



# Louisiana

## Topical Corticosteroids

**Policy #** 00318

**Original Effective Date:** 05/22/2013

**Current Effective Date:** 07/11/2018

*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.*

### **For Patients With "Step Therapy" (generic before brand) ONLY:**

Based on review of available data, the Company may consider brand name topical corticosteroids (including, but not limited to Clobex<sup>®</sup> (clobetasol), Desonate<sup>®</sup> (desonide), Kenalog<sup>®</sup> (triamcinolone), Locoid Lipocream<sup>®</sup> (hydrocortisone), Impoyz<sup>™</sup> (clobetasol) and Olux E<sup>®</sup> (clobetasol)) 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 corticosteroids when one of the following criteria is met:

- The patient has tried and failed one generic prescription topical corticosteroid product for their current condition (e.g. clobetasol, desonide, triamcinolone, hydrocortisone, betamethasone); 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 corticosteroids when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary**.\*\*

### **For Patients With "Prior Authorization" ONLY:**

Based on review of available data, the Company may consider Impoyz (clobetasol) to be eligible for coverage when the patient selection criteria are met:

#### Patient Selection Criteria:

Coverage eligibility will be considered for Impoyz (clobetasol) when the following criteria are met:

- Patient has a diagnosis of moderate to severe plaque psoriasis; AND
- Patient is greater than or equal to 18 years of age; AND
- Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% BSA with plaque psoriasis involving areas that would significantly impact daily function (such as palms or soles of feet); AND

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

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- Patient has tried and failed (e.g. intolerance or inadequate response) TWO prescription GENERIC clobetasol propionate products for at least TWO weeks EACH unless there is clinical evidence or patient history that suggests the use of TWO prescription GENERIC clobetasol propionate products for at least TWO weeks EACH will be ineffective or cause an adverse reaction to the patient. Note: Generic clobetasol formulations include clobetasol propionate cream 0.05%, clobetasol propionate gel 0.05%, clobetasol propionate ointment 0.05%, clobetasol propionate emollient base cream 0.05%; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- Patient has tried and failed (e.g. intolerance or inadequate response) TWO of the following prescription generic super high or high potency topical corticosteroids for at least TWO weeks EACH: betamethasone dipropionate 0.5% cream, lotion, or ointment; halobetasol propionate 0.5% cream or ointment; or desoximetasone, unless there is clinical evidence or patient history that suggests the use of the select prescription generic super high or high potency topical corticosteroids for at least TWO weeks EACH will be ineffective or cause an adverse reaction to the patient.  
*(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 Not Medically Necessary**

Based on review of available data, the Company considers the use of Impoyz (clobetasol) when the patient has less than or equal to 10% of BSA impacted by plaque psoriasis when the plaque psoriasis does not involve areas that would significantly impact daily function and when the patient has not tried and failed two prescription generic clobetasol products AND two additional prescription generic super high or high potency topical corticosteroids to be **not medically necessary.\*\***

### **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 the use of Impoyz (clobetasol) for patients younger than 18 years of age or for any indication other than the treatment of moderate to severe plaque psoriasis to be **investigational.\***

### **For Patients With BOTH “Prior Authorization” AND “Step Therapy”:**

Based on review of available data, the Company may consider brand name topical corticosteroids (including, but not limited to Clobex (clobetasol), Desonate (desonide), Kenalog (triamcinolone), Locoid Lipocream (hydrocortisone), Impoyz (clobetasol) and Olux E (clobetasol)) to be **eligible for coverage** when one of the below patient selection criteria is met:

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### Patient Selection Criteria

Coverage eligibility will be considered for brand name topical corticosteroids when ALL of the specific drug's criteria are met:

- For Impoyz requests ONLY:
  - Patient has a diagnosis of moderate to severe plaque psoriasis; AND
  - Patient is greater than or equal to 18 years of age; AND
  - Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% BSA with plaque psoriasis involving areas that would significantly impact daily function (such as palms or soles of feet); AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - Patient has tried and failed (e.g. intolerance or inadequate response) TWO prescription GENERIC clobetasol propionate products for at least TWO weeks EACH unless there is clinical evidence or patient history that suggests the use of TWO prescription GENERIC clobetasol propionate products for at least TWO weeks EACH will be ineffective or cause an adverse reaction to the patient. Note: Generic clobetasol formulations include clobetasol propionate cream 0.05%, clobetasol propionate gel 0.05%, clobetasol propionate ointment 0.05%, clobetasol propionate emollient base cream 0.05%; AND  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
  - Patient has tried and failed (e.g. intolerance or inadequate response) TWO of the following prescription generic super high or high potency topical corticosteroids for at least TWO weeks EACH: betamethasone dipropionate 0.5% cream, lotion, or ointment; halobetasol propionate 0.5% cream or ointment; or desoximetasone, unless there is clinical evidence or patient history that suggests the use of the select prescription generic super high or high potency topical corticosteroids for at least TWO weeks EACH will be ineffective or cause an adverse reaction to the patient.  
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*
- For all other brand name topical corticosteroid requests:
  - The patient has tried and failed one generic prescription topical corticosteroid product for their current condition (e.g. clobetasol, desonide, triamcinolone, hydrocortisone, betamethasone); 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 Impoyz (clobetasol) when the patient has less than or equal to 10% of BSA impacted by plaque psoriasis when the plaque psoriasis does not involve areas that would significantly impact daily function and when the patient has not tried and failed two prescription generic clobetasol products AND two additional prescription generic super high or high potency topical corticosteroids to be **not medically necessary.\*\***

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Based on review of available data, the Company considers the use of brand name topical corticosteroids (besides Impoyz [clobetasol]) when the patient has not tried and failed one generic prescription topical corticosteroid (e.g. clobetasol, desonide, triamcinolone, hydrocortisone, betamethasone) to be **not medically necessary**.\*\*

### **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 the use of Impoyz (clobetasol) for patients younger than 18 years of age or for any indication other than the treatment of moderate to severe plaque psoriasis to be **investigational**.\*

### **Background/Overview**

Topical corticosteroids possess anti-inflammatory, antipruritic, and vasoconstrictive properties and are generally used for the symptomatic relief of inflammation and/or pruritus associated with acute and chronic corticosteroid-responsive skin conditions. In the United States, these products are divided into 7 groups based on potency with group 1 being super high potency corticosteroids and group 7 being the least potent.

Impoyz contains 0.025% clobetasol propionate cream and is classified as a high potency topical corticosteroid. Impoyz is approved for the treatment of moderate to severe plaque psoriasis in adults. Many generic clobetasol propionate products are available including clobetasol propionate cream 0.05%, clobetasol propionate gel 0.05%, clobetasol propionate ointment 0.05%, and clobetasol propionate emollient base cream 0.05%. In addition, other high potency topical corticosteroids are available in generic formulations. These include betamethasone dipropionate 0.5% cream, lotion, or ointment; halobetasol propionate 0.5% cream or ointment; and desoximetasone. These generic alternatives provide an equally efficacious, yet cost effective alternative to this branded product.

### **Rationale/Source**

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic topical corticosteroids 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 corticosteroid over the available generic topical corticosteroids. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

Impoyz was studied in two double-blind, randomized, vehicle-controlled trials in 532 adult subjects with moderate to severe plaque psoriasis. Subjects were treated twice daily with Impoyz or vehicle cream for 14 days. The primary endpoint was the proportion of subjects who achieved treatment success at Day 15, defined as an Investigator Global Assessment (IGA) score of 0 (clear) or 1 (almost clear) with at least a 2-grade reduction from baseline. In trials 1 and 2, 30.2% and 30.1% of the Impoyz group achieved the

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primary endpoint compared to approximately 9% and 9.7% of the vehicle group. Impoyz was not compared to any of the many available alternative topical corticosteroid products, so no claims of superiority can be made.

### References

1. Impoyz [package insert]. Princeton, NJ. Promius Pharma. 11/2017
2. Express Scripts. Topical Corticosteroids Step Therapy Policy. 2/2018.
3. Comparison of representative topical corticosteroid preparations (classified according to the US system). UpToDate. 2018.

### Policy History

Original Effective Date: 05/22/2013

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05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. New policy.
05/01/2014	Medical Policy Committee review
05/21/2014	Medical Policy Implementation Committee approval. No change to coverage.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. No change to coverage.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. No change to coverage
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. No change to coverage
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Policy updated to include new drug, Impoyz. Added PA criteria for Impoyz and separated policy into step only, step/PA, PA only to address the PA added to Impoyz.

Next Scheduled Review Date: 07/2019

\*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:

- 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
- 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;

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- 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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