



## Ethacrynic Acid Oral Products (Edecrin<sup>®</sup>, generics)

**Policy #** 00630

**Original Effective Date:** 01/01/2019

**Current Effective Date:** 11/13/2023

*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 the oral ethacrynic acid tablet products (e.g. Edecrin<sup>®</sup>, generics) to be **eligible for coverage\*\*** when the below patient selection criteria are met.

#### Patient Selection Criteria

Coverage eligibility will be considered for the oral ethacrynic acid tablet products (e.g. Edecrin, generics) when the criteria are met for the requested drug:

- Edecrin (Brand) tablets:
  - Patient has a documented sulfonamide allergy; AND
  - Patient has tried and failed GENERIC ethacrynic acid tablets unless there is clinical evidence or patient history that suggests the use of generic ethacrynic acid tablets will be ineffective or cause an adverse reaction to the patient.
- ethacrynic acid (generic) tablets:
  - Patient has a documented sulfonamide allergy; OR
  - Patient has tried and failed TWO generic oral loop diuretics (e.g., bumetanide, furosemide, torsemide) unless there is clinical evidence or patient history that suggests the use of the required generic oral loop diuretics (e.g., bumetanide, furosemide, torsemide) will be ineffective or cause an adverse reaction to the patient.

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## **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of the oral ethacrynic acid tablet products (e.g. Edecrin, generics) when the selected drug's patient selection criteria are not met to be **not medically necessary.\*\***

## **Background/Overview**

Edecrin is available in both brand and generic equivalent formulations. Edecrin and its generic are available in both tablet and intravenous forms, however this policy only refers to the oral formulation. Any information regarding Edecrin would be the same for ethacrynic acid when mentioned in this section. Edecrin is approved for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease (including nephrotic syndrome). Edecrin is also approved for the short term management of ascites due to malignancy, idiopathic edema, and lymphedema as well as for the short term management of hospitalized pediatric patients with congenital heart disease or nephrotic syndrome. Edecrin is part of a group of drugs known as the loop diuretics, which inhibits the reabsorption of sodium and chloride in the ascending loop of Henle and distal renal tubule. This ultimately leads to the increased excretion of water, sodium, chloride, magnesium and calcium. Other products exist in the class as well (in generic form) and include drugs such as bumetanide, torsemide, and furosemide. Edecrin's novelty is that it is the only loop diuretic that can be used in patients with sulfonamide allergies. The other generically available loop diuretics provide a much more economical and equally efficacious alternative for those without sulfonamide allergies. Therefore use of Edecrin should be reserved for those with sulfonamide allergies (or those that have failed multiple other generic loop diuretics [for generic requests only]).

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

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

Edecrin is approved for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease (including nephrotic syndrome). Edecrin is also approved for the short term management of ascites due to malignancy, idiopathic edema, and lymphedema as well as for the short term management of hospitalized pediatric patients with congenital heart disease or nephrotic syndrome.

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## **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 the oral ethacrynic acid tablet products are reserved for those in need of a loop diuretic who have a documented sulfonamide allergy OR have at least failed other oral loop diuretics (generic ethacrynic acid requests only).

## **References**

1. Edecrin [package insert]. Merck and Company, Inc. Whitehouse Station, New Jersey.
2. Ethacrynic acid. UpToDate.

## **Policy History**

Original Effective Date: 01/01/2019

Current Effective Date: 11/13/2023

08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. New policy,
10/17/2018	Medical Policy Implementation Committee approval. Clarified that this policy only refers to oral ethacrynic acid products.
10/03/2019	Medical Policy Committee review
10/09/2019	Medical Policy Implementation Committee approval. No change to coverage.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. No change to coverage.
10/07/2021	Medical Policy Committee review
10/13/2021	Medical Policy Implementation Committee approval. No change to coverage.
10/06/2022	Medical Policy Committee review
10/11/2022	Medical Policy Implementation Committee approval. No change to coverage.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. No change to coverage.

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Next Scheduled Review Date: 10/2024

**\*\*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.

‡ 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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