Clinical Policy: Crotamiton (Crotan, Eurax)

Reference Number: ERX.NPA.80
Effective Date: 09.01.18
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Crotamiton (Crotan™, Eurax®) is a scabicidal and antipruritic agent.

FDA Approved Indication(s)
Eurax and Crotan are indicated for:
- Eradication of scabies caused by *Sarcoptes scabiei*
- Symptomatic treatment of pruritic skin

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Crotan and Eurax are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Scabies (must meet all)**:**
1. Diagnosis of scabies;
2. Age ≥ 18 years;
3. Failure of permethrin 5% cream in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed one 60 gram tube per treatment course (one application followed by a second application 24 hours later).

Approval duration: 14 days

B. Pruritus (must meet all)**:**
1. Diagnosis of pruritus;
2. Age ≥ 18 years;
3. Failure of a topical corticosteroid (*see Appendix B for examples*) within the last 3 months unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of an oral antihistamine (*see Appendix B for examples*) within the last 3 months unless contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed one 60 gram tube per month.

Approval duration: 6 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Scabies
1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Pruritus (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Request does not exceed one 60 gram tube per month.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
permethrin 5% (Elimite®, Acticin®)	**Scabies** *Adults, adolescents, children, and infants 2 months and older:* Massage 5% topical cream into the skin from the head to the soles of the feet. Usually 30 grams is sufficient for the average adult. Wash cream off after 8 to 14 hours. One application is generally curative. Although pruritus may persist after treatment, this is rarely a sign of treatment failure and is not an indication for retreatment. Retreatment is indicated if living mites persist after 7 to 14 days of initial treatment.	One application to affected area; do not repeat for ≥ 7 days
Topical corticosteroids (e.g., betamethasone, desonide, desoximetasone, fluocinolone, fluocinonide, halobetasol, hydrocortisone, mometasone, triamcinolone)	**Pruritus** Varies depending on medication	Varies depending on medication
Oral antihistamines (e.g., cetirizine, diphenhydramine, hydroxyzine, loratadine)	**Pruritus** Varies depending on medication	Varies depending on medication

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Eurax should not be applied topically to patients who develop a sensitivity or are allergic to it or who manifest a primary irritation response to topical medications.
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Scabies	Thoroughly massage into the skin of the whole body from the chin down. A second application is advisable 24 hours later. A cleansing bath should be taken 48 hours after the last application.	1 application/day for 2 days, given 24 hours apart
Pruritus	Massage gently into affected areas until medication is completely absorbed. Repeat as needed.	Usually 1 application/day, then as needed

VI. Product Availability

- Cream 10%: 60 g bottle
- Lotion 10%: 60 g bottle

VII. References

1. Crotan Prescribing Information. Charleston, SC: Marnel Pharmaceuticals, Inc. ; January 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed May 3, 2021.
2. Centers for Disease Control and Prevention. Parasites-Scabies. Available at: https://www.cdc.gov/parasites/scabies/health_professionals/meds.html. Updated February 21, 2018. Accessed May 3, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.
4. Weisshaar E1, Szepietowski JC, Darsow U, et al. European guideline on chronic pruritus. Acta Derm Venereol. 2012 Sep;92(5):563-81.
5. Weisshaar E1, Szepietowski JC, Garcovich S, et al. European S2K guideline on chronic pruritus. Acta Derm Venereol. 2019 April;99(5):0001-5555.
6. Millington GWM, Collins A, Lovell CR, et al. British Association of Dermatologists' guidelines for the investigation and management of generalized pruritus in adults without an underlying dermatosis, 2018. Br J Dermatol. 2018 Jan;178(1):34-60

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from ERX.ST.26; scabies: added diagnosis and age; created criteria set for pruritis; references reviewed and updated.	05.08.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.30.20	08.20
3Q 2021 annual review: no significant changes; added Crotan; references reviewed and updated.	05.03.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.