BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Topical Immunomodulators

Policy Number: 9.103
Version Number: 2.0
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☒ 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:

- **Condylox (podofilox) 0.5% Gel**
- **diclofenac gel 3%**
- **fluorouracil 0.5% cream**
- **imiquimod cream**

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

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	**fluorouracil 0.5% cream** 1. A diagnosis of Actinic Keratosis; **AND**

[+] *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.

	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%** 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 **Imiquimod cream 5%** 1. A diagnosis of Actinic Keratosis (AK) or Superficial Basal Cell Carcinoma (sBCC); **AND** a. 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** a. 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** b. 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)
Age Restriction	None
Coverage Duration	fluorouracil 0.5% cream, Condylox: 30 days diclofenac: 90 days imiquimod: 16 weeks
Other criteria	**Reauthorization** **imiquimod cream, Diclofenac gel 3%, 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. For diclofenac gel only, at least one month has elapsed since the end of the last treatment cycle

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

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; removed Eucrisa , topical generic pimecrolimus and tacrolimus from the policy to create separate policies to align with MH PDL requirements	1/1/2021	P&T Committee

Policy Revisions History			
8/12/2021	P&T annual review. Removed Picato (discontinued) and Carac (moved to non-preferred) from policy.	1/1/2022	P&T Committee

Next Review Date

8/2022

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.