**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 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. Please note there is no distinction for the code for familial hypercholesterolemia (FH) between heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH). 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 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.

**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 EVKEEZAinfusion, 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**](https://www.regeneron.com/sites/default/files/Evkeeza_PI.pdf) **for full Prescribing Information.**

**IMPORTANT SAF****ETY INFORMATION (cont’d)**

**Warnings and Precautions (cont’d)**

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

**Adverse Reactions**

**Adults and Pediatric Patients (12 to 17 years):** Common adverse reactions (≥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** [**click here**](https://www.regeneron.com/sites/default/files/Evkeeza_PI.pdf) **for full Prescribing Information.**

For assistance, call us at **1-877-EVKEEZA** (1-877-385-3392) Monday–Friday, 9 am–9 pm Eastern time.



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03/2023 EVK.23.02.0006

**Sample letter of medical necessity**

[Use physician’s letterhead]

[Date]

[Health Plan Contact Name]

[Title]

[Health Plan Organization Name]

[Address]

[City, State ZIP]

Re: [Subject line]

Patient: [Patient Name]

Date of Birth:[Patient DOB]

Insurance Policy ID Number: [Policy ID Number]

Group Number: [Group Number]

Claim Number: [Claim Number]

Dear [Health Plan Contact Name],

I am writing on behalf of my patient, [Patient full name], to document the medical necessity of EVKEEZA® (evinacumab-dgnb). Included below is additional information about the patient’s medical history and diagnosis of [diagnosis] (ICD-10-CM code: [code]), as well as a statement summarizing my treatment rationale.

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

**Overview of HoFH**

Homozygous familial hypercholesterolemia (HoFH) is an ultra-rare, inherited genetic disorder of lipid metabolism.1,2 HoFH is characterized by markedly elevated plasma levels of LDL-C, and the current estimated prevalence is 1 in 250,000 individuals.1-4 HoFH occurs when two copies of the alleles bearing the familial hypercholesterolemia (FH)-causing genes are inherited, one from each parent.1 Physical signs are generally severe and occur at an earlier age in patients with HoFH.2 Patients with HoFH generally have poor response to standard drug therapy and poor prognosis.3,5-9

HoFH represents a considerable burden for patients due to physical signs and limitations caused by the disease, as well as a number of psychosocial factors.1

**Summary of Patient’s Medical History** *Note to physician: Modify this section as appropriate based on your clinical judgment of the patient’s diagnosis and medical condition.*

The patient’s medical history includes [information from clinical diagnosis; information that summarizes the patient’s treatment history; response to past therapies; any recent symptoms and conditions, if applicable; opinion of the patient’s prognosis with and without treatment with EVKEEZA; and the length of time the patient is anticipated to stay on therapy.]

1. Confirmation of patient HoFH clinical diagnosis (directly reference diagnostic criteria outlined in insurance coverage policy):
	* Age at diagnosis and diagnosing clinician [indicate patient report/documentation attached]
	* Untreated cholesterol values [indicate patient report/documentation attached]
	* Treated cholesterol values with standard lipid-lowering therapies (statin, ezetimibe) [indicate patient report/documentation attached]
		+ If not available – directly indicate not available and why
		+ Consider using estimated LDL-C value with statin and/or ezetimibe treatment, based on clinically verifiable sources
	* Familial evidence of high cholesterol, cardiac events
		+ Indicate whether reported by patient, documented, or unavailable and why
		+ Provide for both parents, or if not available indicate why
	* History regarding xanthomas or xantholasmas and age of first presentation
2. Information regarding the patient’s current LDL-C control relative to thresholds established in guidelines, for example a patient with ASCVD or high-risk ASCVD1,10,11
	* Recent LDL-C value with current lipid-lowering therapy regimen
	* Please state target LDL-C for the patient and rationale (associated risk factors)
	* Include your medical prognosis for the patient based on current LDL-C level without additional treatment

[Product Information: Placeholder to include any relevant information copied from PI.]

In summary, EVKEEZA is medically necessary for this patient’s rare medical condition, and [health plan name] should cover this product for my patient without delay. Please contact me at [phone number] if additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician’s name, degree(s), participating provider ID number, and signature]

Enclosures: [Attach EVKEEZA Prescribing Information any additional documentation, as appropriate]

**References: 1.** Cuchel M et al. *Eur Heart J*. 2014;35(32):2146-2157. **2.** Raal FJ et al. *Atherosclerosis*. 2018;277:483-492. **3.** U.S. Food and Drug Administration. April 1, 2021. Accessed October 25, 2022. https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-add-therapy-patients-genetic-form-severely-high-cholesterol **4.** de Ferranti SD et al. *Circulation*. 2016;133(11):1067-1072. **5.** Ito MK et al. *Drugs.* 2015;75:1715-1724. **6.** Bruckert E. *Atheroscler Suppl*. 2014;15(2):26-32. **7.** Thompson GR et al. *Eur Heart J*. 2018;39(14):1162-1168. **8.** Tromp TR et al. *Lancet.* 2022;399(10326):719-728. **9.** Bajaj A and Cuchel M. *J Atheroscler Thromb*. 2022;29(8):1125-1135. **10.** Gidding SS et al. *Circulation*. 2015;132(22):2167-2192. **11.** Lloyd-Jones DM et al. *J Am Coll Cardiol*. 2022;80(14):1366-1418.