AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Evkeeza® (evinacumab-dgnb) **(J1305) (Medical)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Requested Medication is ONE of the following:

- ❑ New Start
- ❑ Continuation of therapy – provide therapy start date: _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage: IV: 15 mg/kg every 4 weeks

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 1 year of age or older

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- ❑ Requested medication is prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology
- ❑ Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment **(submit labs from the past 30 days with request)**
- ❑ Member does **NOT** have heterozygous familial hypercholesterolemia (HeFH)
- ❑ Member has a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by at least **ONE** of the following:
  - ❑ Documented DNA test for functional mutation(s) in LDL receptor alleles or alleles known to affect LDL receptor functionality **(submit test results with request)**
  - ❑ Untreated LDL-C > 500 mg/dL **OR** treated LDL-C ≥ 300 mg/dL along with **ONE** of the following
    - ❑ Cutaneous or tendon xanthoma before 10 years of age
    - ❑ Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (> 190 mg/dL)
- ❑ Member has been receiving stable background lipid lowering therapy for at least 4 weeks **(verified by pharmacy paid claims)**
- ❑ Requested therapy will be used in conjunction with a low-fat or heart-healthy diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, LDL apheresis)
- ❑ Member has had an unsuccessful 3-month trial of **ALL** the following, unless not FDA-approved for use in the member's age **(verified by pharmacy paid claims and/or submitted genetic test results)**:
  - ❑ Highest available (or maximally tolerated) dose of atorvastatin **OR** rosuvastatin
  - ❑ ezetimibe (Zetia®)
  - ❑ PCSK9 inhibitor indicated for HoFH (e.g., Repatha), unless contraindicated or if pathogenic/likely pathogenic null-null variant (e.g. LDLR, APOB, PCSK9, or LDLRAP1) is confirmed by genetic testing
- ❑ Despite pharmacological treatment with a PCSK9 inhibitor, maximally tolerated statin therapy, and ezetimibe, the member's LDL cholesterol remains ≥ 100 mg/dL (or ≥ 70 mg/dL for members with clinical atherosclerotic cardiovascular disease [ASCVD]) while on therapy **(submit pre- and post-treatment cholesterol labs)**
- ❑ If there has been **no response** to a PCSK9 inhibitor (e.g. after an adherent trial, labs show LDL-C has remained the same or increased), PCSK9 inhibitor therapy will be discontinued (**NOTE**: PCSK9 inhibitor therapy may be continued with Evkeeza if LDL-C lowering has been demonstrated while on a PCSK9 inhibitor)

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***Provider please note: If the member is not able to use the maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms**

- ❑ Member must meet **ONE** of the following:
  - ❑ Clinical documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue in addition to **ALL** the following:
    - ❑ Muscle symptoms resolve after discontinuation of statin
    - ❑ Muscle symptoms occurred when re-challenged at a lower dose of the same statin
    - ❑ Muscle symptoms occurred after switching to an alternative statin
    - ❑ Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease)
  - ❑ Member has been diagnosed with rhabdomyolysis associated with statin use and the diagnosis is supported by acute neuromuscular illness or dark urine **AND** an acute elevation in creatine kinase (usually > 5,000 IU/L or 5 times the upper limit of normal [ULN])

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Requested therapy continues to be used in conjunction with a low-fat or heart-healthy diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, LDL apheresis)
- ❑ Member has **NOT** experienced any unacceptable toxicity from therapy (e.g., severe hypersensitivity)
- ❑ Member has experienced a reduction in LDL-C when compared to the initial baseline labs **(submit labs collected within the last 3 months)**

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** ~~3/12/2021; 5/25/2023;~~ ~~11/20/2025;~~ **9/24/2026**
REVISED/UPDATED/REFORMATTED: ~~6/30/2021; 10/11/2021; 10/27/2021;5/15/2023, 12/12/2025;~~ **10/15/2026**