FILSUVEZ (PREAUTHORIZATION REQUIRED)

X.236

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POLICY

Target Agents:

Filsuvez® (birch triterpenes) is FDA approved for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa (EB) in adult and pediatric patients 6 months of age and older.

Initial Evaluation

I. Target Agent(s) may be considered medically necessary when **ALL** the following are met:

A. **ONE** of the following:

1. The requested agent is eligible for continuation of therapy AND ONE of the following:

i. The patient has been treated with the requested agent (starting on samples is not approvable) within the last 90 days **OR**

ii. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

2. The patient has a diagnosis of dystrophic or junctional epidermolysis bullosa confirmed by genetic testing (medical records required) **OR**

B. If the patient has an FDA approved indication, then ONE of the following:

1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**

2. There is support for using the requested agent for the patient's age for the requested indication **AND**

C. The patient does NOT have current evidence or a history of squamous cell carcinoma on the area to be treated **AND**

D. The patient does NOT have an active infection on the area to be treated **AND**

E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

F. The patient will NOT be using the requested agent in combination with a gene therapy agent on the area to be treated **AND**

G. The patient does NOT have any FDA labeled contraindications to the requested agent.

Length of Approval: 4 months

Renewal Evaluation

I. Renewal of the Target Agent(s) may be considered medically necessary when ALL of the following are met:

A. The patient has been previously approved for the requested agent through the plan's Prior Authorization criteria [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**

B. The patient has had clinical benefit with the requested agent **AND**

C. The patient does NOT have current evidence or a history of squamous cell carcinoma on the area to be treated **AND**

E. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

F. The patient will NOT be using the requested agent in combination with a gene therapy agent on the area to be treated **AND**

G. The patient does NOT have any FDA labeled contraindications to the requested agent.

Length of Approval: 12 months

Dates

Original Effective
04-01-2025
Last Review
02-05-2025
Next Review
11-05-2025

CLINICAL RATIONALE

Epidermolysis bullosa (EB) encompasses a number of disorders characterized by recurrent blister formation as the result of structural fragility within the skin and selected other tissues caused by mutations in CLO7A1, the gene encoding the anchoring fibril component, collagen VII. All types and subtypes of EB are rare; the overall incidence and prevalence of the disease within the United States is approximately 19 per one million live births and 8 per one million population, respectively. Clinical manifestations range widely, from localized blistering of the hands and feet to generalized blistering of the skin and oral cavity, and injury to many internal organs.(2)

EB types are divided into four main groups according to the depth below the skin surface at which the blisters occur. Approximately 20% of EB cases are dystrophic (DEB), 10% junctional (JEB), and 70% simplex (EBS); Kindler syndrome is very rare. The genetic errors in EB result in defects in the proteins that make the outer skin layer (epidermis) adhere to the deeper layer (dermis). Some types of EB are inherited dominantly, others are inherited recessively. There are more than 30 clinical subtypes. Each EB subtype is known to arise from mutations within the genes encoding for several different proteins, each of which is intimately involved in the maintenance of keratinocyte structural stability or adhesion

mapping, transmission electron microscopy, and in some cases, by DNA analysis.(2,4)

Optimal patient management requires a multidisciplinary approach and revolves around the protection of susceptible tissues against trauma, use of sophisticated wound care dressings, aggressive nutritional support, and early medical or surgical interventions to correct whenever possible the extracutaneous complications. Prognosis varies considerably and is based on both EB subtype and the overall health of the patient. Currently, there is no cure for EB. Supportive care includes daily wound care, bandaging, and pain management as needed.(2)

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 (+/- 7 days). If a treated wound became infected, it was advised to discontinue treatment to that wound until the infection had resolved. 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 cm^2 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. Squamous cell carcinoma of the skin (SCC) was reported as an adverse event in the double-blind and open-label periods of EASE. Four subjects with recessive dystrophic EB each reported one SCC.(1)

EASE's top-line findings showed that the trial met its main goal, with a significantly greater proportion of Filsuvez-treated patients exhibiting wound closure within 45 days, compared with those using a placebo gel (41.3% vs. 28.9%). This benefit was exclusive to participants with recessive DEB, who showed a 72% higher likelihood of wound closure within 45 days with Filsuvez relative to a placebo gel. No significant differences in wound closure were detected between Filsuvez and a

than those on the placebo gel, these differences failed to reach statistical significance. All participants who completed the three-month period entered the study's extension phase, in which all are using Filsuvez for two years to heal their wounds. The goal is to evaluate the therapy's safety over the long-term.(3)

Safety

Filsuvez has no FDA labeled contraindications for use.

REFERENCES

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