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: Filsuvez® (birch triterpenes) **topical gel**

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight: _____ **Date:** _____

Provider Please Note: For treatment of Junctional Epidermolysis Bullosa (JEB), efficacy of treatment with Filsuvez® has **NOT** been proven to be better than placebo. In the pivotal EASE trial, patients with JEB comprised 11% of the total population (n = 26). At Day 45 (± 7 days), complete wound closure in patients with JEB was greater in patients who received placebo vs. Filsuvez (26.7% vs. 18.6%). Medical necessity approval will be required for treatment of JEB.

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: 3 months

- ❑ Medication will be used for treatment of wounds associated with dystrophic epidermolysis bullosa (DEB) in patients ≥ 6 months of age
- ❑ Member has a diagnosis of DEB confirmed by molecular genetic testing
- ❑ Must be prescribed by or in consultation with a dermatologist or wound care specialist

(Continued on next page)

- ❑ Medication will be applied only to open partial-thickness wounds at dressing changes at least once every 4 days or up to once daily
- ❑ Target wound(s) meets **ALL** the following:
  - ❑ Target wound(s) is clean in appearance and does not appear to be infected
  - ❑ Target wound(s) is 10 cm^2 to 50 cm^2
  - ❑ Target wound(s) is ≥ 21 days and < 9 months old
  - ❑ Squamous cell and/or basal cell carcinoma has been ruled out for the target wound(s)
- ❑ Provider attests treatment will be discontinued until the infection has resolved, if Filsuvez treated wound becomes infected
- ❑ Member has had an unsuccessful 3-month trial of, or contraindication to use of, Vyjuvek™ (beremagene geperpavec-svdt, *medical benefit medication - requires prior authorization*); **Medical chart notes must be submitted for documentation of therapy failure or clinical contraindication to therapy**
- ❑ Medication will **NOT** be used in combination with Vyjuvek™ (beremagene geperpavec-svdt)

Reauthorization: 6 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.

- ❑ Must be prescribed by or in consultation with a dermatologist or wound care specialist
- ❑ Member is currently receiving Filsuvez on previously treated wound(s)
- ❑ All the following criteria must be met **(*Note: If the member is treating a new wound(s) not previously treated with Filsuvez or a reopened recurrent wound(s), then refer to the initial authorization criteria above):**
  - ❑ The target wound(s) remains open
  - ❑ The target wound(s) has decreased in size from baseline **(must submit documentation)**
  - ❑ If a Filsuvez-treated wound becomes infected, treatment will be discontinued until the infection has resolved

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.*