Filsuvez (birch triterpenes)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Epidermolysis bullosa (EB) is a group of rare genetic skin disorders characterized by fragile skin that blisters and tears in response to minor friction or trauma. There are four main types: EB simplex, dystrophic EB (DEB), junctional EB (JEB), and Kindler syndrome. Symptoms range from mild to severe and can include painful open wounds, scarring, disfigurement, and internal complications. There is no cure for EB and management focuses on wound care and preventing complications. Filsuvez (birch triterpenes) gel is a topical medication recently approved for the treatment of wounds associated with DEB and JEB in patients 6 months and older. It contains birch bark extract formulated in sunflower oil and is thought to promote wound healing through anti-inflammatory and keratinocyte stimulating effects.

Definitions

"**Dominant DEB (DDEB)**" is a less severe form of DEB, resulting from mutations in a single copy of the COL7A1 gene.

"**Dystrophic epidermolysis bullosa (DEB)**" is a type of EB caused by mutations in the COL7A1 gene encoding type VII collagen. It can be inherited in an autosomal dominant (DDEB) or autosomal recessive (RDEB) manner.

"**Epidermolysis Bullosa (EB)**" is a group of rare, inherited skin conditions that cause skin to become incredibly fragile, resulting in blisters and tears even from minor friction or trauma.

"**Junctional epidermolysis bullosa (JEB)**" is a type of EB caused by mutations in genes encoding components of the hemidesmosomes and dermal-epidermal junction. It is inherited in an autosomal recessive manner.

"**Recessive DEB (RDEB)**" is a more severe form of DEB, caused by mutations in both copies of the COL7A1 gene.

Policy Statement on Filsuvez (birch triterpenes) Efficacy Information

The Plan considers Filsuvez (birch triterpenes) unproven and not medically necessary for all indications, including in the treatment of wounds associated with dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) at this time. The evidence is currently insufficient to conclude that Filsuvez (birch triterpenes) provides a clinically meaningful benefit:

- While the pivotal phase 3 EASE trial (ClinicalTrials.gov ID NCT03068780) met its primary endpoint, demonstrating a higher rate of complete target wound closure within 45 days with Filsuvez (birch triterpenes) compared to vehicle control (41.3% vs 28.9%, p=0.013), the treatment effect was modest and driven primarily by the recessive DEB (RDEB) subgroup.
    - There were no statistically significant differences in efficacy between Filsuvez (birch triterpenes) and control for the dominant DEB (DDEB) or JEB subgroups, though sample sizes were small.
    - The effect on complete wound closure was not durable, with no significant difference between Filsuvez (birch triterpenes) and control by the end of the 90-day double-blind period.

        - By day 90, the cumulative proportion of patients with first target wound closure was 50.5% for Filsuvez (birch triterpenes) vs. 43.9% for control gel (RR 1.16, 95% CI 0.88–1.52; P = 0.296).
    - The key secondary efficacy endpoints in the EASE trial showed mixed results, with some endpoints not demonstrating statistically significant differences between Filsuvez (birch triterpenes) and control gel - indicating a lack of robust, clinically meaningful benefit.
- There are no evidence-based clinical practice guidelines from authoritative sources that recommend Filsuvez (birch triterpenes) for the treatment of DEB or JEB wounds at this time.

Medical Necessity Criteria for Filsuvez (birch triterpenes)

The Plan considers Filsuvez (birch triterpenes) to be not medically necessary for any indication, including in the treatment of wounds associated with dystrophic epidermolysis bullosa (DEB) and junctional epidermolysis bullosa (JEB) at this time. Therefore, there are no medical necessity criteria for coverage of this product.

Experimental or Investigational / Not Medically Necessary

Filsuvez (birch triterpenes) for any indication or use is considered not medically necessary by the Plan. Non-covered indications include, but are not limited to, the following:

1. Actinic Keratosis (AK).
2. Breast Cancer.
3. Burns.
4. Epidermolysis Bullosa (EB).

References

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Clinical Guideline Revision / History Information

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