



# Louisiana

## Select Dexamethasone Packs

**Policy #** 00564

**Original Effective Date:** 06/21/2017

**Current Effective Date:** 01/01/2019

*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 select brand/generic dexamethasone packs (e.g. Locort™, Zonacort™, Zodex™, Taperdex™, DexPak™, generic dexamethasone packs)<sup>†</sup> to be **eligible for coverage** when the patient selection criterion is met.

### Patient Selection Criteria

Coverage eligibility for select brand/generic dexamethasone packs (e.g. Locort, Zonacort, Zodex, Taperdex, DexPak, generic dexamethasone packs) will be considered when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of generic dexamethasone tablets (non-pack) 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 select brand/generic dexamethasone packs (e.g. Locort, Zonacort, Zodex, Taperdex, DexPak, generic dexamethasone packs) when the patient selection criterion is not met to be **not medically necessary**.\*\*

### **Background/Overview**

Locort, Zonacort, Zodex, Taperdex, DexPak, and generic dexamethasone packs (which all contain dexamethasone tablets) are approved for the treatment of allergic states, dermatologic diseases, endocrine disorders, gastrointestinal diseases, hematologic disorders, neoplastic diseases, nervous system diseases, ophthalmic diseases, renal diseases, respiratory diseases, rheumatic disorders and other miscellaneous conditions. These are identical indications to generic dexamethasone tablets. Zonacort and Locort are both available in packs that contain twenty-one 1.5 mg dexamethasone tablets for use during a 7 day titration as well as packs containing forty-one 1.5 mg dexamethasone tablets for use during an 11 day titration. Zodex and Taperdex are both available in packs that contain twenty-one 1.5 mg dexamethasone tablets for use during a 6 day titration as well as packs containing forty-nine 1.5 mg dexamethasone tablets for use during a twelve day titration. DexPak and the generic dexamethasone pack currently available are supplied in 6, 10, and 13 day titration packs containing 21, 35, and fifty-one 1.5 mg dexamethasone tablets, respectively. Generic dexamethasone (non-pack form) is commonly available in 0.5 mg, 0.75 mg, 1.5 mg, 2 mg, 4 mg, and 6 mg tablets. There is no difference in the dexamethasone tablets contained in Locort, Zonacort, Zodex, Taperdex, DexPak, and generic dexamethasone packs versus the generically available dexamethasone 1.5 mg tablets (in non-pack form).

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### **FDA or Other Governmental Regulatory Approval**

#### **U.S. Food and Drug Administration (FDA)**

Locort, Zonacort, Zodex, Taperdex, DexPak, and generic dexamethasone packs (which all contain dexamethasone tablets) are approved for the treatment of allergic states, dermatologic diseases, endocrine disorders, gastrointestinal diseases, hematologic disorders, neoplastic diseases, nervous system diseases, ophthalmic diseases, renal diseases, respiratory diseases, rheumatic disorders and other miscellaneous conditions.

### **Rationale/Source**

No additional studies were performed with these drugs to demonstrate any differences in clinical efficacy or safety based on a difference in packaging. Locort, Zonacort, Zodex, Taperdex, DexPak, and generic dexamethasone packs are simply dexamethasone 1.5 mg tablets that are packaged in set day dosage packs that carry an exorbitant price versus generically available dexamethasone 1.5 mg tablets (in non-pack form).

### **References**

1. Locort [package insert]. Allegis Pharmaceuticals. Canton, Mississippi. Revised March 2017.
2. Zonacort [package insert]. Key Therapeutics, LLC. Revised February 2017.
3. Taperdex [package insert]. Xspire Pharma. Ridgeland, Mississippi. January 2018.
4. Zodex [package insert]. Xspire Pharma. Ridgeland, Mississippi. July 2017.
5. DexPak [package insert]. Valeant Pharmaceuticals. Bridgewater, New Jersey.

### **Policy History**

Original Effective Date: 06/21/2017

Current Effective Date: 01/01/2019

06/01/2017 Medical Policy Committee review

06/21/2017 Medical Policy Implementation Committee approval. New policy.

06/07/2018 Medical Policy Committee review

06/20/2018 Medical Policy Implementation Committee approval. Added Zodex and Taperdex to the policy.

10/04/2018 Medical Policy Committee review

10/17/2018 Medical Policy Implementation Committee approval. Added DexPak and generic dexamethasone packs to the policy. Changed the title to "Select Dexamethasone Packs".

Next Scheduled Review Date: 10/2019

\*\*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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