

Clinical Policy: Chloramphenicol Sodium Succinate

Reference Number: LA.PHAR.388

Effective Date:

Last Review Date: 03.21

Line of Business: Medicaid

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Description

Chloramphenicol sodium succinate is an antibiotic that binds to 50S ribosomal subunits.

FDA Approved Indication(s)

Chloramphenicol sodium succinate is indicated for the treatment of:

- Acute infections caused by *Salmonella typhi**
**In treatment of typhoid fever some authorities recommend that chloramphenicol be administered at therapeutic levels for 8 to 10 days after the patient has become afebrile to lessen the possibility of relapse.*
- Serious infections caused by susceptible strains:
 - *Salmonella* species
 - *H. influenza*, specially meningeal infections
 - *Rickettsia*
 - Lymphogranuloma-psittacosis group
 - Various gram-negative bacteria causing bacteremia, meningitis or other serious gram-negative infections
 - Other susceptible organisms which have been demonstrated to be resistant to all other appropriate antimicrobial agents
- Cystic fibrosis regimens

Limitation(s) of use: Chloramphenicol sodium succinate is not recommended for the routine treatment of the typhoid carrier state.

Policy/Criteria

Prior authorization is required. Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Louisiana Healthcare Connections that chloramphenicol sodium succinate is medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. All FDA-Approved Indications (must meet all):

1. Prescribed by or in consultation with an infectious disease specialist;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with chloramphenicol was started prior to discharge;
4. Dose does not exceed one of the following (a or b):

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- a. Adults and pediatrics: 100 mg/kg per day;
- b. Neonates: 50 mg/kg per day.

Approval duration:

Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

II. Continued Therapy

A. All FDA-Approved Indications (must meet all):

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
 - a. Adults and pediatrics: 100 mg/kg per day;
 - b. Neonates: 50 mg/kg per day.

Approval duration:

Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy –LA.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): history of previous hypersensitivity and/or toxic reaction to chloramphenicol, for the treatment of trivial infections or where it is not indicated

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(colds influenza, infections of the throat), as a prophylactic agent to prevent bacterial infections

- Boxed warning(s): serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia)

V. Dosage and Administration

<u>Indication</u>	<u>Dosing Regimen</u>	<u>Maximum Dose</u>
<u>Infection</u>	<u>Adult/Pediatric: 50 mg/kg/day IV in divided doses at 6-hour intervals</u>	<u>Adult/Pediatric: 100 mg/kg/day</u>
	<u>Neonate/Pediatric patients with immature metabolic processes: 25 to 50 mg/kg/day IV in 4 equal doses at 6-hour intervals</u>	<u>Neonate: 50 mg/kg/day</u>

VI. Product Availability

Vial for reconstitution: 1 g/10 mL

VII. References

1. Chloramphenicol sodium succinate Prescribing Information. Lake Zurich, IL: Fresenius Kabi USA, LLC.; December 2019. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=aed29594-211d-49ef-813f-131975a8d0e3>. Accessed November 25, 2020.
2. Tunkel AR, Glaser CA, Bloch KC, et al. The management of encephalitis: clinical practice guidelines by the Infectious Diseases Society of America. August 2008. Clinical Infectious Diseases;47:303-27.
3. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft-tissue infections. October 2005. Clinical Infectious Diseases;41:1373-406.
4. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft-tissue infections: 2014 Update by the Infectious Diseases Society of America. April 2014. Clinical Infectious Diseases;59:10-52.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<u>HCPCS Codes</u>	<u>Description</u>
<u>J0720</u>	<u>Injection, chloramphenicol sodium succinate, up to 1 gm</u>

<u>Reviews, Revisions, and Approvals</u>	<u>Date</u>
<u>Converted corporate to local policy</u>	<u>03.2021</u>

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Reviews, Revisions, and Approvals	Date

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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