Select Nitrofurantoin Products

Policy # 00715
Original Effective Date: 01/01/2021
Current Effective Date: 07/08/2024

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 nitrofurantoin 25 mg capsules (generic, Macrodantin®)‡ or branded Nitrofurantoin 50mg/5 mL suspension for the treatment of urinary tract related infections to be **eligible for coverage**** when the below patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for nitrofurantoin 25 mg capsules (generic, Macrodantin) or branded Nitrofurantoin 50mg/5 mL suspension will be considered when the following criteria are met for the requested drug:

- For nitrofurantoin 25 mg capsule (generic, Macrodantin) requests:
    - Patient has a diagnosis of a urinary tract related infection; AND
    - If requested drug is the brand Macrodantin 25 mg capsules: Patient has tried and failed (e.g., intolerance or inadequate response) the generic equivalent nitrofurantoin 25 mg capsules unless there is clinical evidence or patient history that suggests the use of the generic equivalent nitrofurantoin 25 mg capsules will be ineffective or cause an adverse reaction to the patient.

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For branded Nitrofurantoin 50mg/5 mL suspension requests:
    - Patient has a diagnosis of a urinary tract related infections; AND
    - Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets and/or capsules; AND

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

- Patient is not currently taking any medication in tablet or capsule form; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- There is clinical evidence or patient history that suggests the use of nitrofurantoin 25 mg/5 mL suspension will be/was ineffective or will/did cause an adverse reaction to the patient.
  *(Note: This specific patient selection 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 brand Macrodantin 25 mg capsules when the patient has NOT tried and failed the generic equivalent nitrofurantoin 25 mg capsules to be **not medically necessary.****

Based on review of available data, the Company considers the use of branded Nitrofurantoin 50mg/5 mL suspension when the patient has NOT tried and failed nitrofurantoin suspension 25 mg/5 mL, does NOT have a gastrostomy tube (G-tube) or is otherwise able to swallow tablets and/or capsules, and when the patient is taking any other medication in tablet or capsule form 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 nitrofurantoin 25 mg capsules (generic, Macrodantin) for non-FDA approved indications to be **investigational.***

Based on review of available data, the Company considers the use of branded Nitrofurantoin 50 mg/5 mL suspension for non-FDA approved indications to be **investigational.***

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Background/Overview

Nitrofurantoin is approved for the treatment of urinary tract related infections. The branded nitrofurantoin 25 mg product, Macrodantin, has a generic equivalent available. Recently, the 25 mg strength of nitrofurantoin has been utilized in large quantities for nasal rinses and foot soaks, which are not FDA-approved indications. The safety and efficacy of these non-FDA approved uses have not been proven. Nitrofurantoin is also available as a generic 25mg/5 ml suspension with a concentration supplied in a 230 mL bottle and as branded Nitrofurantoin 50mg/5 mL suspension supplied in a 60 mL bottle.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Nitrofurantoin is approved for the treatment of urinary tract infections.

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 25 mg strength of nitrofurantoin (brand or generic) and branded Nitrofurantoin suspension 50mg/5 mL are utilized for their FDA approved indication (for which they were approved based on safety and efficacy). The intent is to also ensure that the generic equivalent nitrofurantoin 25 mg capsules is used prior to the brand product, Macrodantin 25 mg capsules, and generic nitrofurantoin 25mg/5 mL suspension is used prior to the branded Nitrofurantoin 50mg/5 mL suspension.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of generic products mentioned in the patient selection criteria for each requested drug and/or indication will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using the branded products over the generic products included in the patient

selection criteria for each requested drug and/or indication listed in this policy. This policy also takes into consideration whether or not a patient is able to swallow.

References

1. Macrodantin [package insert]. Almatica Pharma, Inc. Updated July 2019.
2. Nitrofurantoin suspension [package insert]. Rising Pharma Holdings, Inc. East Brunswick, NJ. Updated April 2024.

Policy History

Original Effective Date: 01/01/2021
Current Effective Date: 07/08/2024

09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. New policy.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Changed policy title from "nitrofurantoin 25mg capsules (generic, Macrodantin)" to "Select Nitrofurantoin Products". Added a new product, branded Nitrofurantoin suspension 50mg/5 mL with its associated criteria. Added product information to background and rationale.

Next Scheduled Review Date: 06/2025

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*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.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.