MEDICAL MUTUAL®

Drug Policy

Policy:	**Topical Retinoid Products**	**Annual Review Date:**
		12/21/2023
Impacted Drugs:	**Brand and Generic Tretinoin-, Adapalene-, Tazarotene-, Trifarotene- Containing Products**	**Last Revised Date:**
		12/21/2023

OVERVIEW

Topical retinoids (e.g., trifarotene, tretinoin, adapalene, and tazarotene) can be used in regimens of care for all types and severities of acne in children and adolescents of all ages. Topical retinoids can be used as monotherapy or in combination with other products such as antibiotics. Differin (adapalene) is a naphthoic acid derivative that selectively binds to come nuclear retinoic acid receptors (RARs) without binding to cellular receptors. Differin's selectivity enhances keratinocyte differentiation without inducing severe irritation and redness. There are multiple formulations that are indicated for the treatment of acne vulgaris. Differin comes in a cream, gel/jelly, and a lotion with generics also including a swab formulation. Differin gel is available as an over-the-counter product while all other forms (brand and generic) are prescription only. The active ingredient, adapalene, is also available as a combination product including benzyl peroxide called Epiduo and Epiduo Forte. Epiduo is indicated for patients ≥9 years of age, while Epiduo Forte is indicated for patients ≥ 12 years of age. Benzoyl peroxide-containing products are generally indicated for the treatment or prevention of mild-to-moderate acne vulgaris.

Altreno, Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X, and their generic formulations are topical tretinoin products indicated for treatment of acne vulgaris. Veltin and Ziana are topical combination products that contain clindamycin phosphate along with tretinoin that are indicated for the treatment of acne vulgaris. Renova is indicated as adjunctive treatment for mitigation (palliation) of fine wrinkles in persons who use comprehensive skin care and sun avoidance programs. Refissa is indicated as adjunctive treatment for mitigation (palliation) of fine wrinkles, mottled hyperpigmentation, and tactile roughness of facial skin in patients who do not achieve such palliation using comprehensive skin care and sun avoidance programs alone. Topical tretinoin has been used to treat numerous other medical skin conditions in addition to acne vulgaris. Some indications have minimal published clinical data and thus appear experimental. Topical tretinoin products have also been used to treat a variety of cosmetic skin conditions such as wrinkles, stretch marks, liver spots, premature aging, and photo-aged or photo-damaged skin.

Tazarotene is a retinoid prodrug that is converted to an active metabolite which binds selectively to the beta and gamma subtypes of the retinoic acid receptors. Tazorac gel is indicated for the topical treatment of stable plaque psoriasis of up to 20% body surface area (BSA) involvement and for treatment of patients with mild to moderate facial acne vulgaris. Tazorac cream is indicated for treatment of plaque psoriasis and acne vulgaris. The cream formulation is also marketed as Avage which is indicated as an adjunctive agent for the mitigation (palliation) of facial fine wrinkling, facial mottled hyper- and hypo-pigmentation, and benign facial lentigines when a comprehensive skin care and sunlight program is utilized. Fabior foam is indicated for the topical treatment of acne vulgaris in patients ≥ 12 years of age. Arazlo lotion is indicated for the

topical treatment of acne vulgaris in patients 9 years of age and older. In addition to acne vulgaris and plaque psoriasis, topical tazarotene has been used to treat other medical skin conditions, such as basal cell carcinoma and congenital ichthyoses. Topical tazarotene has also been used to treat cosmetic skin conditions such as wrinkles, premature aging, and treatment of photo-aged or photo-damaged skin.

POLICY STATEMENT

This policy involves the use of topical retinoid products. Prior authorization is recommended for pharmacy benefit coverage of topical retinoid products. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Automation: Patients between the ages of 18 and 30 years of age with a history of one Preferred drug within the 180-day look-back period are excluded from preferred step therapy. An age edit targeting patients aged > 30 years is recommended to monitor for appropriate use and to screen for cosmetic use. For patients > 30 years of age, coverage will be determined by the prior authorization criteria and the Preferred Specialty Management criteria.

Prior authorization and prescription benefit coverage is not recommended for Avage, Renova, or Refissa

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of topical retinoid products is recommended in those who meet the following criteria:

1. **Patients > 30 years of age**
   Criteria: *Approve if the patient meets the following criteria (A or B):*
   - **A.** The patient is using the requested medication for the treatment of acne vulgaris; OR
   - **B.** The patient is using generic tazarotene for the treatment of stable plaque psoriasis of up to 20% body surface area involvement.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

PREFERRED SPECIALTY MANAGEMENT

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

MEDICAL MUTUAL®

Drug Policy

Automation: Patients between the ages of 18 and 30 years of age with a history of one Preferred drug within the 130-day look-back period are excluded from preferred step therapy. An age edit targeting patients aged > 30 years is recommended to monitor for appropriate use and to screen for cosmetic use. For patients > 30 years of age, coverage will be determined by the prior authorization criteria and the Preferred Specialty Management criteria.

*NOTE: Epiduo Forte or Retin-A Micro Pump with DAW9 will count as a Preferred product.

Preferred Products
- Generic adapalene
- Generic adapalene/benzoyl peroxide combination
- Generic clindamycin/tretinoin combination
- Generic tazarotene
- Generic tretinoin

Non-Preferred Products
- Aklief
- Altreno
- Arazlo
- Avita
- Differin
- Epiduo
- Epiduo Forte*
- Retin-A
- Retin-A Micro
- Retin-A Micro Pump
- Tretin-X
- Ziana

TOPICAL RETINOID PREFERRED STEP THERAPY CRITERIA
Patients ≥ 18 years of age will be targeted in this preferred step therapy program

1. Coverage is provided for a non-preferred medication in situations where the patient has had an inadequate response, experienced intolerance, OR has a contraindication to one preferred topical retinoid product.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

MEDICAL MUTUAL®

Drug Policy

Topical retinoid products have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Cosmetic Conditions.** (e.g., alopecia, hyperpigmentation, liver spots, melasma/cholasma, seborrheic keratosis, stretch marks, scarring, wrinkles, premature aging, photo-aged or photo-damaged skin, mottled hyper- and hypopigmentation, benign facial lentigines, roughness, telangiectasia, skin laxity, keratinocytic atypia, melanocytic atypia, dermal elastosis). Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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