PRIOR AUTHORIZATION POLICY

POLICY: Topical Retinoid – Tretinoin Products Prior Authorization Policy

- Altreno™ (tretinoin lotion – Dow Pharmaceuticals, a division of Valeant Pharmaceuticals)
- Atralin™ (tretinoin gel – Valeant Pharmaceuticals, generics)
- Avita® (tretinoin cream, gel – Mylan, generics [Avita gel 0.025% is brand only])
- Retin-A® (tretinoin cream, gel – Valeant Pharmaceuticals, generics)
- Retin-A® Micro® (tretinoin gel microsphere – Valeant Pharmaceuticals, generic)
- Retin-A Micro® Pump (tretinoin gel microsphere – Valeant Pharmaceuticals, generics [Retin-A Micro gel 0.06% and 0.08% are branded products only])
- Tretin•X® (tretinoin cream – Onset Dermatologicals)
- Veltin™ (clindamycin phosphate 1.2% and tretinoin 0.025% gel – Aqua Pharmaceuticals)
- Ziana® (clindamycin phosphate 1.2% and tretinoin 0.025% gel – Valeant Pharmaceuticals, generics)

REVIEW DATE: 08/05/2020

OVERVIEW

The following topical tretinoin products are indicated for the topical treatment of acne vulgaris: Altreno, Atralin, Avita, Retin-A, Retin-A Micro, Tretin•X, and generics.[1,2] Renova® and Refissa® are also topical tretinoin products; these products are not indicated for use in the treatment of acne vulgaris.[1]

Ziana and Veltin are combination gel products containing clindamycin phosphate 1.2% and tretinoin 0.025%; these products are indicated for the topical treatment of acne vulgaris in patients aged ≥ 12 years.[1,2]

Topical tretinoin products have 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.[2]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of topical tretinoin products. All approvals are provided for the duration noted below.

Prior Authorization and prescription benefit coverage is not recommended for Renova or Refissa.

Automation: An age edit targeting patients > 30 years of age is recommended to monitor for appropriate use and to screen for cosmetic use. Therefore, patients ≤ 30 years of age will be approved at the point-of-service. For patients > 30 years of age, coverage will be determined by the prior authorization criteria.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of topical tretinoin products is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acne Vulgaris.** Approve for 3 years.

Other Uses with Supportive Evidence

2. **Treatment of Other Non-Cosmetic Conditions Not Listed Above**. Approve for 1 year.
   Note: Examples of other non-cosmetic conditions include acne rosacea, actinic keratosis/treatment of precancerous lesions, ichthyosis, diabetic foot ulcers, mucositis, warts, lichen planus, lichen sclerosis, pseudofolliculitis, oral leukoplakia, molluscum contagiosum, Darier's disease (keratosis follicularis), dermatitis/eczema, folliculitis, keratosis pilaris, basal cell carcinoma (skin cancer), confluent and reticulated papillomatosis, and cutis laxa.

II. Coverage of clindamycin plus tretinoin combination products (Ziana, generics; Veltin) is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acne Vulgaris.** Approve for 1 year.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of topical tretinoin products and topical clindamycin/tretinoin products is not recommended in the following situations:

1. **Cosmetic Conditions.** Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.
   Note: Examples of cosmetic conditions include liver spots, stretch marks, scarring, solar elastosis, premature aging, treatment of photo-aged or photo-damaged skin, solar lentigines, skin roughness, mottled hyperpigmentation, age spots, wrinkles, geographic tongue, hyperpigmentation (caused by folliculitis, acne, or eczema), melasma/cholasma, alopecia androgenetic, alopecia areata, seborrheic keratosis, milia, nevus, poikiloderma (of Civatte), purpura (actinic/solar), keloids, and sebaceous hyperplasia.

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

REFERENCES

1. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2020. Available at: http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&qs=. Accessed on July 29, 2020. Search term: tretinoin.
2. DRUGDEX® System. Thomson Reuters (Healthcare) Inc. Available at: http://www.micromedexsolutions.com/micromedex2/librarian/. Accessed on July 29, 2020. Search term: tretinoin..