pa health & wellness

Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2022**
Policy Number: PA.CP.PHAR.388	**Effective Date: 01/01/2018** **Revision Date: 01/2022**
Policy Name: Chloramphenicol Sodium Succinate	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2022 annual review: added option for continuation of therapy following hospital discharge in Section II; references reviewed and updated.

Name of Authorized Individual (Please type or print):	**Signature of Authorized Individual:**
Venkateswara R. Davuluri, MD	

Clinical Policy: Chloramphenicol Sodium Succinate

Reference Number: PA.CP.PHAR.388
Effective Date: 10.2018
Last Review Date: 01.2022

Coding Implications
Revision Log

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 PA Health & Wellness® 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. Request is for continuation of intravenous therapy initiated in an acute care hospital from which member was discharged;
3. Dose does not exceed one of the following (a or b):
   a. Adults and pediatrics: 100 mg/kg/day;
   b. Neonates: 50 mg/kg/day.

Approval duration: 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): PA.CP.PMN.53.

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed:
   a. Adults and pediatrics: 100 mg/kg/day;
   b. Neonates: 50 mg/kg/day.

Approval duration: 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies, 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): PA.CP.PMN.53.

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 – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
C&S: culture and sensitivity
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 September 23, 2021.
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. 15 July 2014. Clinical Infectious Diseases;59(2): 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	10/18	
1Q 2019 annual review: references reviewed and updated.	01/19	
1Q 2020 annual review: references reviewed and updated.	01/2020	
1Q 2021 annual review: references reviewed and updated.	01/2021	
1Q 2022 annual review: added requirement for therapy following hospital discharge in Section II; references reviewed and updated.	01/2022	