BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Topical Acne Products

Policy # 00343
Original Effective Date: 02/20/2013
Current Effective Date: 02/19/2014

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 brand name topical acne products including, but not limited to products containing dapsone (e.g., Aczone®)‡, azelaic acid (e.g., Azelex®)‡, benzoyl peroxide (e.g., Zoderm®‡, Benziq®)‡, sulfacetamide (e.g., Klaron®)‡, sulfacetamide/sulfur (e.g., Avar®, Zetacet®)‡, erythromycin (e.g., Del-Mycin®)‡, clindamycin (e.g., Clindets®, Evoclin®)‡, and combinations of these products (e.g., Benzamycin PAK®, Inova®)‡ to be **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria
Coverage eligibility will be considered for brand name topical acne products when one of the following criteria is met:

- The patient has tried and failed one generic prescription topical benzoyl peroxide, clindamycin, erythromycin, or sodium sulfacetamide containing product; or
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of brand name topical acne products when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

Background/Overview

Topical acne products are used in the treatment of acne. Benzoyl peroxide containing products are generally indicated for the treatment or prevention of mild to moderate acne vulgaris. Azelaic acid is indicated for the topical treatment of mild to moderate inflammatory acne vulgaris and for the treatment of inflammatory pustules and papules of mild to moderate acne rosacea. Topical clindamycin, erythromycin, and dapsone gel are indicated for the treatment of acne vulgaris. Sulfacetamide sodium and sulfur are antimicrobial and antiseptic agents, respectively which aid in the removal of keratin and drying of the skin. Guidelines do not prefer any of the specific brand name agents over their generically similar products for the treatment of acne.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to

the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a brand name topical acne product over the available generic topical acne products. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Express Scripts. Topical Acne Products Step Therapy Policy. 10/2013.
2. James WD. Acne. N Engl J Med. 2005;352(14):1463-1472.
3. Katsambas AD, Stefanaki C, Cunliffe WJ. Guidelines for treating acne. Clin Dermatol. 2004;22:439-444.
4. Benzashave® medicated shaving cream [package insert]. Fairfield, NJ; Doak Dermatologics: August 2005.
5. Clinical Pharmacology © 2013. Available at http://www.clinicalpharmacology-ip.com/Default.aspx. Accessed on: January 16, 2013. Search Terms: azelaic acid, benzoyl peroxide, clindamycin, dapsone, erythromycin, sulfur, sulfacetamide.
6. Thiboutot D, Gollnick, Vincenzo B, et al on behalf of the Global Alliance to Improve Outcomes in Acne. New insights into the management of acne: An update from the Global Alliance to Improve Outcomes in Acne Group. J Am Acad Dermatol. 2009;60:S1-50).

Policy History

Original Effective Date: 02/20/2013
Current Effective Date: 02/19/2014
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. No change to coverage.
Next Scheduled Review Date: 02/2015

*****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.

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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.