Topical Vitamin D Analogs

Medical Necessity Criteria

This policy addresses coverage criteria for topical vitamin D analogs.

Coverage for Topical Vitamin D Analog products varies across plans. Refer to the customer’s benefit plan document for coverage details.

Where coverage requires the use of preferred products, the following criteria apply.

| Enstilar® (calcipotriene 0.005% / betamethasone 0.064% foam) | Standard Drug List Plan / Performance Drug List Plan |
| | Value Drug List Plan / Advantage Drug List Plan |
| | Legacy Drug List Plan |

All of the following:
- Documented intolerance or inability to use calcipotriene 0.005% / betamethasone 0.064% ointment
- Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: calcipotriene cream, ointment, solution
- Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for tazarotene cream
- Inability to use calcipotriene and betamethasone components separately
EFFECTIVE 1/1/2020

<table>
<thead>
<tr>
<th>Standard Drug List Plan / Performance Drug List Plan Value Drug List Plan / Advantage Drug List Plan Legacy Drug List Plan</th>
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</table>
| Taclonex® (calcipotriene 0.005% / betamethasone 0.064% ointment) All of the following:  
- Documented intolerance to one generic formulation of Taclonex ointment  
- Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: calcipotriene cream, ointment, solution  
- Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for tazarotene cream  
- Inability to use calcipotriene and betamethasone components separately |
| Taclonex® (calcipotriene 0.005% / betamethasone 0.064% suspension) All of the following:  
- Documented intolerance or inability to use calcipotriene 0.005% / betamethasone 0.064% ointment  
- Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: calcipotriene cream, ointment, solution  
- Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for tazarotene cream  
- Inability to use calcipotriene and betamethasone components separately |

Initial and reauthorization is up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Topical Vitamin D Analogs are considered experimental, investigational or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

*If you’re a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

### FDA Approved Indications

<table>
<thead>
<tr>
<th>Product</th>
<th>FDA Approved Indications</th>
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<tbody>
<tr>
<td>Enstilar (calcipotriene / betamethasone foam)</td>
<td>Enstilar is indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older.</td>
</tr>
<tr>
<td>Taclonex (calcipotriene / betamethasone ointment)</td>
<td>Taclonex Ointment is indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.</td>
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</tbody>
</table>
| Taclonex (calcipotriene / betamethasone suspension) | Taclonex Suspension is indicated for the topical treatment of:  
- Plaque psoriasis of the scalp and body in patients 18 years and older  
- Plaque psoriasis of the scalp in patients age 12 to 17 years |

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Recommended Dosing

<table>
<thead>
<tr>
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<tr>
<td><strong>Enstilar</strong> (calcipotriene / betamethasone foam)</td>
<td>Apply Enstilar Foam to affected areas once daily for up to 4 weeks. Rub in Enstilar Foam gently. Discontinue use when control is achieved. Instruct patients not to use more than 60 g every 4 days.</td>
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<tr>
<td><strong>Taclonex</strong> (calcipotriene / betamethasone ointment)</td>
<td>Apply an adequate layer of Taclonex Ointment to the affected area(s) once daily for up to 4 weeks. Taclonex Ointment should be rubbed in gently and completely. Patients 18 years and older should not use more than 100 g per week and patients 12 to 17 years should not use more than 60 g per week. Treatment of more than 30% body surface area is not recommended.</td>
</tr>
<tr>
<td><strong>Taclonex</strong> (calcipotriene / betamethasone suspension)</td>
<td>Apply Taclonex Suspension to affected areas once daily for up to 8 weeks. Therapy should be discontinued when control is achieved. Patients 18 years and older should not use more than 100 g per week and patients 12 to 17 years should not use more than 60 g per week.</td>
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Drug Availability

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<tr>
<td><strong>Enstilar</strong> (calcipotriene / betamethasone foam)</td>
<td>Each gram of Enstilar Foam contains 50 mcg of calcipotriene (0.005%) and 0.5 mg of betamethasone (0.064%).</td>
</tr>
<tr>
<td><strong>Taclonex</strong> (calcipotriene / betamethasone ointment)</td>
<td>Each gram of Taclonex Ointment contains 50 mcg of calcipotriene (0.005%) and 0.5 mg of betamethasone (0.064%).</td>
</tr>
<tr>
<td><strong>Taclonex</strong> (calcipotriene / betamethasone suspension)</td>
<td>Each gram of Taclonex Topical Suspension contains 50 mcg of calcipotriene (0.005%) and 0.5 mg of betamethasone (0.064%).</td>
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Background

**Therapeutic Alternatives**
Taclonex ointment has an FDA approved generic therapeutic equivalent. Therapeutic alternatives to Enstilar, Taclonex ointment and suspension include the following drugs: calcitriol ointment; calcineurin inhibitors (pimecrolimus, tacrolimus); corticosteroids (betamethasone, clobetasol); retinoids (tazarotene).

**Professional Societies/Organizations**
American Academy of Dermatology (AAD) guidelines for the management of psoriasis and psoriatic arthritis state the majority of patients with psoriasis have limited disease (<5% body surface area involvement) and can be treated with topical agents, which generally provide a high efficacy-to-safety ratio. The AAD point out the choice of vehicle can significantly alter the use and penetration of the medication and therefore alter the efficacy. Topical corticosteroids are the cornerstone of treatment for the majority of patients with psoriasis, particularly those with limited disease and an important advantage of the vitamin D analogues is their potential to function in a corticosteroid-sparing fashion. (Menter, 2009)

**Off Label Uses**
AHFS Drug Information 2019 Edition does not have a monograph for Enstilar or Taclonex.
Comparative Studies
There are no clinical studies comparing Enstilar or Taclonex with other therapeutic alternatives.

Generics
The FDA’s generic drug approval process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Generic drugs must establish the following for approval:

- contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA’s good manufacturing practice regulations required for innovator products

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn’t allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

References