including LDL-C
- Current or previous lipid therapies
- Family history of coronary disease, particularly if it occurred at an early age for the patient's parents
- Supporting clinical studies
- Peer-reviewed literature
- Prescribing Information for EVKEEZA

It is important to note that supplying the information for the appeal does not guarantee the health plan will provide reimbursement for EVKEEZA. The information is not intended to substitute for or influence the physician's independent medical judgment.

Visit [EVKEEZAhcp.com](http://EVKEEZAhcp.com) for more information, including full Prescribing Information.

There are numerous reasons why health plans may deny a PA for EVKEEZA. Although the reasons vary by plan, some of the most common include:

- Insufficient documentation on the PA request
- Health plan claims lack of medical necessity for EVKEEZA
- EVKEEZA is not covered by the patient's health plan because it is a rare disease medication, requiring escalation

Please keep in mind, just as reasons for denial vary, so do each health plan's requirements for the appeal. It is important to check with the patient's health plan to ensure you have all the information you need to proceed with the appeal.

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; LDL-C=low-density lipoprotein cholesterol.

### INDICATION

EVKEEZA is an angiotensin-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.

### IMPORTANT SAFETY INFORMATION

#### Contraindication

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

#### 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 additional Important Safety Information on next page and [click here](#) for full Prescribing Information.



Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).





**Evkeeza**<sup>®</sup>  
(evinacumab-dgnb)  
Injection

# Ordering

## EVKEEZA

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

Introduction

Patient access with myRARE<sup>®</sup>

Benefits verification

Pursuing coverage

Ordering

Coding and billing

Financial support options

## > Ordering EVKEEZA

Once you have confirmed that your patient has coverage for EVKEEZA and determined whether EVKEEZA will be acquired through a buy-and-bill or “white bagging” arrangement, you can begin coordination of product acquisition.

### EVKEEZA product acquisition

EVKEEZA is available in 2 vial sizes:

Drug name/strength	11-digit NDC #
> EVKEEZA 345 mg/2.3 mL (150 mg/mL)	61755-0013-01
> EVKEEZA 1200 mg/8 mL (150 mg/mL)	61755-0010-01

Vial size and quantity should be selected to minimize the amount of waste.

### EVKEEZA is available through 2 distribution channels



#### Contracted specialty distributor

Order EVKEEZA from the exclusive authorized distributor, FFF Enterprises, Inc.

**Phone:** 1-800-843-7477

**Website:** [www.fffenterprises.com](http://www.fffenterprises.com)



#### Contracted specialty pharmacy

A payer may direct your office, or your office may choose, to obtain EVKEEZA from a specialty pharmacy. Orsini Specialty Pharmacy is the exclusive specialty pharmacy for EVKEEZA.

**Phone:** 1-800-410-8575

**Website:** [www.orsini.com](http://www.orsini.com)

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



## > Delivery and storage considerations for EVKEEZA



**Watch for deliveries:** EVKEEZA is shipped in an insulated box with gel packs sufficient to keep its temperature at 2 °C to 8 °C for at least 24 hours from the time it leaves the distributor or specialty pharmacy. Ensure staff is watching for the package.



**Inspect and unpack:** Deliveries to the office should be immediately inspected for damage, then opened, unpacked, and contents placed into the office’s medication refrigerator. Follow the storage and handling instructions in the EVKEEZA Prescribing Information. Promptly report any delivery damage to the distributor or specialty pharmacy.



**Rotate stock:** When placing EVKEEZA into the medication refrigerator, it is a good idea to inspect current stock, including expiration dates, and to rotate the stock if it is not patient specific. Use stock with the closest expiration date first.



**Monitor and protect:** To best protect your inventory of EVKEEZA, refrigerators should have temperature monitoring and alarm devices for deviations. Calibration is also a good practice. Because power outages may occur without warning, consider using a backup generator.

### Product return information

In the event EVKEEZA is rendered unusable after purchase or receipt, product may be returned to Regeneron and replaced in certain circumstances. Returns are subject to adherence to Regeneron policies and procedures regarding the return of product and the rights of Regeneron, at its sole discretion, to deny replacement when misuse is suspected. **All product should be returned as a condition of replacement.\***

### Product return procedure

1. myRARE® can help you assess what return options may be available for your situation or you can work directly with Regeneron Medical Information by calling **1-877-EVKEEZA** (1-877-385-3392) and select **Option 4**
2. Complete the Return Product Eligibility Certification form in its entirety and return with the following:
  - a. Proof of purchase for units being returned or other documentation as requested
  - b. In the case of broken vial(s), pictures documenting the damage
3. Completed forms and supporting documents may be faxed to **1-615-827-0164** or emailed to **return@regeneron.com**
4. Hold/quarantine the product to be returned and follow instructions in the product retrieval kit
5. Once approved, replacement product typically ships within 1 business day of approval of the request

For returns of product damaged in shipment, please contact your distributor or specialty pharmacy.

For product complaints, please call

**1-877-EVKEEZA** (1-877-385-3392) **Option 4**, Monday–Friday, 9 AM–9 PM Eastern time

\*Broken vial(s) do not have to be returned, but pictures documenting the damage should be submitted. Subject to certain exceptions in accordance with Regeneron policy.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.





# Coding and billing

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# A resource for coding, billing, and reimbursement of EVKEEZA

This section provides **coding and billing information** to assist you with understanding the **reimbursement of EVKEEZA administered in the office or hospital outpatient setting.**



**This section includes:**

- **Diagnosis coding:** ICD-10-CM codes
- **Administration coding:** Current Procedural Terminology (CPT®) codes\*
- **Product coding:** Healthcare Common Procedure Coding System (HCPCS) Level II codes
- **Revenue codes**
- **Product information**



The following 2 most common billing claim forms from the Centers for Medicare & Medicaid Services (CMS) are available at [www.cms.gov/medicare/forms-notice/cms-forms-list](http://www.cms.gov/medicare/forms-notice/cms-forms-list):

- **CMS-1500** (print) or 837P (electronic) for physician office reimbursement
- **UB-04** (also known as CMS-1450) (print) or 837I (electronic) for hospital outpatient reimbursement

The coding information discussed in this guide is provided for informational purposes only, is subject to change, and should not be construed as legal advice. The codes listed herein may not apply to all patients or to all health plans. Conversely, additional codes not listed in this guide may apply to some patients. Providers should follow payer-specific coding requirements and exercise independent clinical judgment when selecting codes and submitting claims to accurately reflect the services and products furnished to a specific patient. Information provided in this guide is effective as of **October 2025.**

\*CPT Copyright 2025 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# > A resource for coding, billing, and reimbursement of EVKEEZA (cont'd)

## Diagnosis coding: ICD-10-CM codes

The diagnosis code selected should reflect the highest level of specificity available as documented in the patient’s medical record.

The following ICD-10-CM diagnosis code is the most specific code available for homozygous familial hypercholesterolemia (HoFH).

ICD-10-CM code	Description
E78.010	Homozygous familial hypercholesterolemia (HoFH)

## Administration coding: CPT codes for EVKEEZA

CPT codes are assigned by physicians and by hospitals for outpatient services involving the administration of medications, including EVKEEZA.

EVKEEZA is an angiopoietin-like 3 antibody 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 HoFH. EVKEEZA is delivered by intravenous (IV) infusion.

The following CPT codes apply to the administration of EVKEEZA.

CPT code	Description
<i>IV administration—therapeutic codes</i>	
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
<i>IV administration—chemotherapy codes</i>	
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug

LDL-C=low-density lipoprotein-cholesterol.

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# > A resource for coding, billing, and reimbursement of EVKEEZA (cont'd)

## Product coding: HCPCS Level II codes for EVKEEZA

### > Permanent J-code

HCPCS Level II codes help identify medications, including EVKEEZA, and are assigned in addition to the CPT code.

HCPCS J-code	Description	Billing units
J1305	Injection, evinacumab-dgnb, 5 mg	5 mg=1 billing unit

Medicare requires the use of the JW modifier for reporting discarded amounts of drug. **Effective July 1, 2023**, the JZ modifier is required for reporting there was no discarded drug.

## Revenue coding for hospital administration

Revenue codes allow hospitals to capture cost data for billing of services provided.

Revenue code	Description
<i>Administration</i>	
0510	Clinic
0500	Outpatient services
<i>Drug</i>	
0636	Drugs requiring detailed coding
0250	Drugs and biologicals
0260	IV therapy

### > Product information for EVKEEZA

Drug name/strength	10-digit NDC #	11-digit NDC #*
EVKEEZA 345 mg/2.3 mL (150 mg/mL)	61755-013-01	61755-0013-01
EVKEEZA 1200 mg/8 mL (150 mg/mL)	61755-010-01	61755-0010-01

\*The product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets general billing standards. The zero-fill location is indicated in bold.

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).





## > Example scenarios

Please see the below **example dosing scenarios** for EVKEEZA and how they may be recorded on the **CMS-1500 form**. Check with the applicable payer for specific requirements.



### Dosing example 1

**Patient weight: 55 kg (121 lb)**

15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **825 mg**

# of 345 mg/2.3-mL vials required: 3

# of 1200 mg/8.0-mL vials required: 0

- **Box 24 A:** In the red shaded area, the NDC should be submitted using “N4” followed by the 11 digits, quantity qualifier, and units of measure; in this case, N461755001301ML6.9

- **Box 24 G:** An 825-mg dose would be billed as “J1305: 165 units; J1305-JW: 42 units” (5 mg of EVKEEZA=1 billing unit)



### Dosing example 2

**Patient weight: 75 kg (165 lb)**

15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **1125 mg**

# of 345 mg/2.3-mL vials required: 0

# of 1200 mg/8.0-mL vials required: 1

- **Box 24 A:** In the red shaded area, the NDC should be submitted using “N4” followed by the 11 digits, quantity qualifier, and units of measure; in this case, N461755001001ML8.0

- **Box 24 G:** An 1125-mg dose would be billed as “J1305: 225 units; J1305-JW: 15 units” (5 mg of EVKEEZA=1 billing unit)



### Dosing example 3

**Patient weight: 92 kg (203 lb)**

15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **1380 mg**

# of 345 mg/2.3-mL vials required: 4

# of 1200 mg/8.0-mL vials required: 0

- **Box 24 A:** In the red shaded area, the NDC should be submitted using “N4” followed by the 11 digits, quantity qualifier, and units of measure; in this case, N461755001301ML9.2

- **Box 24 G:** A 1380-mg dose would be billed as “J1305-JZ: 276 units” (5 mg of EVKEEZA=1 billing unit)



### “White-bagging” scenario

When an EVKEEZA prescription is filled by a third party, such as a specialty pharmacy, the provider only bills for the administration of the product. The product’s J-code should still be included on the form, but the rate should be recorded as “0” or a nominal amount (eg, \$0.01) or as accepted by the payer

**Patient weight: 113 kg (249 lb)**

15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **1695 mg**

# of 345 mg/2.3-mL vials required: 2

# of 1200 mg/8.0-mL vials required: 1

- **Box 24 A:** In the red shaded area, the NDC should be submitted using “N4” followed by the 11 digits, quantity qualifier, and units of measure; in this case, 2 different vial sizes are used and are listed separately, N461755001301ML4.6 and N461755001001ML8.0

- **Box 24 F:** In a white-bagging scenario, enter 0 or a nominal amount for the charges

- **Box 24 G:** A 1695-mg dose would be billed as “J1305: 339 units; J1305-JW: 39 units” (5 mg of EVKEEZA=1 billing unit)

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.



## > Sample annotated CMS UB-04 form<sup>2\*</sup>

The CMS UB-04 form is commonly used for billing for EVKEEZA when it is administered in hospital outpatient settings.

This sample claim form is intended for informational purposes only. The coding information provided is subject to change and should not be construed as billing advice. Use of the coding information provided is not a guarantee that reimbursement will be provided. Providers are responsible for ensuring that claims submitted are appropriate and accurately reflect the services and products furnished to a specific patient. There are 81 fields or lines on a UB-04 form and they are referred to as Form Locators (FL). Please confirm the accuracy of the codes you use to bill for EVKEEZA with each payer.

FL 42

List revenue codes in ascending order. Enter the appropriate numeric revenue code in FL 42 to explain each charge in FL 47

FL 43

For each revenue code reported in FL 42, provide a narrative description or standard abbreviation in FL 43. If an NDC is required, submit "N4" followed by the 11-digit NDC, quantity qualifier, and units of measure. If using both vial sizes, these values should be listed separately

FL 44

Enter the appropriate CPT and HCPCS codes and modifiers for procedures, services, and supplies, as required by the specific payer. Medicare and most payers require drug waste to be recorded. Enter HCPCS code J1305 and use modifier JZ if zero drug was wasted (ie, J1305-JZ) or record waste on a separate line with the JW modifier (ie, J1305-JW)

FL 46

Enter the number of EVKEEZA units administered. If a separate line item was created for waste as J1305-JW, clearly indicate the number of units discarded. Both lines will be processed for payment

FL 67

Enter the appropriate ICD-10-CM diagnosis code(s) for the patient's diagnosis

The image shows a sample CMS UB-04 form with several callouts pointing to specific fields:

- FL 42:** Points to the 'REVENUE CODE' column (FL 42) in the procedure table.
- FL 43:** Points to the 'DESCRIPTION' column (FL 43) in the procedure table.
- FL 44:** Points to the 'CPT / HCPCS CODE' column (FL 44) in the procedure table.
- FL 46:** Points to the 'UNITS' column (FL 46) in the procedure table.
- FL 67:** Points to the 'ICD-10-CM CODE' column (FL 67) in the procedure table.

The form includes sections for patient information (1-10), admission and condition codes (11-29), procedure codes and amounts (30-37), HCPCS codes and amounts (38-49), payer information (50-57), insurer information (58-62), and other administrative fields (63-79).

\*CMS 837I (not shown) is the electronic equivalent of CMS-1450/UB-04. It should be used if you submit your claims electronically.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.

my  
**RARE**  
for Evkeeza® (evinacumab-dgnb)

**Evkeeza**<sup>®</sup>  
(evinacumab-dgnb)  
Injection

# > Example scenarios

Please see the below **example dosing scenarios** for EVKEEZA and how they may be recorded on the **CMS UB-04 form**. Check with the applicable payer for specific requirements.

**Dosing example 1**  
**Patient weight: 55 kg (121 lb)**  
 15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **825 mg**  
 # of 345 mg/2.3-mL vials required: 3  
 # of 1200 mg/8.0-mL vials required: 0

- **FL 42 and 43:** Insert the revenue codes in ascending order. In this case, 0510 was used for the clinic and 0636 was used for the product. The NDC should be submitted using “N4” followed by 11 digits, quantity qualifier, and units of measure; in this case, N461755001301ML6.9
- **FL 45:** Include date of service
- **FL 46:** An 825-mg dose would be billed as “J1305: 165 units; J1305-JW: 42 units” (5 mg of EVKEEZA=1 billing unit)

**Dosing example 2**  
**Patient weight: 75 kg (165 lb)**  
 15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **1125 mg**  
 # of 345 mg/2.3-mL vials required: 0  
 # of 1200 mg/8.0-mL vials required: 1

- **FL 42 and 43:** Insert the revenue codes in ascending order. In this case, 0510 was used for the clinic and 0636 was used for the product. The NDC should be submitted using “N4” followed by 11 digits, quantity qualifier, and units of measure; in this case, N461755001001ML8.0
- **FL 45:** Include date of service
- **FL 46:** An 1125-mg dose would be billed as “J1305: 225 units; J1305-JW: 15 units” (5 mg of EVKEEZA=1 billing unit)

**Dosing example 3**  
**Patient weight: 92 kg (203 lb)**  
 15 mg/kg of EVKEEZA® (evinacumab-dgnb) required: **1380 mg**  
 # of 345 mg/2.3-mL vials required: 4  
 # of 1200 mg/8.0-mL vials required: 0

- **FL 42 and 43:** Insert the revenue codes in ascending order. In this case, 0510 was used for the clinic and 0636 was used for the product. The NDC should be submitted using “N4” followed by 11 digits, quantity qualifier, and units of measure; in this case, N461755001301ML9.2
- **FL 45:** Include date of service
- **FL 46:** A 1380-mg dose would be billed as “J1305-JZ: 276 units” (5 mg of EVKEEZA=1 billing unit)

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.





# Financial support options for EVKEEZA

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

# > Financial support options for EVKEEZA

myRARE® is a Patient Support Program for EVKEEZA that offers your patients a range of support services. myRARE can explain the features and requirements of the support offered.

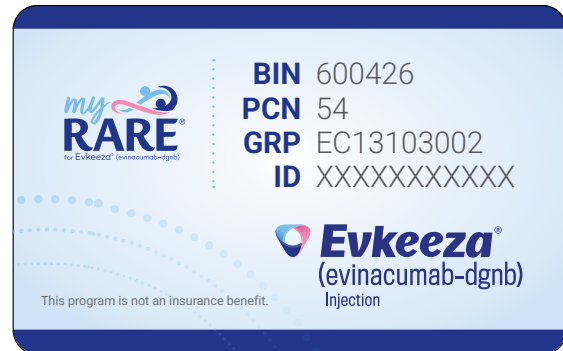
## myRARE Copay Card for EVKEEZA\*

Patients may pay as little as \$0 copay for EVKEEZA, up to a \$25,000 calendar year maximum.

### Program eligibility criteria:

- Patient has private (commercial) insurance with approved coverage for EVKEEZA
- Patient has a **valid prescription** for an FDA-approved indication
- Patient **lives in the 50 United States, the District of Columbia, or Puerto Rico**
- There is **no income requirement** to qualify for this program

*Other conditions may apply. Visit EVKEEZA.com for full terms and conditions.*



For eligible patients, the program covers: Up to \$25,000 in assistance per calendar year toward EVKEEZA patient out-of-pocket treatment costs, including deductibles, copays, and coinsurance for drug and administration charges.†

### There are 3 ways patients can enroll in the myRARE Copay Card Program

- 1 Visit [www.myRARE.com](http://www.myRARE.com) to enroll through our patient engagement site
- 2 **Work with their doctor to fill out an EVKEEZA Start Form**—Copay enrollment will be completed for all eligible patients who are confirmed to have commercial insurance through the myRARE benefits investigation process
- 3 Call **1-877-EVKEEZA** (1-877-385-3392) **Option 1**, Monday–Friday, 9 AM–9 PM Eastern time, to be screened for eligibility

FDA=US Food and Drug Administration.

\*Not an insurance or debit card program. This program is not valid for prescriptions covered by or submitted for reimbursement under Medicaid, Medicare, Veterans Affairs, Department of Defense, TRICARE, or similar federal or state programs. This program does not cover or provide support for supplies for EVKEEZA. This program is not valid where prohibited by law, taxed, or restricted. Patients who are residents of Rhode Island or Massachusetts are not eligible for EVKEEZA administration assistance. myRARE reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Additional program conditions apply. See EVKEEZA.com.

†Administration charge coverage is effective for dates of service of January 23, 2023, and beyond.

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).



# > myRARE® Patient Assistance Program for EVKEEZA

The PAP can help eligible patients who are uninsured or functionally uninsured to receive EVKEEZA at no cost.

**Up to 12 months of EVKEEZA at no cost for eligible patients\*:**

- Income of **≤500% of the federal poverty level OR \$100,000**
- **Insurance status:**
  - Uninsured: no medical OR pharmacy benefits
  - Functionally uninsured: coverage and all available appeals are clinically denied
  - Medicare Advantage and Part D: out-of-pocket costs exceed 5% of patient’s monthly income

Additional criteria and program conditions apply.

## > Additional patient support

### myRARE alternate coverage referral

myRARE offers support for eligible patients without insurance coverage or with inadequate insurance coverage for EVKEEZA and may provide information to HCPs about third-party, alternate coverage resources.

myRARE will identify these potential resources, explain the support they provide, and give the patient the necessary program contact information (names, phone numbers, and locations). myRARE does not influence or control alternate coverage resources and cannot guarantee that support will be provided.

### Referrals to ancillary support groups

myRARE can help connect patients with additional support that may enable and empower them to start and stay on therapy.

\*Qualified Medicare patients are eligible until December 31 of the enrollment year.

Please see Important Safety Information on pages 3 and 4 and full Prescribing Information.




## > References

1. Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 26: completing and processing form CMS-1500 data set. Updated August 9, 2024. Accessed October 2, 2025. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>
2. Centers for Medicare & Medicaid Services. Medicare claims processing manual. Chapter 25: completing and processing the form CMS-1450 data set. Updated December 20, 2023. Accessed October 2, 2025. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf>

Please see Important Safety Information on pages 3 and 4 and full [Prescribing Information](#).

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