Acne and Rosacea Products
Adapalene, Brimonidine Gel (Mirvaso), Clindamycin/Benzoil Peroxide, Dapsone (Aczone 5% gel), Ivermectin 1% cream (Soolantra), Metronidazole (topical), Tazarotene, Tretinoin
Effective: 7/1/15

<table>
<thead>
<tr>
<th>Clinical Documentation and Prior Authorization Required</th>
<th>Type of Review – Case Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Fax: 617-673-0956</td>
</tr>
</tbody>
</table>

**OVERVIEW**

**FDA-APPROVED INDICATIONS**
- Adapalene is indicated for the topical treatment of acne vulgaris.
- Mirvaso (brimonidine gel) is indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age and older.
- Clindamycin/benzoil peroxide is indicated for the topical treatment of inflammatory acne vulgaris.
- Aczone (dapsone gel) is indicated for the topical treatment of acne vulgaris.
- Metronidazole (topical) is indicated for topical application in the treatment of inflammatory papules and pustules of rosacea.
- Soolantra (ivermectin 1% cream) is indicated for the treatment of inflammatory lesions of rosacea.
- Tazorac (tazarotene) 0.05% and 0.1% cream are indicated for the topical treatment of plaque psoriasis. Tazorac 0.1% cream is also indicated for the topical treatment of acne vulgaris.
- Tazorac (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. Tazorac 0.1% gel is also indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.
- Tretinoin is indicated for topical application in the treatment of acne vulgaris.

Preferred topical products for the treatment of acne include: erythromycin 2% gel and solution, clindamycin 1% gel, lotion and solution, benzoil peroxide 2.5%, 5% and 10% lotion, gel and wash, sulfacetamide 10% lotion and sulfacetamide 10%/sulfur 5% lotion.

Preferred topical products for the treatment of rosacea include: metronidazole 0.75% cream and 0.75% gel, azelaic 15% gel, clindamycin 1% gel and lotion, and sulfacetamide 10% lotion.

Topical vitamin A derivative products: Generic tretinoin cream (0.025%, 0.05%, 0.1%) and gel (0.01%, 0.025%) are the preferred vitamin A derivative products. 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.

**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of products used for acne and rosacea for members when the following criteria for a particular regimen are met and limitations do not apply:

- **Adapalene**
  - The member had an insufficient response to therapy with tretinoin
  - The request is for a generic (AB-rated) formulation

- **Brimonidine Gel (Mirvaso)**
  - The member is at least 18 years of age with the diagnosis of persistent (nontransient) erythema of rosacea
  - The member had an insufficient response to at least two alternative topical products, e.g. metronidazole, sulfacetamide, azelaic acid, retinoid, clindamycin
**Clindamycin/Benzoyl Peroxide**
- The member had an insufficient response to concurrent therapy with the individual topical ingredients, clindamycin and prescription-strength benzoyl peroxide.
- The request if for a generic (AB-rated) formulation

**Dapsone (Aczone 5% gel)**
- The member had an insufficient response to therapy with at least two alternative topical products, erythromycin, clindamycin, sulfacetamide or sulfacetamide/sulfur

**Ivermectin 1% cream (Soolantra)**
- The member had an insufficient response to therapy with two preferred alternative topical medications for rosacea, metronidazole and azelaic acid

**Metronidazole (topical)**
- The member had an insufficient response to therapy with metronidazole 0.75% cream, gel or lotion

**Tazarotene**
- The member had an insufficient response to therapy with tretinoin **OR**
- The request is for an alternative dermatological inflammatory condition, such as plaque psoriasis

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

**Upon renewal,**
- The member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is medically necessary.

**LIMITATIONS**
- Approval duration will be limited to two years.
- Products packaged as medicated swabs or in pump dispensers are non-covered when bulk packaging is available.
- These products will not be approved for cosmetic purposes.
- Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

**CODES**
None

**REFERENCES**
1. Soolantra (ivermectin 1% cream) [prescribing information]. Fort Worth, TX; Galderma Laboratories, L.P.; December 2014.

**APPROVAL HISTORY**
- 04/14/15: Reviewed by the Pharmacy and Therapeutics Committee. Criteria modified to include Soolantra; approval duration modified to two years.
- 12/9/14: Reviewed by the Pharmacy and Therapeutics Committee. New guideline incorporating individual
criteria of affected agents; approval duration of one year applied to all products.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan – Network Health offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable product formulary in the Pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.