AvMed

PHARMACY 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 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Lipfendra® (enlicitide)

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: _____

Quantity Limit: 30 tablets per 30 days

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: 12 months

Section I. Universal Criteria: Applicable for **ALL** Diagnoses

- ❑ Medication will be used as adjunct to low-fat diet and exercise
- ❑ Provider has **COMPLETED** Sections II, IIIa or IIIb and IV (if applicable) below

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Section II. Diagnosis: (select one below)

❑ Diagnosis: Hypercholesterolemia

- ❑ Member is 18 years of age or older
- ❑ Member meets **ONE** of the following:
  - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL
  - ❑ Member has an estimated 10-year risk for ASCVD greater than 7.5% and a baseline LDL-C between 70 to 189 mg/dL
  - ❑ Member is an adult with diabetes mellitus with LDL-C ≥ 70 mg/dL
  - ❑ Member has Atherosclerotic Cardiovascular Disease (ASCVD) confirmed by at least **ONE** of the following:
    - ❑ History of acute coronary syndrome
    - ❑ Previous myocardial infarction
    - ❑ Stable or unstable angina
    - ❑ Peripheral arterial disease
    - ❑ Coronary artery disease
    - ❑ Member has undergone coronary or other arterial revascularization procedure in the past
    - ❑ History of non-hemorrhagic stroke
    - ❑ History of transient ischemic attack
- ❑ Member does **NOT** have homozygous familial hypercholesterolemia (HoFH)
- ❑ Provider has completed sections IIIa or IIIb and IV (if applicable)

❑ Diagnosis: Heterozygous familial hypercholesterolemia (HeFH)

- ❑ Member is 18 years of age or older
- ❑ Member has heterozygous familial hypercholesterolemia (HeFH) as confirmed by **ONE** of the following:
  - ❑ Member has an untreated low-density lipoprotein cholesterol (LDL-C) ≥ 190 mg/dL (prior to treatment with antihyperlipidemic therapy)
  - ❑ Member has genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene
  - ❑ Member has been diagnosed with heterozygous familial hypercholesterolemia by meeting **ONE** of the following diagnostic criteria thresholds:
    - ❑ Member's Dutch Lipid Network criteria score is > 5
    - ❑ Member's Simone Broome criteria meets the threshold for "definite" or "possible (or probable)" familial hypercholesterolemia

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- ❑ Member does **NOT** have homozygous familial hypercholesterolemia (HoFH)
- ❑ Provider has completed sections IIIa or IIIb and IV (if applicable)

Section IIIa. FOR ALL DIAGNOSES: Skip to Section IIb **IF** member is unable to tolerate statin therapy

- ❑ Member has tried **ONE** of the following statin therapies as a single-entity or combination product for at least 8 consecutive weeks:
  - ❑ High intensity statin therapy with atorvastatin (generic Lipitor) ≥ 40 mg daily
  - ❑ High intensity statin therapy rosuvastatin (generic Crestor) ≥ 20 mg daily
  - ❑ Moderate-intensity statin therapy (member unable to tolerate high intensity therapy)
  - ❑ Low intensity statin therapy (member unable to tolerate moderate intensity therapy
- ❑ Member must meet **ONE** of the following:
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 70 mg/dL
  - ❑ Member's LDL-C after 8-week trial of maximally tolerated statin therapy remains ≥ 55 mg/dL in those with a diagnosis of ASCVD
- ❑ Provide member's LDL levels below **(submit current lab results)**:

  LDL baseline: _____ **LDL post-treatment:** _____

Section IIIb. FOR ALL DIAGNOSES: Contraindication to statin therapy

- Select below if the member is unable to tolerate low, moderate, and high intensity statin therapy as evidenced by intolerable and persistent symptoms to **TWO** different statins (i.e., more than 2 weeks); Please provide previously attempted statin name, strength & therapy initiation date below:

  Drug Name: _____ **Strength:** _____ **Date started:** _____

  Drug Name: _____ **Strength:** _____ **Date started:** _____

  - ❑ Member is unable to tolerate statin therapy due to the occurrence of at least **ONE** of the following symptoms:
    - ❑ Myalgia (muscle symptoms without CK elevations)
    - ❑ Myositis (muscle symptoms with CK elevations < 10 times upper limit of normal)
    - ❑ Member has experienced rhabdomyolysis or muscle symptoms with CK elevations > 10 times upper limit of normal
    - ❑ Member has a labeled contraindication to **ALL** statins as documented in medical records
  - ❑ Re-initiation of statin therapy has been attempted and failed
  - ❑ Provide member's LDL levels below **(submit current lab results)**:

    LDL baseline: _____ **LDL post-treatment:** _____

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Section IV. FOR ALL DIAGNOSES:

- ❑ Member must meet **ONE** of the following:
  - ❑ Member has tried and failed at least 90 days of therapy with Repatha® **(verified by claims, chart notes, and/or labs)**
  - ❑ Member has a contraindication or intolerance to Repatha® **(verified by chart notes and/or labs)**

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.

- ❑ Member has experienced a positive clinical response to Lipfendra® therapy (e.g., decreasing low-density lipoprotein cholesterol (LDL-C), total cholesterol, non-high-density lipoprotein (non-HDL-C)) and continues to have need of requested medication
- ❑ Please provide member's LDL levels below **(submit current lab results)**:

  LDL baseline: _____ **LDL post-treatment:** _____

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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.****