TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Acne and Rosacea Medications

Effective: October 1, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ 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. Panretin 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.

Medication Name	Coverage
Azelaic Acid Products	
Azelaic acid 15% gel (generic Finacea)	Covered;QL
Finacea (azelaic acid) 15% foam	PA;QL
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;QL
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;QL
Clindamycin-benzoyl peroxide 1.2-5% gel	PA;QL
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	
Differin (adapalene) OTC 0.1% gel	Covered
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
Miscellaneous	
Dapsone (generic Aczone) 5, 7.5% gel	PA;QL
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 and Differin OTC

AND

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

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 therapy with azelaic acid 15% gel

Azelaic acid cream (Azelex)

1. Documented diagnosis of acne

AND

2. An inadequate response or intolerance 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 topical products, e.g. metronidazole, sulfacetamide, azelaic acid, retinoid, clindamycin

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 with two preferred alternative topical medications for rosacea (e.g., metronidazole, azelaic acid)

Metronidazole 1% cream (Noritate) (topical)

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 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:** the 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 noted, 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
Azelaic acid 15% gel	50 grams per prescription
Finacea (azelaic acid) 15% foam	50 grams per prescription
Azelex (azelaic acid) 20% cream	30 grams per fill
Clindamycin-benzoyl peroxide 1-5% gel	50 grams per 30 days
Clindamycin-benzoyl peroxide 1.2-5% gel	50 grams per 30 days
Benzoyl peroxide-erythromycin 5-3% gel	23 grams per 30 days
Dapsone 5% gel	60 grams per 30 days
Dapsone 7.5% gel	60 grams per 30 days

CODES

None

REFERENCES

1. Aczone 5% (dapsone) [prescribing information]. Madison, NJ: Allergan, Inc.; May 2018.
2. Aczone 7.5% (dapsone) [prescribing information]. Exton, PA: Almirrall, LLC.; September 2019.
3. Adapalene cream [prescribing information]. Melville, NY: Fougera Pharmaceuticals Inc.; December 2013.
4. Maier LE. Management of Rosacea. Available from: http://www.uptodate.com/contents/management-of-rosacea, accessed, December 2013.
5. Drugs for Acne, Rosacea and Psoriasis. Treatment Guidelines from The Medical Letter. Vol 11: January 2013.
6. Differin (adapalene) 0.1% cream [prescribing information]. Fort Worth, TX: Galderma Laboratories, LLC; November 2011.
7. Duac (benzoyl peroxide/clindamycin) [prescribing information]. Research Triangle Park, NC. Stiefel Laboratories, Inc.;April 2015.
8. Mirvaso (brimonidine) [prescribing Information]. Fort Worth, TX: Galderma Laboratories, L.P.;November 2017.
9. Panretin 0.1% gel (alitretinoin) [prescribing information]. San Antonio, TX: DPT Laboratories, Ltd; September 2019.
10. Retin-A (tretinoin) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; September 2019.
11. Soolantra (ivermectin 1% cream)[prescribing information]. Fort Worth, TX; Galderma Laboratories, L.P.; July 2018.
12. Tazorac cream [prescribing information]. Irvine, CA. Allergan, Inc.; July 2017
13. Tazorac gel [prescribing information]. Madison, NJ. Allergan, Inc.; April 2018.
14. 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

December 9, 2014: Reviewed by the Pharmacy and Therapeutics Committee. New guideline incorporating individual criteria of affected agents; approval duration of one year applied to all products.

Subsequent endorsement date(s) and changes made:

1. April 14, 2015: Criteria modified to include Soolantra; approval duration modified to two years.
2. September 16, 2015: Approval duration approved for life of plan
3. January 1, 2016: Administrative change to rebranded template.
4. May 10, 2016: Added criteria for Panretin. Added Aczone 7.5% gel to existing criteria for dapsone gel.
5. May 9, 2017: Administrative update, adding Tufts Health RITogether to the template.
6. July 11, 2017: Added trial of Differin OTC to prescription adapalene approval criteria.

7. July 10, 2018: Effective 7/16/18, updated criteria for tretinoin products to indicate coverage of preferred products for Members 0 through 25 years of age. Removed benzoyl peroxide 2.5%, 5%, and 10% lotion from the list of preferred benzoyl peroxide agents due to the products no longer being available. Effective 1/1/19, added criteria specific for Noritate as well as nonpreferred benzoyl peroxide products.
8. February 12, 2019: Effective 4/9/19, updated MNG to include generic benzoyl peroxide 4% wash as a preferred product. Administrative changes made to template.
9. June 9, 2020: Effective 6/15/20, updated MNG to reflect that benzoyl peroxide 6% cleanser, clindamycin 1% swab, and metronidazole 1% gel are covered without PA. Updated the limitations section of the MNG to clarify that unless otherwise noted, products packaged as medicated swabs or in pump dispensers are non-covered when bulk packaging is available, and added quantity limitations. Removed criteria for metronidazole 1% gel. Updated dapsone criteria to include benzoyl peroxide as a previous trial option. Effective 10/1/20, updated MNG to reflect that Azelex cream, Finacea foam, benzoyl peroxide 2.5% cleanser, and benzoyl peroxide-erythromycin 5-3% gel require Prior Authorization. Added criteria for non-preferred azelaic acid and benzoyl peroxide/erythromycin combination products.

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.