Pharmacy Policy Bulletin: J-1345 Filsuvez (birch triterpenes) – Commercial and Healthcare Reform	
Number: J-1345	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1345-002	**Original Date:** 01/31/2024
Effective Date: 12/20/2024	**Review Date:** 12/4/2024

Drugs Product(s):	• Filsuvez (birch triterpenes)
FDA-Approved Indication(s):	• Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.

Background:	• The exact mechanism of action of Filsuvez is unknown. Filsuvez is an herbal product that contains a dry extract from two species of birch bark. This birch bark contains the triterpenes betulin, betulinic acid, erythrodiol, lupeol acid, and oleanolic acid. Birch tree triterpenes are hypothesized to promote would healing through inflammation reduction and stimulation of keratinocytes, which maintain the skin barrier. • Epidermolysis bullosa (EB) is a rare genetic skin disorder characterized by blister formation from mechanical trauma. Dystrophic and junctional epidermolysis bullosa (DEB and JEB, respectively) are two of the four major forms of EB; DEB is caused by mutations in only the COL7A1 gene, while JEB is caused by various genetic mutations including COL7A1, laminin-332, and integrin alpha 6 beta. DEB can be further characterized based on whether the mutation was autosomal dominant (DDEB) or recessive (RDEB). In JEB, blisters form in the lamina lucida connective tissue below the epithelium, and in DEB blisters form in the deeper sublamina densa. JEB accounts for approximately 25% of EB cases, and DEB occurs in 5% of patients with EB. In the United States (US), the prevalence of EB is estimated to be 1 out of 53,000 live births. • With EB, the skin is very fragile and blisters easily. Blisters and skin erosions result from minor injury or friction, such as rubbing or scratching. The signs and symptoms of DEB and JEB are highly variable among affected individuals. In mild cases, blistering may primarily affect the hands, feet, knees, and elbows. Severe cases of DEB and JEB involve widespread blistering that can lead to vision loss, scarring, and other serious medical problems. Prognosis is dependent on mutation type and severity of disease with severe JEB having a

	50% mortality by the age of 2 years and RDEB having an increased risk of mortality by 30 years old. • The efficacy of Filsuvez for the treatment of wounds associated with DEB and JEB was evaluated in one randomized, double-blind, placebo-controlled trial in 223 adult and pediatric patients 6 months of age and older for a duration of 90 days. The primary efficacy endpoint was proportion of subjects with first complete closure of the target wound by Day 45. Efficacy for total wound closure of a single wound beyond 90 days was not studied. • CD-10 Code Information: o ICD-10: Q81 “Epidermolysis bullosa” may apply to junctional epidermolysis bullosa; however, the prescriber must specify the diagnosis. o ICD-10: Q81.8 “Other epidermolysis bullosa” may apply to junctional epidermolysis bullosa; however, the prescriber must specify the diagnosis. • Prescribing Considerations: o Filsuvez can be applied either directly to the wound or to the wound dressing. o Each tube of Filsuvez is single use.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Filsuvez may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is 6 months of age or older.

B. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has a diagnosis of dystrophic epidermolysis bullosa (DEB) (ICD-10: Q81.2).

2. The member has a diagnosis of junctional epidermolysis bullosa (JEB) (no ICD-10 code).

C. The member has one or more open wounds.

II. Reauthorization

When a benefit, reauthorization of Filsuvez may be approved when the following criterion is met **(A. and B.)**:

A. The prescriber attests that the target wound responded positively to therapy.

B. The prescriber attests that the member requires additional courses of treatment.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

IV. Coverage of oncology drug(s) listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 3 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Filsuvez (birch triterpenes) [package insert]. London, UK: Amryt Pharma; December 2023.
2. DynaMed. Inherited Epidermolysis Bullosa. Available at: https://www.dynamed.com/condition/inherited-epidermolysis-bullosa. Accessed October 15, 2024.
3. Epidermolysis Bullosa News. Filsuvez (birch triterpenes) for epidermolysis bullosa. Available at: https://epidermolysisbullosanews.com/filsuvez/. Accessed October 15, 2024.
4. Chiesi global rare disease. Chiesi Global Rare Diseases Receives FDA Approval for FILSUVEZ® (birch triterpenes) topical gel for the Treatment of Epidermolysis Bullosa. Available at: https://chiesirarediseases.com/media/fda-approval-for-filsuvez-topical-gel. Accessed October 15, 2024.
5. Has C, El Hachem M, Buckova H, et al. Practical Management of Epidermolysis Bullosa: Consensus Clinical Position Statement from the European Reference Network for Rare Skin Diseases. *JEADV* 2021, 35, 2349-2360.