Medical Necessity Guidelines: Acne and Rosacea Medications

Effective: November 1, 2023

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0988	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

- Aczone (dapsone gel) is indicated for the topical treatment of acne vulgaris.
- Adapalene is indicated for the topical treatment of acne vulgaris.
- Clindamycin/benzoyl peroxide is indicated for the topical treatment of inflammatory acne vulgaris.
- Metronidazole (topical) is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.
- Mirvaso (brimonidine gel) is indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age and older.
- Panretin (alitretinoin) is indicated for topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma. Pancretin is not indicated when systemic anti-KS therapy is required (e.g., more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement).
- Soolantra (ivermectin 1% cream) is indicated for the treatment of inflammatory lesions of rosacea.
- Tazarotene 0.05% and 0.1% cream are indicated for the topical treatment of plaque psoriasis. Tazarotene 0.1% cream is also indicated for the topical treatment of acne vulgaris.
- Tazarotene 0.05% and 0.1% gel are indicated for the topical treatment of patients with stable plaque psoriasis of up to 20% body surface area involvement. Tazarotene 0.1% gel is also indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.
- Tazarotene 0.1% topical foam is indicated for the topical treatment of acne vulgaris.
- Tretinoin is indicated for topical application in the treatment of acne vulgaris.
- Winlevi (clascoterone) 1% cream is a topical androgen receptor antagonist for the treatment of acne vulgaris in patients 12 years of age and older.

Medication Name	Coverage
Azelaic Acid Products	
Azelaic acid 15% gel (generic Finacea)	Covered
Finacea (azelaic acid) 15% foam	PA
Azelex (azelaic acid) 20% cream	PA;QL
Benzoyl Peroxide Products	
Benzoyl peroxide 2.5, 5, 10% gel	Covered
Benzoyl peroxide 4, 8% gel	PA
Benzoyl peroxide 4, 5, 6, 10% cleanser	Covered
Benzoyl peroxide 2.5, 7% cleanser	PA
Benzoyl peroxide 5.3, 9.8% foam	PA
Benzoyl peroxide – erythromycin 5-3% gel	PA
Erythromycin Products	
Erythromycin 2% gel	Covered
Erythromycin 2% solution	Covered
Clindamycin Products	
Clindamycin 1% gel	Covered
Clindamycin 1% lotion	Covered
Clindamycin 1% solution	Covered
Clindamycin 1% foam	PA
Clindamycin 1% swab	Covered
Clindamycin–Benzoyl Peroxide Combination Products	
Clindamycin-benzoyl peroxide 1-5% gel	PA

Medication Name	Coverage
Clindamycin-benzoyl peroxide 1.2-5% gel	PA
Metronidazole Products	
Metronidazole 0.75% cream	Covered
Metronidazole 0.75% gel	Covered
Metronidazole 0.75% lotion	Covered
Metronidazole 1% gel	Covered
Noritate (metronidazole) 1% cream	PA
Vitamin A Derivatives	
Adapalene 0.1% cream	STPA*
Adapalene 0.1% gel (RX)	STPA*
Adapalene 0.1% lotion	STPA*
Tretinoin 0.025, 0.05, 0.1% cream	0 through 25 years of age: Covered 26 years of age and older: PA
Tretinoin 0.01, 0.025% gel	0 through 25 years of age: Covered 26 years of age and older: PA
Tretinoin 0.05% gel	PA
Altreno (tretinoin) 0.05% lotion	PA
Tazarotene 0.05, 0.1% cream	STPA*
Tazarotene 0.05, 0.1% gel	STPA*
Fabior (tazarotene) 0.1% foam	PA
Tretinoin microsphere 0.04, 0.1% gel	PA
Panretin (alitretinoin) 0.1% gel	PA
Androgen Receptor Antagonist	
Winlevi (clascoterone) 1% cream	PA
Miscellaneous	
Dapsone (generic Aczone) 5, 7.5% gel	PA
Mirvaso (brimonidine) 0.33% gel	PA
Soolantra (ivermectin) 1% cream	PA

*Adapalene and tazarotene will process with a step edit at the point-of-sale if there is a prior claim for tretinoin within the last 180 days.

PA = Prior Authorization; QL = Quantity Limit; STPA = Step Therapy Required

COVERAGE GUIDELINES

The plan may authorize coverage of products used for acne and rosacea for Members, when **all** of the following criteria are met:

Adapalene

1. The Member had an insufficient response to therapy with tretinoin

Alitretinoin (Panretin)

1. Documented diagnosis of AIDS-related Kaposi's sarcoma

AND

2. Documentation the Member does not require systemic anti-Kaposi's sarcoma therapy

Azelaic Acid Foam (Finacea)

1. Documented diagnosis of rosacea

AND

2. An inadequate response or intolerance to generic metronidazole gel and at least one additional generic topical agent used for the treatment of rosacea

Azelaic Acid Cream (Azelex)
1. Documented diagnosis of acne

AND

2. An inadequate response to therapy with tretinoin

Benzoyl peroxide
1. The Member had an insufficient response to therapy with two of the preferred benzoyl peroxide products

Brimonidine Gel (Mirvaso)
1. The Member is at least 18 years of age with the diagnosis of persistent (nontransient) erythema of rosacea

AND

2. The Member had an insufficient response to at least two alternative generic topical products, e.g. metronidazole, sulfacetamide, retinoid, clindamycin

Clascoterone Cream (Winlevi)
1. The Member has a diagnosis of acne vulgaris

AND

2. The Member is 12 years of age or older

AND

3. The Member has had an inadequate response or intolerance to two or contraindication to all of the following:
    a. Spironolactone
    b. Topical antibiotic (e.g., clindamycin, erythromycin)
    c. Oral tetracycline (e.g., minocycline, doxycycline)
    d. Retinoic acid derivative (e.g., tretinoin, adapalene, isotretinoin)
    e. Benzoyl peroxide

Clindamycin Foam
1. The Member has had an inadequate response to therapy with two preferred topical clindamycin formulations

Clindamycin/Benzoyl Peroxide
1. The Member had an insufficient response to concurrent therapy with the individual topical ingredients, clindamycin and prescription-strength benzoyl peroxide.

AND

2. The request if for a generic (AB-rated) formulation

Erythromycin/Benzoyl Peroxide
1. The Member has had an inadequate response to concurrent therapy with the individual topical ingredients, erythromycin and prescription-strength benzoyl peroxide

AND

2. The request if for a generic (AB-rated) formulation

Dapsone (Aczone 5 and 7.5% gel)
1. The Member had an insufficient response to therapy with at least two alternative topical products: benzoyl peroxide, erythromycin, clindamycin, sulfacetamide or sulfacetamide/sulfur

Ivermectin 1% cream (Soolantra)
1. The Member had an insufficient response to therapy metronidazole and at least one additional generic topical agent used for the treatment of rosacea

Noritate (metronidazole) 1% cream
1. The Member had an insufficient response to therapy with metronidazole 0.75% cream, gel or lotion

AND

2. The Member had an insufficient response to therapy with generic metronidazole 1% gel

Tazarotene

1. The Member had an insufficient response to therapy with tretinoin

OR

2. The request is for an alternative dermatological inflammatory condition, such as plaque psoriasis

Tretinoin (Criteria apply to all nonpreferred agents for all Members as well as for preferred agents for Members 26 years of age and older)

1. The request is for the treatment of acne, rosacea, cutaneous carcinoma, keratosis follicularis or verruca plana (flat warts)

AND

2. **If the request is for a non-preferred formulation (e.g. tretinoin microspheres) or a brand-name product:** Member had an insufficient response to therapy with at least two preferred tretinoin formulations. Preferred formulations include generic tretinoin 0.025%. 0.05% and 0.1% cream, and generic tretinoin 0.01% and 0.025% gel

LIMITATIONS

1. Unless otherwise note, products packaged as medicated swabs or in pump dispensers are non-covered when bulk packaging is available.
2. These products will not be approved for cosmetic purposes.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
4. Quantity limits are as follows:

Medication Name	Quantity Limit
Azelex (azelaic acid) 20% cream	30 grams per fill

CODES

None

REFERENCES

1. Aczone 5% (dapsone) [prescribing information]. Irvine, CA: Allergan, Inc.; May 2018.
2. Aczone 7.5% (dapsone) [prescribing information]. Malvern, PA: Almirall, LLC; August 2021.
3. Adapalene cream [prescribing information]. Melville, NY: Fougera Pharmaceuticals Inc.; December 2013.
4. Azelex (azelaic acid) cream [prescribing information]. Exton, PA: Almirall, LLC; June 2019.
5. Differin (adapalene) 0.1% cream [prescribing information]. Fort Worth, TX: Galderma Laboratories, LLC; November 2011.
6. Duac (benzoyl peroxide/clindamycin) [prescribing information]. Research Triangle Park, NC. Stiefel Laboratories, Inc.; April 2015.
7. Finacea (azelaic acid) foam [prescribing information]. Madison, NJ: LEO Pharma Inc.; December 2020.
8. Finacea (azelaic acid) gel [prescribing information]. Madison, NJ: LEO Pharma Inc.; November 2021.
9. Graber E. Acne vulgaris: overview of management. UpToDate. Available at: www.uptodate.com. Accessed: 17 July 2023.
10. Maier LE. Management of rosacea. UpToDate. Available at: www.uptodate.com. Access 17 July 2023.
11. Mirvaso (brimonidine) [prescribing Information]. Fort Worth, TX: Galderma Laboratories, L.P.; December 2022.
12. Noritate (metronidazole) 1% cream [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; June 2020.
13. Panretin 0.1% gel (alitretinoin) [prescribing information]. Dublin, Ireland: Concordia Pharmaceuticals; May 2020.
14. Retin-A (tretinoin) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2019.
15. Soolantra (ivermectin 1% cream) [prescribing information]. Dallas, TX; Galderma Laboratories, L.P.; October 2022.
16. Tazorac (tazarotene cream) [prescribing information]. Exton, PA: Almirall, LLC; August 2019.
17. Tazorac (tazarotene gel) [prescribing information]. Exton, PA: Almirall, LLC; August 2019.

18. Winlevi (clascoterone) cream [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries Limited; July 2022.
19. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines for the management of acne vulgaris. *J Am Acad* Dermatol. 2016;74:94-73.

APPROVAL HISTORY

October 11, 2022: Reviewed by the Pharmacy and Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective November 1, 2023, updated Winlevi criteria to require step through with two agents or contraindication to all step through agents.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services