# Topical Tretinoins and Tretinoin Combination Products

**Policy #** 00342
Original Effective Date: 02/20/2013
Current Effective Date: 02/21/2018

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

**When Services May Be Eligible for Coverage**
*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider topical tretinoin products (including, but not limited to Retin-A®‡, Retin-A Micro®‡, Avita®‡, Tretin X®‡, Atralin®‡† gel, tretinoin powders, and other generic topical tretinoin products) and topical tretinoin/clindaymcin combination products (including, but not limited to Ziana®‡or Veltin®‡) to be **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria
Coverage eligibility will be considered in patients greater than 30 years of age for topical tretinoin products or for topical tretinoin/clindamycin combination products when one of the following criteria is met:

- Requested drug is a topical tretinoin product or a topical tretinoin/clindamycin combination product, and the patient has a diagnosis of acne vulgaris; or
- Requested drug is a topical tretinoin product, and the patient has a diagnosis of: acne rosacea, cystic acne, actinic [solar] keratosis (precancerous lesions), ichthyosis, diabetic foot ulcers, mucositis, warts, keloids, lichen planus, lichen scleroses, pseudofolliculitis, oral leukoplakia, molluscum contagiosum, or Darier's disease (keratosis follicularis); or
- Requested drug is a topical tretinoin product, and the patient has a diagnosis of: skin cancers, dermatitis, folliculitis, keratosis pilaris, sebaceous hyperplasia, sebaceous cyst, milia, eczema, or confluent and reticulated papillomatosis, AND the patient has tried at least one other therapy for the current diagnosis.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

**When Services Are Considered Investigational**
*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers, with the exception of cosmetic indications, the use of topical tretinoin/clindamycin combination products in the absence of an acne vulgaris diagnosis to be **investigational.***

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Based on review of available data, the Company considers, with the exception of cosmetic indications, the use of topical tretinoin products in the absence of an acne vulgaris diagnosis OR in the absence of a non-cosmetic indication, included in the above patient selection criteria, to be **investigational.***

**When Services Are Considered Not Medically Necessary**
Based on review of available data, the Company considers the use of topical tretinoin products for use in skin cancers, dermatitis, folliculitis, keratosis pilaris, sebaceous hyperplasia, sebaceous cyst, milia, eczema, or confluent and reticulated papillomatosis, without first trying at least one other therapy for the diagnosis, to be **not medically necessary.****

**When Services Are Not Covered**
The use of topical tretinoins or topical tretinoin/clindamycin combination products as treatment of wrinkles or other cosmetic conditions are a contract exclusion and is therefore **not covered.**

## Background/Overview

Brand and generic topical tretinoins are indicated for the treatment of acne vulgaris. Combination products containing clindamycin phosphate and tretinoin gel (e.g., Ziana and Veltin) are indicated for the topical treatment of acne vulgaris in patients aged ≥ 12 years.

Topical tretinoins 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.

## Rationale/Source

The use of topical tretinoin products should be limited to the treatment of medical conditions. The use of the combination of clindamycin plus tretinoin (e.g., Ziana, Veltin) should be limited to the treatment of acne vulgaris. Patient selection criteria are based on information collected in a review of the available data.

## References


1. Express Scripts. Topical Tretinoin Products Prior Authorization Policy. 6/2013.
2. DRUGDEX®‡System. Thomson Reuters (Healthcare) Inc. Available at: http://www.thomsonhc.com. Accessed on 6/4/2013. Search terms: tretinoin.


## Policy History

Original Effective Date: 02/20/2013
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| 02/07/2013 | Medical Policy Committee review |
| 02/20/2013 | Medical Policy Implementation Committee approval. New policy. |
| 02/06/2014 | Medical Policy Committee review |
| 02/19/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/05/2015 | Medical Policy Committee review |
| 02/18/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |
| 02/04/2016 | Medical Policy Committee review |


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*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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