Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 275.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Pedmark (sodium thiosulfate)

I. Policy:
Pedmark (sodium thiosulfate)

II. Purpose/Objective:
To provide a policy of coverage regarding Pedmark (sodium thiosulfate)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Cisplatin-induced ototoxicity is caused by irreversible damage to hair cells in the cochlea hypothesized to be due to a combination of reactive oxygen species (ROS) production and direct alkylation of DNA leading to cell death. Pedmark (Sodium thiosulfate) interacts directly with cisplatin to produce an inactive platinum species. In addition, sodium thiosulfate can enter cells through the sodium sulfate cotransporter 2 and cause intracellular effects such as the increase in antioxidant glutathione levels and inhibition of intracellular oxidative stress. Both activities may contribute to the ability of sodium thiosulfate to reduce the risk of ototoxicity. Concurrent incubation of sodium thiosulfate with cisplatin decreased the in vitro cytotoxicity of cisplatin to tumor cells; delaying the addition of sodium thiosulfate to these cultures prevented the protective effect.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature

Pedmark (sodium thiosulfate) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

- Documentation of age greater than or equal to 1 month but less than or equal to 18 years of age **AND**
- Prescribed by or in consultation with a hematologist or oncologist **AND**
- Medical record documentation of a localized, non-metastatic solid tumor **AND**
- Medical record documentation that the patient will receive a cisplatin infusion with an infusion time less than or equal to 6 hours **AND**
- Medical record documentation that Pedmark is being used to reduce the risk of ototoxicity associated with cisplatin **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months and will require medical record documentation of clinical improvement or lack of progression and documentation that the patient is continuing to receive a cisplatin-based chemotherapy regimen. The medication will no longer be covered if the patient experienced toxicity. worsening of disease, or if the member is not to continue on a cisplatin-based chemotherapy regimen.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/21/23

Revised:

Reviewed: