 **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 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. Please note there is no distinction in the code for heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH). Ensure the specific diagnosis of HoFH is referenced in the letter

Some health plans require a medical exception letter 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 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.

**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** **SAFETY INFORMATION (cont’d)**

**Warnings and Precautions (cont’d)**

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

**Adverse Reactions**

**Adults and Pediatric Patients (12 to 17 years):** Common adverse reactions (≥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.23.02.0008

**Sample letter of medical exception**

[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 to request a medical exception for [Patient full name] for the treatment of [diagnosis] with EVKEEZA® (evinacumab-dgnb). It is my professional opinion that EVKEEZA is medically appropriate and necessary and should be covered and reimbursed for this patient.

EVKEEZAis 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 poorer 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.*

[Patient full name] has been under my care for [diagnosis] since [date of diagnosis]. Included for your consideration is [Patient first name]’s medical history and diagnosis of [diagnosis] (ICD-10-CM code: [code]), a statement summarizing my reasons for treating [Patient full name] with EVKEEZA, and a copy of the Prescribing Information for EVKEEZA.

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; and opinion of the patient’s prognosis with and without treatment with EVKEEZA.]

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

In summary, it is my professional judgment that it is in the best interest of [Patient full name] to be treated with EVKEEZA® (evinacumab-dgnb), and I am requesting approval for treatment with EVKEEZA. Please call me at [phone number] if I can be of further assistance or if you require additional information.

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.