



## **Ortikos™ (budesonide extended release capsules 6 mg, 9 mg)**

**Policy #** 00740

**Original Effective Date:** 04/12/2021

**Current Effective Date:** 04/10/2023

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 Ortikos™† (budesonide extended release capsules 6 mg, 9 mg) to be **eligible for coverage\*\*** when the patient selection criteria are met.

#### Patient Selection Criteria

Coverage eligibility for Ortikos (budesonide extended release capsules 6 mg, 9 mg) will be considered when the following criteria are met:

- Patient has a diagnosis of mild to moderate Crohn’s disease; AND
- Patient’s disease involves the ileum and/or the ascending colon; AND
- Patient meets the following:
  - If the request is for treatment of active disease:
    - Patient is 8 years of age or older; AND
    - Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC budesonide EC (enteric coated) 3 mg strength capsules at the recommended dose for at least 8 weeks unless there is clinical evidence or patient history that suggests the use of GENERIC budesonide EC 3 mg strength capsules at the recommended dose for at least 8 weeks will be ineffective or cause an adverse reaction to the patient; 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) a different (other than budesonide) GENERIC corticosteroid product for the treatment of the condition unless there is clinical evidence or patient history that suggests the use of a GENERIC corticosteroid product, other than budesonide, will be ineffective or cause an adverse reaction to the patient; OR  
(*Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met*)
- If the request is for maintenance of clinical remission:
  - Patient is 18 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC budesonide EC (enteric coated) 3 mg strength capsules at the recommended dose for at least 12 weeks unless there is clinical evidence or patient history that suggests the use of GENERIC budesonide EC 3 mg strength capsules at the recommended dose for at least 12 weeks will be ineffective or cause an adverse reaction to the patient; 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) a GENERIC immunomodulator (e.g., azathioprine, methotrexate, mercaptopurine) unless there is clinical evidence or patient history that suggests the use of these products 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 Ortikos (budesonide extended release capsules 6 mg, 9 mg) when the patient has not tried and failed the prerequisite medications to be **not medically necessary.\*\***

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Based on review of available data, the Company considers the use of Ortikos (budesonide extended release capsules 6 mg, 9 mg) when the patient has not tried and failed the prerequisite medications for the specified amount of time (where applicable) 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 Ortikos (budesonide extended release capsules 6 mg, 9 mg) when the patient selection criteria are not met (except those denoted as **not medically necessary**\*\*) to be **investigational**.\*

## Background/Overview

Ortikos is a corticosteroid indicated for the treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years of age and older. It is also indicated for maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults. Ortikos should be taken once daily. In the treatment of active disease, the length of therapy is 8 weeks for adults and 10 weeks in pediatrics. Therapy for the maintenance of clinical remission is limited to 3 months duration in the package insert. Continued treatment for more than 3 months has not been shown to provide substantial clinical benefit. It should be noted that Ortikos was not studied in its own unique clinical trials. Its approval was based on clinical studies of other oral budesonide products, such as the available generic 3 mg enteric coated capsules. The generic budesonide 3 mg enteric coated capsules (used at the recommended dosage) offer a much more economical option compared to Ortikos.

In general, for induction of remission in patients with Crohn's disease, initial therapy includes oral glucocorticoids (e.g., budesonide, prednisone). Once remission is achieved, immunomodulators, such as methotrexate, mercaptopurine, and azathioprine, are used. More severe disease would likely warrant treatment with newer monoclonal antibody products.

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

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

Ortikos is a corticosteroid indicated for the treatment of mild to moderate active Crohn's disease involving the ileum and/or the ascending colon, in patients 8 years of age and older. It is also indicated for maintenance of clinical remission of mild to moderate Crohn's disease involving the ileum and/or the ascending colon for up to 3 months in adults.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The intent of this policy is to ensure that this medication is being used for its FDA approved indication as well as within the appropriate age range. Taking three generic budesonide enteric coated 3 mg capsules to equal 9 mg offers a vastly more economical option for therapy vs. Ortikos. Ortikos offers no known clinical advantage versus the available budesonide 3 mg enteric coated capsules.

## **References**

1. Ortikos [package insert]. Ferring Pharmaceuticals Inc. Parsippany, New Jersey. Updated October 2019.
2. Overview of the medical management of mild (low risk) Crohn disease in adults. UpToDate. Updated October 2020. Accessed February 2021.

## **Policy History**

Original Effective Date: 04/12/2021

Current Effective Date: 04/10/2023

03/04/2021 Medical Policy Committee review

03/10/2021 Medical Policy Implementation Committee approval. New policy.

03/03/2022 Medical Policy Committee review

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03/09/2022 Medical Policy Implementation Committee approval. No change to coverage.

03/02/2023 Medical Policy Committee review

03/08/2023 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 03/2024

**\*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 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:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**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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