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Pharmacy Policy

Topical Immunomodulators

Policy Number: 9.103
Revision Number: R0
Version Effective Date: 1/1/2021

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☐ MassHealth - MCO
	☐ MassHealth - ACO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

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

Prior Authorization Policy

Products Affected:

- **Carac (fluorouracil) 0.5% cream**
- **Condylox (podofilox) 0.5% Gel**
- **diclofenac gel 3%**
- **Elidel**
- **pimecrolimus cream 1%**
- **Eucrisa (crisaborole) 2% ointment**
- **fluorouracil* 0.5% cream**
- **Picato (ingenol mebutate) 0.05% and 0.015% gel**
- **tacrolimus 0.1% ointment**
- **Protopic**
- **imiquimod cream**

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

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Concurrent therapy with tacrolimus and pimecrolimus
Required Medical Information	**Carac 0.5% cream (fluorouracil) , fluorouracil 0.5% cream** 1. A diagnosis of Actinic Keratosis; **AND** 2. An inadequate response or intolerance to 5-fluorouracil 2% solution or 5-fluorouracil 5% cream/solution **Condylox Gel 0.5%** 1. A diagnosis of External Genital Warts (EGW); **AND** 2. An intolerance to the generic podofilox solution **Diclofenac gel 3%, Picato gel 0.05% and 0.015%** 1. A diagnosis of Actinic Keratosis; **AND** 2. An inadequate response or intolerance to office-based treatments OR have been considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments; **AND** 3. An inadequate response to a full treatment course or intolerance/contraindication to a trial of a covered 5-fluorouracil product and imiquimod **Eucrisa 2% ointment** 1. A diagnosis of atopic dermatitis; **AND** 2. Inadequate response, intolerance/contraindication to a trial of 2 products from Topical- Atopic dermatitis class (See Appendix A) **Imiquimod cream 5%** 1. A diagnosis of Actinic Keratosis (AK) or Superficial Basal Cell Carcinoma (sBCC); **AND** An inadequate response or intolerance to office-based treatments OR have been considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments; **OR** 2. A diagnosis of External Genital Warts (EGW); **AND** Office-based treatments have been tried and failed or considered and ruled out as options due to the nature/number of lesions or limited resources to provide such treatments; **AND** An inadequate response to a full treatment course or intolerance/contraindication (i.e. pregnancy) to a trial of podofilox solution; OR the patient is immunocompromised (e.g. HIV) or is diagnosed with Anal Intraepithelial Neoplasia (AIN) **tacrolimus ointment 0.1% and 0.03%, Protopic, pimecrolimus cream 1%, Elidel** 1. A diagnosis of atopic dermatitis; **AND** 2. Favorable benefit vs. risk if the member is less than two years of age; **AND** 3. If request is for brand Elidel, member has tried and failed two (2) preferred products (see Appendix A)

Age Restriction	Eucrisa: 3 months of age and older
Prescriber Restriction	None
Coverage Duration	Picato: 3 days Carac, fluorouracil 0.5% cream, Condylox: 30 days diclofenac: 3 months imiquimod: 16 weeks Eucrisa, pimecrolimus, Elidel, tacrolimus/Protopic: 12 months
Other criteria	**Reauthorization** **imiquimod cream, Picato gel, Diclofenac gel 3%, Carac, fluorouracil 0.5%, Condylox Gel:** 1. There is a recurrence of active lesions and treatment with another course of therapy is required; **AND** 2. Member has been informed of preventative measures; **AND** 3. At least one month has elapsed since the end of the last treatment cycle (for Diclofenac gel only). **pimecrolimus, Elidel, tacrolimus/Protopic, and Eucrisa:** 1. Patient has been re-evaluated within the last 12 months 2. Patient has disease stabilization or improvement in disease and is tolerating treatment.

Appendix A – Topical – Atopic Dermatitis Preferred Drugs

Pimecrolimus (generic for Elidel)
Protopic
Tacrolimus (generic for Protopic)

Clinical Background Information and References

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

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; added brand Protopic to policy to align with NH state PDL preferred agents; updated age limit for Eucrisa	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

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.