SENTARA HEALTH PLANS

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

<u>Directions</u>: <u>The prescribing physician must sign and clearly print name (preprinted stamps not valid)</u> on this request. All other information may be filled in by office staff; <u>fax to 1-800-750-9692</u>. No additional phone calls will be necessary if all information (including phone and fax $\#_s$) on this form is correct. <u>If the information provided is not complete, correct, or legible, the authorization process can be delayed.</u>

Drug Requested: Filsuvez[®] (birch triterpenes) topical gel

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

Member Name:	
Member Sentara #:	
Prescriber Name:	
Prescriber Signature:	
Office Contact Name:	
Phone Number:	Fax Number:
DEA OR NPI #:	
DRUG INFORMATION: Author	ization may be delayed if incomplete.
Drug Name/Form/Strength:	
	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 <u>NOT</u> 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 (\pm 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 \geq 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 <u>ALL</u> the following:
 - **□** Target wound(s) is clean in appearance and does not appear to be infected
 - $\Box \quad \text{Target wound(s) is 10 cm}^2 \text{ to 50 cm}^2$
 - **\Box** 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 <u>NOT</u> be used in combination with VyjuvekTM (beremagene geperpavec-svdt)

<u>Reauthorization</u>: 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.**

<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>