

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
**(generic)**

**ELIDEL**  
**(pimecrolimus)**

**Status: CVS Caremark® Criteria**  
**Type: Initial Prior Authorization**

## POLICY

### FDA-APPROVED INDICATIONS

Elidel (pimecrolimus) Cream, 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.

Elidel Cream, 1% is not indicated for use in children less than 2 years of age.

### Compendial Uses

Psoriasis<sup>3</sup> - on the face, genitals, or skin folds<sup>6</sup>

Atopic Dermatitis for patients under 2 years of age<sup>4,5</sup>

Vitiligo on the head or neck<sup>7,8</sup>

## COVERAGE CRITERIA

### **Atopic Dermatitis**

Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (eczema) when ONE of the following criteria are met:

- The patient is less than 2 years of age
- The requested drug will be used on sensitive skin areas (e.g., face, genitals, or skin folds)
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least ONE first line therapy agent (e.g., medium or higher potency topical corticosteroid)

### **Psoriasis**

Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds.

### **Vitiligo**

Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck.

## CONTINUATION OF THERAPY

### **Atopic Dermatitis**

Authorization may be granted when the requested drug is being prescribed for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (eczema) when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement [e.g., improvement in or resolution of any of the following signs and symptoms: erythema (redness), edema (swelling), xerosis (dry skin), erosions, excoriations (evidence of scratching), oozing and crusting, lichenification (epidermal thickening), OR pruritus (itching)]

### **Psoriasis**

Elidel PA Policy UDR 04-2024.docx

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Authorization may be granted when the requested drug is being prescribed for psoriasis on the face, genitals, or skin folds when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., clear, or almost clear outcome, patient satisfaction, etc.)

### **Vitiligo**

Authorization may be granted when the requested drug is being prescribed for vitiligo on the head or neck when the following criteria is met:

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., meaningful repigmentation)

### **DURATION OF APPROVAL (DOA)**

- 491-A:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 12 months
  - Less than 2 years of age: DOA: 3 months
- 759-A:
  - 2 years of age and older: Initial therapy DOA: 3 months; Continuation of therapy DOA: 36 months
  - Less than 2 years of age: DOA: 3 months

### **REFERENCES**

1. Elidel [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed February 12, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/12/2024).
4. Eichenfield LF, Tom WL, et al. Guidelines of Care for the Management of Atopic Dermatitis: Section 2. Management and Treatment of Atopic Dermatitis with Topical Therapies. *J Am Acad Dermatol*. 2014 Jul;71:116-32.
5. Sigurgeirsson B, Boznanski A, et al. Safety and Efficacy of Pimecrolimus in Atopic Dermatitis: A 5-Year Randomized Trial. *Pediatrics*. 2015;135(4): 594-606.
6. Elmetts CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol*. 2021 Feb;84(2):432-470.
7. Kubelis-López DE, Zapata-Salazar NA, et al. Updates and new medical treatments for vitiligo (Review). *Exp Ther Med*. 2021;22(2):797.
8. Eleftheriadou V, Atkar R, et al. British Association of Dermatologists guidelines for the management of people with vitiligo 2021. *The British Journal of Dermatology*. 2022;186(1):18-29.
9. Eichenfield LF, Tom WL, et. al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. *J Am Acad Dermatol* 2014; 70:338-51.
10. Sidbury RS, Alikhan A, Berovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023; 89(1): e1-e20.