

Pharmacy Policy

Acne and Rosacea Agents

Policy Number: 9.908

Version Number: 2.0

Version Effective Date: 3/1/2022

Product Applicability	<input type="checkbox"/> All Plan+ Products
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<input checked="" type="checkbox"/> MassHealth - MCO
	<input checked="" 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) 20% cream**
- **Mirvaso (brimonidine) 0.33% gel**
- **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**
- **Winlevi (clascoterone) 1% cream**
- **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
Exclusion Criteria	None

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Required Medical Information	<p>Azelex cream 20%, Winlevi 1% cream</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 ; AND 3. An inadequate response, intolerance, or contraindication to a trial of a covered topical tretinoin product (see Appendix A for covered tretinoin products) <p>Mirvaso 0.33% gel</p> <ol style="list-style-type: none"> 1. A diagnosis of persistent (non-transient) facial erythema of rosacea <p>tazarotene 0.1% cream</p> <ol style="list-style-type: none"> 1. A diagnosis of acne vulgaris; AND <ol style="list-style-type: none"> a. An inadequate response, intolerance, or contraindication to a trial of Differin 0.1% Gel OTC; AND b. 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 plaque psoriasis; AND <ol style="list-style-type: none"> a. An inadequate response, intolerance, or contraindication to a trial of a prescription-strength topical corticosteroid <p>tretinoin cream and gel (covered without a PA for members < 26 years of age)</p> <p>Members 26 years of age and older:</p> <ol style="list-style-type: none"> 1. A diagnosis of acne vulgaris <p>Zilxi 1.5% foam</p> <ol style="list-style-type: none"> 1. A diagnosis of rosacea with inflammatory lesions; AND 2. An inadequate response, intolerance, or contraindication to a trial of at least two of the following: topical metronidazole, azelaic acid gel, or ivermectin cream
Age Restriction	<p><u>Mirvaso, Zilxi</u>: 18 years and older</p> <p><u>Tazarotene</u>: 12 years and older (acne) or 18 years and older (plaque psoriasis)</p> <p><u>Winlevi</u>: 12 years and older</p> <p>Note: tretinoin requires PA only for ages 26 and older</p>
Prescriber Restriction	<p>None</p>

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Coverage Duration	12 months

Appendix A

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

Clinical Background Information and References

1. Azelex (azelaic acid cream) [prescribing information]. Almirall, LLC; Exton, PA. October 2019
2. 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.
3. Eichenfield LF, et al. Evidence-Based Recommendations for the Diagnosis and Treatment of Pediatric Acne. *Pediatrics* 2013;131: S163 -S186
4. Goldstein BG, Goldstein AG. Rosacea. UptoDate,[®] accessed October 2021; available from <http://uptodate.com>
5. Graber E. Treatment of acne vulgaris. UptoDate,[®], accessed October 2021; available from <http://uptodate.com>
6. Maier LE. Management of Rosacea. UptoDate,[®] updated June 14th,2106. accessed October 2021; available from <http://uptodate.com>
7. Prescribing information. Aczone[®], dapsone gel 7.5%. Allergan Inc., Irvine CA. May 2018
8. Prescribing Information. Mirvaso[®], brimonidine tartrate topical. Galderma Laboratories LP. Fort Worth, TX. July 2021
9. Prescribing Information. SOOLANTRA[®], ivermectin cream 1%. Galderma Laboratories LP. Fort Worth, TX. November 2019
10. Retin-A (tretinoin cream) [package insert]. Bausch Healht US, LLC; Bridgewater, NJ. September 2019
11. Retin-A Micro (tretinoin gel) [package insert]. Valeant Pharmaceuticals International, Inc; Laval, Quebec, Canada. October 2017
12. 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.
13. Tazarotene cream [package insert]. Cosette Pharmaceuticals, Inc.; South Plainfield, NJ. August 2020
14. Winlevi (clascoterone cream) [package insert]. Sun Pharmaceuticals Industries, Inc.; Cranbury, NJ. September 2021
15. 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

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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	1/1/2021	P&T Committee
11/11/2021	P&T Annual Review. Added Winlevi & Zilxi to PA. Removed rosacea from Azelex approval criteria. Simplified diagnosis for Mirvaso. Added age limits.	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.

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