

**Regence BlueCross BlueShield of Oregon • Regence BlueShield  
Regence BlueCross BlueShield of Utah • Regence BlueShield of Idaho  
Independent licensees of the Blue Cross and Blue Shield Association**

**Medication Policy Manual**

**Policy No:** dru067

**Topic:** Topical Tretinoin

**Date of Origin:** May 20, 1997

- Altinac<sup>®</sup>
- Atralin<sup>®</sup>
- Retin A<sup>®</sup>
- Solage<sup>®</sup>
- Avita<sup>®</sup>
- Renova<sup>®</sup>
- Retin A Micro<sup>®</sup>

**Revised/Effective Date:** July 17, 2009

**Next Review Date:** July 2010

**IMPORTANT REMINDER**

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

**Description**

Tretinoin is FDA approved for the treatment of acne and fine facial wrinkles (cosmetic). Topical administration of tretinoin increases cell turnover in the skin which is also of use in the treatment of other skin conditions.

## **Policy/Criteria**

- I.** Most contracts require prior authorization approval of topical tretinoin prior to coverage. Topical tretinoin may be considered medically necessary in patients with precancerous and other pathologic conditions including, but not limited to, the conditions listed in Appendix 1.
  
- II.** Administration and Authorization Period
  - A.** Regence considers topical tretinoin to be a self-administered medication.
  - B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.
  
- III.** Topical tretinoin is considered not medically necessary when used for cosmetic indications, including, but not limited to:
  - A.** Liver spots.
  - B.** Melasma.
  - C.** Photo-aged skin.
  - D.** Wrinkles.

## **Position Statement**

- While topical tretinoin is used for the treatment of melasma, photo-aged skin, wrinkles and liver spots, it has not been shown to improve health outcomes in those conditions. Therefore, these indications are considered cosmetic. Benefit contracts exclude coverage of cosmetic indications. <sup>[3,9,12-14]</sup>
  
- The American Academy of Dermatology Association recognizes topical tretinoin (a naturally occurring form of vitamin A) as an effective treatment for mild to moderate acne. <sup>[5]</sup>
  - \* The drug is applied as a cream, lotion, gel, or microsphere gel.

- \* With exception of a microsphere gel preparation, tretinoin gels, creams and lotions are generically available.
- \* Differentiation of efficacy and potential for skin irritation with these products is dependent on the tretinoin concentration and vehicle used. Of these preparations, creams generally have the least irritation, with liquid preparations having the most. <sup>[1]</sup>
- \* Comparative studies show that the microsphere gel formulation has better tolerability and less skin irritation than the 0.1% cream and gel preparations. <sup>[2]</sup> However, comparative efficacy of tretinoin gel microsphere 0.1% and tretinoin cream 0.1% has not been established.

### *Clinical Efficacy*

- Topical tretinoin is also used for several forms of skin cancer and dermatologic conditions including lamellar ichthyosis, keratosis follicularis, mollusca contagiosa, verrucae plantaris, verrucae planae juvenilis, hyperpigmented lesions in blacks, ichthyosis vulgaris, bullous congenital ichthyosiform and pityriasis rubra pilaris. <sup>[3, 4]</sup>
- Tretinoin 0.05% topical solution applied for 10 minutes each day directly to the wound bed of diabetic foot ulcers increased the proportion of healed ulcers over a 16 week period. (p<0.03). <sup>[8]</sup>
- The combination of clindamycin/tretinoin hydrogel was more effective than either agent or vehicle alone in the treatment of patients with acne vulgaris, but the combination may be less effective than clindamycin/benzoyl peroxide. <sup>[6-7]</sup>

### *Safety*

- The skin of certain sensitive individuals may become excessively red, edematous, blistered, or crusted. <sup>[10]</sup>
- Temporary hyper- or hypopigmentation has been reported with repeated application of topical tretinoin. <sup>[10]</sup>
- Some individuals have been reported to have heightened susceptibility to sunlight while under treatment with topical tretinoin. <sup>[10]</sup>
- Topical tretinoin is considered a Pregnancy Category C. <sup>[10]</sup>

## Appendix 1: Examples of precancerous and other pathologic conditions

- Acne vulgaris	- Hyperpigmented lesions in Black patients	- Mollusca contagiosa
- Acute promyelocytic leukemia	- Ichthyosis vulgaris	- Osteoma cutis
- Black hairy tongue	- Kaposi's sarcoma	- Pityriasis rubra pilaris
- Bullous congenital ichthyosiform	- Keratoacanthoma	- Porokeratosis
- Cutaneous horn	- Keratosis follicularis (skin disorder of small, red bumps)	- Solar keratosis
- Diabetic foot ulcers	- Lamellar ichthyosis	- Verrucae planus
- Geographic tongue	- Leukoplakia	- Verrucae planae juvenilis

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Cross References
None

Codes	Number	Description
N/A		