BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Acne and Rosacea Agents

Policy Number: 9.908
Version Number: 2.0
Version Effective Date: 3/1/2022

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:

- **adapalene cream**
- **adapalene gel**
- **Mirvaso (brimonidine) 0.33% gel** (non-formulary)
- **tazarotene 0.1% cream**
- **tretinoin cream– *covered without a PA for members <26 years of age***
- **tretinoin gel – *covered without a PA for members <26 years of age***
- **Zilxi (minocycline) 1.5% foam**

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

Covered Use	All FDA approved indications not otherwise excluded

[+] *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.

Required Medical Information	**adapalene gel and cream (Rx)** 1. A diagnosis of acne vulgaris; ***AND*** a. An inadequate response, intolerance, or contraindication to a trial of a covered topical tretinoin product(see Appendix A for covered tretinoin products); ***OR*** 2. A diagnosis of rosacea; ***AND*** a. An inadequate response, intolerance, or contraindication to a trial of metronidazole cream or gel **Mirvaso 0.33% gel** 1. A diagnosis of persistent (non-transient) facial erythema of rosacea **tazarotene 0.1% cream** 1. A diagnosis of acne vulgaris; ***AND*** a. An inadequate response, intolerance or contraindication to a trial ofadapalene cream or gel; ***AND*** b. An inadequate response, intolerance or contraindication to a trial of covered topical tretinoin formulations (See Appendix A for covered tretinoin products); ***OR*** 2. A diagnosis of plaque psoriasis; ***AND*** a. An inadequate response, intolerance or contraindication to a trial of a prescription-strength topical corticosteroid **Tretinoin cream and gel** (covered without a PA for members < 26 years of age) ***Members 26 years of age and older:*** 1. A diagnosis of acne vulgaris **Zilxi 1.5% foam** 1. A diagnosis of rosacea with inflammatory lesions; ***AND*** 2. An inadequate response, intolerance, or contraindication to a trial of topical metronidazole andazelaic acid gel
Age Restriction	Mirvaso, Zilxi: 18 years and older Tazarotene: 12 years and older (acne) or 18 years and older (plaque psoriasis) **Note**: tretinoin requires PA only for ages 26 and older
Coverage Duration	12 months

Appendix A

Tretinoin cream 0.025%	
Tretinoin cream 0.05%	Tretinoin gel 0.05%
Tretinoin cream 0.1%	
Tretinoin gel 0.01%	
Tretinoin gel 0.025%	

Clinical Background Information and References

1. Del Rosso JQ et al. Consensus Recommendations from the American Acne & Rosacea Society on the Management of Rosacea, Part 2: A Status Report on Topical Agents. Cutis. 2013 Dec; 92(6):277-84.
2. Eichenfield LF, et al. Evidence-Based Recommendations for the Diagnosis and Treatment of Pediatric Acne. Pediatrics 2013;131: S163 -S186
3. Goldstein BG, Goldstein AG. Rosacea. UptoDate,® accessed 2012 Oct; available from http://uptodate.com
4. Graber E. Treatment of acne vulgaris. UptoDate, updated October 26, 2021. UpToDate.com accessed Oct 2021;
5. Maier LE. Management of Rosacea. UptoDate,® updated JJanuary 5, 2021. accessed Oct 2021; available from http://uptodate.com
6. Prescribing information. Aczone®, dapsone gel 7.5%. Allergan Inc., Irvine CA. February 2016
7. Prescribing Information. Mirvaso®, brimonidine tartrate topical. Galderma Laboratories LP. Fort Worth, TX. August 2013.
8. Prescribing Information. Oracea®, doxycycline capsules 40 mg. Collagenex Pharmaceuticals, Inc. Newtown, PA 18940. May 2006.
9. Prescribing Information. SOOLANTRA®, ivermectin cream 1%. Galderma Laboratories LP. Fort Worth, TX. December 2014.
10. Rhofade [package insert]. Allergan; Irvine, CA. Approved 1/2017
11. Strauss JS, Krowchuk DP, Leyden JJ, Lucky AW, Shalita AR, Siegfried EC, et al; American Academy of Dermatology. Guidelines of care for acne vulgaris management. J Am Acad Dermatol. 2007 Apr [cited 2011 Oct];56(4):651-663.
12. Zilxi (minocycline aerosol, foam) [package insert]. VYNE Therapeutics, Inc.; Bridgewater, NJ. February 2021

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	9.155 Acne and Rosacea Agents Policy retired; new policy created; added differin gel 0.1% OTC to policy; added adapalene to policy	1/1/2021	P&T Committee
2/3/2021	Differin gel 0.1% OTC removed from policy. Tretinoin 0.04% gel added to policy.	2/3/2021	P&T Committee
11/11/2021	P&T Annual Review. Add Zilxi to policy. Remove tretinoin microsphere gel (0.04%, 0.1%) from policy. Simplify Mirvaso diagnosis. Add age limits. Switch trial/failure of Differin OTC to adapelene cream/gel.	3/1/2022	P&T Committee

Next Review Date

11/2022

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.