

**Pharmacy Policy**

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**Topical Immunomodulators**

**Policy Number:** 9.103

**Version Number:** 2.0

**Version Effective Date:** 1/1/2022

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| <b>Product Applicability</b> <input type="checkbox"/> <b>All Plan+ Products</b>      |                                                                                                                                                                                                                                                                                              |
| <p><b>Well Sense Health Plan</b></p> <input type="checkbox"/> New Hampshire Medicaid | <p><b>Boston Medical Center HealthNet Plan</b></p> <input type="checkbox"/> MassHealth - MCO<br><input type="checkbox"/> MassHealth - ACO<br><input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct<br><input type="checkbox"/> Senior Care Options |

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

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**Products Affected:**

- **Condylox (podofilox) 0.5% Gel**
- **Eucria (crisaborole) 2% ointment**
- **tacrolimus 0.1% and 0.3% ointment**

The Plan may authorize coverage of the above products for members meeting the following criteria:

|                                     |                                                                                                                                                                                                            |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Covered Use</b>                  | All FDA approved indications not otherwise excluded                                                                                                                                                        |
| <b>Exclusion Criteria</b>           | Concurrent therapy with tacrolimus and pimecrolimus                                                                                                                                                        |
| <b>Required Medical Information</b> | <p><b>Condylox Gel 0.05%</b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of External Genital Warts (EGW); <b>AND</b></li> <li>2. An intolerance to the generic podofilox solution</li> </ol> |

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|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                               | <p><b>Eucrisa 2% ointment</b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of atopic dermatitis; <b>AND</b></li> <li>2. Inadequate response, intolerance/contraindication to a moderate or high potency topical corticosteroid ; <b>AND</b></li> <li>3. Inadequate response, intolerance/contraindication to one topical calcineurin inhibitor (tacrolimus or pimecrolimus)</li> </ol> <p><b>tacrolimus ointment 0.1% and 0.03%</b></p> <ol style="list-style-type: none"> <li>1. A diagnosis of atopic dermatitis; <b>AND</b></li> <li>2. A clinical reason why treatment with a moderate to high potency topical steroid is not appropriate (inadequate response, skin atrophy, or use on an area of the body at high risk for skin atrophy, such as the face or skin folds); <b>AND</b></li> <li>3. Favorable benefit vs. risk if the member is less than two years of age</li> </ol> |
| <b>Age Restriction</b>        | Eucrisa: 3 months of age and older                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Prescriber Restriction</b> | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Coverage Duration</b>      | Condylox: 30 days approval<br>Eucrisa and tacrolimus: 1 year                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Other criteria</b>         | <p><b>Reauthorization</b></p> <p><b>Condylox Gel:</b></p> <ol style="list-style-type: none"> <li>1. There is a recurrence of active lesions and treatment with another course of therapy is required; <b>AND</b></li> <li>2. Member has been informed of preventative measures</li> </ol> <p><b>tacrolimus and Eucrisa:</b></p> <ol style="list-style-type: none"> <li>1. Patient has been re-evaluated within the last 12 months; <b>AND</b></li> <li>2. Patient has disease stabilization or improvement in disease and is tolerating treatment.</li> </ol>                                                                                                                                                                                                                                                                                                                                         |

## Clinical Background Information and References

1. Breen, E, Bleday, R. Condylomata Acuminata (anogenital warts). UptoDate,<sup>®</sup> Updated January 2017; Accessed 2017 Oct; available from <http://uptodate.com>
2. Centers for Disease Control and Prevention, Workowski KA, Berman SM. HPV infection and genital warts. Sexually transmitted diseases treatment guidelines 2006. MMWR Morb Mortal Wkly Rep 2006 Aug 4;55(RR-11):62-7.
3. Eichenfield LF, 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(1):116-32.
4. Eucrisa<sup>™</sup>[package insert] Palo Alto, CA; Anacor Pharmaceuticals, Inc. December 2016.

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5. Goldstein B. et al. General principles of dermatologic therapy and topical corticosteroid use. Comparison of representative topical corticosteroid preparations (classified according to the US system. UpToDate, Updated March 2016. Accessed October 2017. Available from <http://www.Uptodate.com>
6. Krabowski AC, Eichenfield If, Dohil MA. Management of Atopic Dermatitis in the Pediatric Population. Pediatrics 2008;122;812-824.
7. Lacey CJ, Woodhall SC, Wikstrom A, Ross J. 2012 European guideline for the management of anogenital warts. J Eur Acad Dermatol Venereol. 2012 Mar 12.
8. Prescribing Information. Protopic® Ointment, tacrolimus. Astellas Pharma US, Inc. Grand Island, NY 14072. May 2012.
9. Relative Potency of Selected Topical Corticosteroid Products. Accessed October 2017. Lexicomp Online. Copyright © 1978-2017 Lexicomp, Inc. All Rights Reserved. Available from: <https://fco.factsandcomparisons.com/>
10. Roy M, Bryson P. Treatment of external genital warts and pre-invasive neoplasia of the lower tract. In: Canadian consensus guidelines on human papillomavirus. J Obstet Gynaecol Can 2007 Aug;29(8 Suppl 3):S37-41.
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12. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. J Allergy Clin Immunol. 2013 Feb;131(2):295-9.e1-27.
13. Weston W, Howe W. Treatment of atopic dermatitis (eczema). Up to Date®, updated July 2017; accessed Oct 2017; available from: <http://www.uptodate.com>

| Original Approval Date | Original Effective Date | Policy Owner      | Approved by                             |
|------------------------|-------------------------|-------------------|-----------------------------------------|
| 12/1/2020              | 1/1/2021                | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee |

| Policy Revisions History |                                                                                                                                                                                                                                        |                         |               |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------------|
| Review Date              | Summary of Revisions                                                                                                                                                                                                                   | Revision Effective Date | Approved by   |
| 12/1/2020                | 9.027 Topical Immunomodulators Policy retired, new policy created, moved Picato gel, imiquimod cream to covered; moved pimecrolimus, Carac, fluorouracil 0.5% cream, diclofenac gel 3% to non preferred; updated age limit for Eucrisa | 1/1/2021                | P&T Committee |
| 8/12/2021                | P&T Annual Review. No changes.                                                                                                                                                                                                         | 1/1/2022                | P&T Committee |

### Next Review Date

8/2022

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## Other Applicable Policies

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## Reference to Applicable Laws and Regulations, If Any

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### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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