AETNA BE	TTER HEALTH®		* ad	etna [®]
Coverage Policy/Guideline				
Name:	Filsuvez		Page:	1 of 2
Effective Date: 3/26/2024			Last Review Date:	02/08/2024
Applies to:	⊠Illinois	□Florida	⊠New Jersey	
	⊠Maryland	⊠Florida Kids	⊠Pennsylvania Kids	
	□Michigan	⊠Virginia	\square Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Filsuvez under the patient's prescription drug benefit.

Description:

FDA-Approved Indication

Indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adults and pediatric patients 6 months of age and older.

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Filsuvez

Policy/Guideline:

Submission of the following information is necessary to initiate the prior authorization review:

- A. Medical records documenting clinical manifestations of disease.
- B. Laboratory test results supporting diagnosis.

Prescriber Specialties

This medication must be prescribed by or in consultation with a dermatologist or wound care specialist.

Criteria for Initial Approval

Epidermolysis Bullosa (EB)

Authorization may be granted for treatment of wounds in members with dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) when ALL the following criteria are met:

- A. Member is 6 months of age or older.
- B. Member has clinical manifestations of disease (e.g., extensive skin blistering, skin erosions, scarring).
- C. Member has laboratory test results confirming diagnosis (i.e., genetic testing, immunofluorescence mapping [IFM], or transmission electron microscopy [TEM]).
- D. Filsuvez will not be administered to wound(s) that are currently healed.

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Continuation of Therapy

Epidermolysis Bullosa (EB)

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

- 1. Filsuvez [package insert]. Wahlstedt, Germany: Lichtenheldt GmbH; December 2023.
- 2. Has C, Liu L, Bolling MC, et al. Clinical practice guidelines for laboratory diagnosis of epidermolysis bullosa. *Br J Dermatol.* 2020; 182: 574-592.