Medication Policy Manual

**Topic:** Topical Tretinoin:
- Atralin™
- Avita®
- Renova®
- Retin A®
- Retin-A Micro®
- Tretin-X®
- Refissa®
- tretinoin (generic)

**Committee Approval:** June 12, 2015

**Effective Date:** July 1, 2015

**Policy No:** dru067

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

**Next Review Date:** June 2016

**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. Tretinoin for cosmetic indications is generally a benefit not covered by member contracts regardless of medical necessity. If tretinoin for cosmetic indications is a covered benefit, contract language will be applied to determine coverage.

This policy applies to generic and branded topical tretinoin products; however, prior authorization is not required for generic tretinoin in patients less than or equal to 25 years of age.
Policy/Criteria

I. For **generic topical tretinoin products**, prior authorization approval is as follows:

   A. For members less than or equal to 25 years of age, generic topical tretinoin products may be covered without prior authorization.

   B. For members greater than 25 years of age, most contracts require prior authorization of generic topical tretinoin products prior to coverage. Generic 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. For **branded topical tretinoin products**, most contracts require prior authorization approval prior to coverage. Branded topical tretinoin products may be considered medically necessary when criteria A and B below are met:

   A. Diagnosis of precancerous or other pathologic condition including, but not limited to, the conditions listed in Appendix 1.

   AND

   B. Treatment with a generic topical tretinoin product has been ineffective or not tolerated.

III. Administration and Authorization Period

   A. OmedaRx 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.

IV. 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. \[1-5\]

- The American Academy of Dermatology recognizes topical tretinoin (a naturally occurring form of vitamin A) as an effective treatment for mild to moderate acne. \[6\]
* 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. \[7\]
* Comparative studies show that the microsphere gel formulation has better tolerability and less skin irritation than the 0.1% cream and gel preparations. \[8\]
  However, comparative efficacy of tretinoin gel microsphere 0.1% and tretinoin cream 0.1% has not been established.

- Generic topical tretinoin is recommended as an initial treatment option for the treatment of acne in pediatric patients; therefore, prior authorization is not required for generic topical tretinoin in patients less than or equal to 25 years of age. \[15\]

- Topical tretinoin is available generically in a variety of forms including cream, gel, emollient cream, and microsphere gel. Generic topical tretinoin provides the best value. There is no evidence any topical tretinoin product is safer or more effective than another.

Clinical Efficacy

- Topical tretinoin is also used for several forms of skin cancer and dermatologic conditions including, but not limited to, lamellar ichthyosis, keratosis follicularis, mollusca contagiosa, verrucae plantaris, verrucae planae juvenilis, hyperpigmented lesions in black patients, ichthyosis vulgaris, bullous congenital ichthyosiform and pityriasis rubra pilaris. \[5,9\]

- 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. \(p<0.03\). \[10\]

- 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. \[11,12\]
Safety
- The skin of certain sensitive individuals may become excessively red, edematous, blistered, or crusted. [13,14]
- Temporary hyper- or hypopigmentation has been reported with repeated application of topical tretinoin. [13,14]
- Some individuals have been reported to have heightened susceptibility to sunlight while under treatment with topical tretinoin. [13,14]
- Topical tretinoin is considered Pregnancy Category C. [13,14]

Appendix 1: Examples of precancerous and other pathologic conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
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<tbody>
<tr>
<td>Acne vulgaris</td>
<td>Hyperpigmented lesions in black patients</td>
</tr>
<tr>
<td>Acute promyelocytic leukemia</td>
<td>Ichthyosis vulgaris</td>
</tr>
<tr>
<td>Black hairy tongue</td>
<td>Kaposi’s sarcoma</td>
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<tr>
<td>Bullous congenital ichthyosiform</td>
<td>Keratoacanthoma</td>
</tr>
<tr>
<td>Cutaneous horn</td>
<td>Keratosis follicularis (skin disorder of small, red bumps)</td>
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<tr>
<td>Diabetic foot ulcers</td>
<td>Lamellar ichthyosis</td>
</tr>
<tr>
<td>Geographic tongue</td>
<td>Leukoplakia</td>
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<tr>
<td>Mollusca contagiosa</td>
<td>Osteoma cutis</td>
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<tr>
<td>Pityriasis rubra pilaris</td>
<td>Porokeratosis</td>
</tr>
<tr>
<td>Solar keratosis</td>
<td>Verrucae planus</td>
</tr>
<tr>
<td>Verrucae planae juvenilis</td>
<td>Psoriasis</td>
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<tr>
<td>Palmoplantar hyperkeratosis</td>
<td>Psoriasiform hand dermatitis</td>
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References


