SENTARA HEALTH PLANS

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

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

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **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.

Quantity Limit (max daily dose) [NDC Unit]:

- **Evkeeza 345 mg/2.3 mL single-dose vial: 2 vials per 28 days**
- **Evkeeza 1200 mg/8 mL single-dose vial: 1 vial per 28 days**

Max Units (per dose and over time) [HCPCS Unit]:

- **1690 mg every 28 days**

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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 5 years of age or older
- ❑ 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 **(please submit labs with request)**
- ❑ Member does **NOT** have heterozygous familial hypercholesterolemia (HeFH)
- ❑ Requested medication is prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology
- ❑ 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, Juxtapid, LDL apheresis)
- ❑ Member has had an unsuccessful 3-month trial of **ALL** the following **(verified by pharmacy paid claims)**:
  - ❑ Highest available (or maximally tolerated) dose of atorvastatin **OR** rosuvastatin
  - ❑ ezetimibe (Zetia®)
  - ❑ PCSK9 inhibitor indicated for HoFH (e.g., Repatha), unless contraindicated
- ❑ Despite pharmacological treatment with a PCSK9 inhibitor, maximally tolerated statin therapy, and ezetimibe, the member's LDL cholesterol ≥ 100 mg/dL (or ≥ 70 mg/dL for members with clinical atherosclerotic cardiovascular disease [ASCVD]) while on therapy

***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**

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- ❑ 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, Juxtapid, LDL apheresis)
- ❑ Member has experienced an absence of unacceptable toxicity from therapy (e.g., severe hypersensitivity)
- ❑ Member has had a reduction in LDL-C when compared to the initial baseline labs **(please submit labs collected within the last 30 days)**

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.****