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Last P&T Approval/Version: 04/30/2025
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Policy Number: C27686-A

Filsuvez (birch triterpenes gel)

PRODUCTS AFFECTED

Filsuvez (birch triterpenes gel)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Epidermolysis Bullosa

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. EPIDERMOLYSIS BULLOSA:
   1. Documented diagnosis of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB)
      AND

2. Documentation diagnosis was confirmed by immunofluorescence, electron microscopy, or antigen mapping [DOCUMENTATION REQUIRED]
   AND
3. Documentation that member has not received, or is not being considered for gene therapy, or investigational cellular therapy
   AND
4. Documentation member is receiving standard of care wound therapy
   AND
5. Documentation of the presence of open partial-thickness wounds associated with DEB or JEB for ≥21 days
   AND
6. Documentation of member baseline wound evaluation (e.g., lesion distribution, severity, BSA, etc.) and goals for treatment to be used to evaluate efficacy of therapy at renewal

CONTINUATION OF THERAPY:

A. EPIDERMOLYSIS BULLOSA:

1. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
2. Documentation of positive clinical response as demonstrated by any of the following: improved wound closure, severity of wound infection, improved total body wound burden, or improved itching before wound dressing changes [DOCUMENTATION REQUIRED]
   AND
3. FOR CONTINUATION OF THERAPY PAST 9 MONTHS OF CONTINUOUS USE: Medial record documentation of improvement with Filsuvez (birch triterpenes gel) greater than any historic previous therapies or concurrent therapies used by the member that would provide medical justification of continuation of therapy past 9 months.

DURATION OF APPROVAL:

Initial authorization: 3 months, Continuation of Therapy: 3 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified dermatologist, geneticist, or dermatopathologist [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

6 months of age and older

QUANTITY:

1 tube (23.4grams) every OTHER day

Maximum Quantity Limits – up to 1 tube every other day; max 351grms/30 days
MOLINA REVIEWER NOTE: If documentation is submitted that a member's affected BSA is >12%, please allow greater than 1 tube every other day [see OTHER SPECIAL CONSIDERATIONS].

PLACE OF ADMINISTRATION:

The recommendation is that topical medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Topical

DRUG CLASS:
Wound dressings

FDA-APPROVED USES:
Indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Epidermolysis bullosa (EB) is one of several genetic dermatologic disorders associated with skin fragility. In general, these are associated with skin blistering; EB is the classical prototype. In recent years, several new gene associations and clinical subtypes have been identified. The spectrum of disease was reclassified by consensus expert review in 2020 considering clinical and molecular data, both genotype and phenotype. Initial classification models were based upon the level of skin cleavage which led to many of the physically identifiable phenotypic characteristics. The definitive physical manifestations are peeling, blistering, erosions, ulcerations, and wounds. The spectrum of severity can range from minor skin findings to lethal disorders. Newer classification schema focus on molecular data when known. There are four major classical types of EB-EB simplex (EBS), junctional EB (JEB), dystrophic EB (DEB) and Kindler EB (KEB) in addition to EB related disorders. DEB has three subtypes, a dominant and a recessive form. The recessive form is more severe and caused by mutations in the collagen gene COL7A1. Type VII collagen helps bind the dermis to the outer epidermis at the basement membrane. While initial diagnosis is typically clinical due to visible manifestations, subsequent biopsy, immunofluorescence, and molecular genetic diagnosis is used for prognostication, treatment, and planning purposes (Has, 2020).

The efficacy of FILSUVEZ for the treatment of partial-thickness wounds associated with inherited EB was evaluated in a randomized, double-blind, placebo-controlled trial in adults and pediatric subjects 6 months of age and older (EASE; NCT03068780) with dystrophic EB (DEB) and junctional EB (JEB). Subjects were randomized 1:1 to receive FILSUVEZ (n=109) or placebo topical gel (n=114) and instructed to apply approximately 1 mm (0.04 inch) of the investigational product to all their wounds at each dressing change (every 1 to 4 days) for 90 days. At randomization, 1 wound was selected by the investigator as the target wound for the evaluation of the primary efficacy endpoint. The target wound was defined as a partial-thickness wound of 10-50 cm2 in surface area and present for 21 days to 9 months prior to screening.

Of the 223 subjects randomized, the median age was 12 years (range: 6 months to 81 years), 70% were under 18 years of age, and 60% were male and 40% were female. Eighty three (83)% of subjects were White, 5% were Asian, 1% were Black or African American, and 10% were other races or did not have race recorded. For ethnicity, 35% identified as Hispanic or Latino and 65% identified as not Hispanic or Latino. Of these 223 subjects, 195 had DEB, of which 175 subjects had recessive DEB (RDEB) and 20 had dominant DEB (DDEB); in addition, there were 26 subjects with JEB and 2 subjects with EB simplex.

The primary endpoint was the proportion of subjects with first complete closure of the target wound by Day 45 of the 90-day double-blind phase of the study, based on clinical assessment by the investigator.

Table 2: Efficacy Results for the Treatment of Partial-Thickness Wounds in Subjects with EB in Trial EASE (Full Analysis Set)

Efficacy Parameter	FILSUVEZ N=109	Placebo Gel N=114	95% CI for the Treatment Difference
Proportion of subjects with first complete closure of target wound within 45 days	41.3%	28.9%	(0.8, 25.6)
By EB subtype[a]			
RDEB (n=175)	44.0%	26.2%	(3.9, 31.6)
DDEB (n=20)	50.0%	50.0%	(-47.8, 47.8)
JEB (n=26)	18.2%	26.7%	(-40.4, 23.5)
Proportion of subjects with first complete closure of target wound within 90 days	50.5%	43.9%	(-6.2, 20.0)

[a] Two subjects with EB simplex are not included
CI=Confidence interval

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Filsuvez (birch triterpenes gel) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Filsuvez (birch triterpenes gel) include: No labeled contraindications.

OTHER SPECIAL CONSIDERATIONS:
Filsuvez (birch triterpenes) topical gel, 10% (w/w) is a colorless to slightly yellowish, opalescent, non-aqueous gel and is supplied in 25 mL white aluminum tubes containing 3.4 grams of gel per tube (NDC 76431-310-01).

Each sterile tube is for **one-time use only.** Once opened, the product should be used immediately and discarded after use. Apply a 1 mm layer of Filsuvez to the affected wound surface. Do not rub in the gel. Cover the wound with a sterile non-adhesive wound dressing. Alternatively, apply a generous layer of Filsuvez directly to the dressing so that the gel is in direct contact with the wound.

In the EASE trial, patients changed their bandages every 1 to 4 days. Most patients changed bandages/applied Filsuvez daily or every other day. The mean BSAP of EB partial thickness wounds at baseline in the trial was about 12%. For an adult, 1 tube should be enough to liberally cover more than a 12% BSA, this would also be true for pediatric patients of any age since they have a smaller total BSA.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Filsuvez GEL 10% 25mL single-use sterile tube

REFERENCES

1. Filsuvez (birch triterpenes) topical gel [prescribing information]. Wahlstedt, Germany: Pharmazeutische Fabrik; May 2024.
2. Kern JS, et al. Oleogel-S10 Phase 3 study "EASE" for epidermolysis bullosa: study design and rationale. Trials. 2019;20(1):350. doi:10.1186/s13063-019-3362-z
3. Study Protocol BEB-13. Double-blind, randomised, vehicle-controlled, phase III, efficacy and safety study with 24-month open-label follow-up of Oleogel-S10 in patients with inherited epidermolysis bullosa. Version 6.0. April 18, 2019. Accessed March 18, 2024. https://storage.googleapis.com/ctgov2-large-docs/80/NCT03068780/Prot_000.pdf
4. Has C, Bauer JW, Bodemer C, Bolling MC, Bruckner-Tuderman L, Diem A, Fine JD, Heagerty A, Hovnanian A, Marinkovich MP, Martinez AE, McGrath JA, Moss C, Murrell DF, Palisson F, Schwieger-Briel A, Sprecher E, Tamai K, Uitto J, Woodley DT, Zambruno G, Mellerio JE. Consensus reclassification of inherited epidermolysis bullosa and other disorders with skin fragility. Br J Dermatol. 2020 Oct;183(4):614-627. doi: 10.1111/bjd.18921. Epub 2020 Mar 11. PMID: 32017015
5. Denyer J, Pillay E, Clapham J. Best practice guidelines for skin and wound care in epidermolysis bullosa. An International Consensus. Wounds International, 2017. https://www.debra.org/sites/default/files/howto/More%20EB%20Guides/SkinWoundCareCPG.pdf
6. Kern JS, et al. Efficacy and safety of Oleogel-S10 (birch triterpenes) for epidermolysis bullosa:results from the phase III randomized double-blind phase of the EASE study. Br J Dermatol. 2023;188(1):12-21. doi:10.1093/bjd/ljac001

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable Revisions: Required Medical Information Place of Administration References	Q2 2025
NEW CRITERIA CREATION	Q2 2024