Clinical Policy: Sulfamethazole/Trimethoprim Injection

Reference Number: CP.HNMC.30
Effective Date: 07.01.17
Last Review Date: 02.18 Revision Log
Line of Business: Medicaid - HNMC

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

Description

Sulfamethazole/trimethoprim injection is a synthetic antibacterial combination product.

FDA approved indication

Sulfamethazole/trimethoprim injection is indicated:

- For the treatment of *Pneumocystis carinii* pneumonia in children and adults
- For the treatment of enteritis caused by susceptible strains of *Shigella flexneri* and *Shigella sonnei* in children and adults
- For the treatment of severe or complicated urinary tract infections due to susceptible strains of *Escherichia coli, Klebsiella* species, *Enterobacter* species, *Morganella morganii,* and *Proteus* species when oral administration of sulfamethoxazole and trimethoprim is not feasible and when the organism is not susceptible to single-agent antibacterials effective in the urinary tract

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Sulfamethazole/trimethoprim is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Pneumonia (must meet all)**:**

1. Diagnosis of *Pneumocystis carinii* pneumonia;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with sulfamethoxazole/trimethoprim was started prior to discharge.

Approval duration: Length of benefit

B. Enteritis (must meet all)**:**

1. Diagnosis of enteritis caused by susceptible strains of *Shigella flexneri* or *Shigella sonnei*;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with sulfamethoxazole/trimethoprim was started prior to discharge;

Approval duration: Length of benefit

C. Urinary Tract Infection (must meet all)**:**
1. Diagnosis of severe or complicated urinary tract infection due to susceptible strains of *Escherichia coli*, *Klebsiella* species, *Enterobacter* species, *Morganella morganii*, or *Proteus* species: oral administration is not feasible, and the organism is not susceptible to single-agent antibacterials effective in the urinary tract;
2. Member was discharged from an acute care hospital;
3. Intravenous therapy with sulfamethoxazole/trimethoprim was started prior to discharge;

Approval duration: Length of benefit

D. Other diagnoses/indications
1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (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 [examples: labs, sign/symptom reduction, no disease progression, no significant toxicity, etc];

Approval duration: Length of benefit

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 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
UTI: Urinary Tract Infection

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Pneumonia	15 to 20 mg/kg/day trimethoprim component IV divided in 3 or 4 equal doses every 6 to 8 hours for up to 14 days	20 mg/kg
Enteritis	Loading dose: 15 mg/kg IV over 1 hour	4 g/day

Indication	Dosing Regimen	Maximum Dose
	Maintenance dose: 7.5 mg/kg IV every 6 hours, starting 6 hours after loading dose, for 7 to 10 days or longer as clinically indicated	
Urinary Tract Infection	Trimethoprim component 8 to 10 mg/kg/day IV in 2 to 4 equally divided doses every 6, 8, or 12 hours for up to 14 days for severe or complicated UTIs	60 mL

VI. Product Availability

Intravenous Solution: 80 MG/1 ML-16 MG/1 ML

VII. Workflow Document

N/A

VIII. References

1. Sulfamethazole and Trimethoprim Prescribing Information. North Wales, PA: Teva Parenteral Medicines, Inc.; July 2016. Available at: www.accessdata.fda.gov. Accessed July 21, 2017.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 27, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.01.17	02.18

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.

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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.

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