

Pharmacy Policy

Acne and Rosacea Agents

Policy Number: 9.908

Revision Number: R1

Version Effective Date: 1/1/2021

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

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

Prior Authorization Policy

Products Affected:

- **Azelex (azelaic acid) cream**
- **Mirvaso (brimonidine) 0.33% gel**
- **tretinoin cream and gel – covered without a PA for members <26 years of age**
- **Retin-A cream and gel - covered without a PA for members <26 years of age**

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

Covered Use	All FDA approved indications not otherwise excluded
Required Medical Information	<p>Azelex (azelaic acid) cream 20%</p> <p>Documentation of the following:</p> <ol style="list-style-type: none"> 1. A diagnosis of Acne vulgaris; AND 2. An inadequate response, intolerance or contraindication to a trial of Differin 0.1% Gel OTC

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	<p>formulation; AND</p> <p>3. An inadequate response, intolerance or contraindication to a trial of covered topical tretinoin formulations (See Appendix A for covered tretinoin products)); OR</p> <p>4. A diagnosis of Rosacea; AND</p> <p>5. An inadequate response, intolerance, or contraindication to a trial of metronidazole cream or gel</p> <p>Mirvaso 0.33% gel</p> <p>Documentation of the following:</p> <p>1. A diagnosis of Erythematotelangiectatic rosacea (rosacea with persistent diffuse centro-facial erythema)</p> <p>Tretinoin cream (0.025%, 0.05%, 0.1%) and gel (0.01%, 0.025% and 0.05%);</p> <p>Retin-A cream and gel (0.01%, 0.025%, 0.05%)</p> <p><i>Covered without a PA for members < 26 years of age.</i></p> <p><i>Members 26 years of age and older:</i></p> <p>Documentation of the following:</p> <p>1. A diagnosis of Acne Vulgaris;</p>
Age Restriction	Tretinoin cream (0.025%, 0.05%, 0.1%) and gel (0.01%, 0.025% and 0.05%); Retin-A cream (0.025%, 0.05% and 0.1%) and gel (0.01% and 0.025%,) only covered without a PA for less than 26 years of age.
Coverage Duration	Initial: 12 months

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 July 2016. UpToDate.com accessed Oct 2016;
5. Maier LE. Management of Rosacea. UptoDate,[®] updated June 14th,2106. accessed Oct 2016; available from <http://uptodate.com>
6. Maier, L. Management of Rosacea. Last updated: April 25, 2017. Accessed 2017 October. Available at: <http://uptodate.com>

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7. Maier, L. Management of Rosacea. UptoDate. Last updated: October 3, 2018. Accessed October 21, 2018. <https://www.uptodate.com>
8. Prescribing information. Aczone®, dapson gel 7.5%. Allergan Inc., Irvine CA. February 2016
9. Prescribing Information. Mirvaso®, brimonidine tartrate topical. Galderma Laboratories LP. Fort Worth, TX. August 2013.
10. Prescribing Information. Oracea®, doxycycline capsules 40 mg. Collagenex Pharmaceuticals, Inc. Newtown, PA 18940. May 2006.
11. Prescribing Information. SOOLANTRA®, ivermectin cream 1%. Galderma Laboratories LP. Fort Worth, TX. December 2014.
12. Rhofade [package insert]. Allergan; Irvine, CA. Approved 1/2017
13. 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.

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	9.155 Acne and Rosacea Agents Policy retired; new policy created; removed tazarotene from PA to align with NH state PDL	1/1/2021	P&T Committee, NH DHHS

Appendix A:

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

Next Review Date

2021

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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.

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