Clinical Policy: Chloramphenicol Sodium Succinate

Reference Number: CP.PHAR.388
Effective Date: 12.01.18
Last Review Date: 02.21
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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

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 health plans affiliated with Centene Corporation® 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):
   a. Adults and pediatrics: 100 mg/kg per day;
   b. Neonates: 50 mg/kg per day.

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All FDA-Approved Indications (must meet all)**:**
1. Currently receiving medication via Centene 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/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene 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 for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.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 (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

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

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.

HCPCS Codes	Description
J0720	Injection, chloramphenicol sodium succinate, up to 1 gm

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.14.18	11.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.30.18	02.19
1Q 2020 annual review: no significant changes; added renewal criteria to allow for continuity of care upon hospital discharge; references reviewed and updated.	10.28.19	02.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	11.25.20	02.21

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.