Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 150.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Sustol (granisetron ER)

I. Policy:
Sustol (granisetron ER)

II. Purpose/Objective:
To provide a policy of coverage regarding Sustol (granisetron ER)

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:
Sustol (granisetron ER) is a selective 5-hydroxytryptamine3 receptor (5-HT3) antagonist with minimal affinity for other serotonin receptors, alpha- or beta-adrenoreceptors, dopamine2, or histamine1 receptors. 5-HT3 receptors are located peripherally on the vagal nerve terminals and centrally in the chemoreceptor trigger zone. During chemotherapy that induces vomiting, serotonin is released and stimulates 5-HT3, which evokes vagal afferent discharge, inducing vomiting. Granisetron blocks serotonin stimulation and subsequent vomiting after emetogenic stimuli.

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

Sustol (granisetron ER) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when the following criteria are met:

- Medical record documentation that Sustol is being used for the prevention of acute or delayed nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone **AND**
- Medical record documentation that member has a treatment failure or contraindication to Aloxi (palonosetron)

OR

- Medical record documentation that Sustol is being used for prevention of acute or delayed chemotherapy induced nausea and vomiting from low, or minimally emetogenic chemotherapy for members who have a treatment failure or contraindication to Aloxi (palonosetron) **AND** ondansetron OR granisetron **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone.

The following antineoplastic agents are considered MODERATELY emetogenic (not a complete list):

- Aldesleukin >12-15 million IU/m^2
- Amifostine >300 mg/m^2
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Carboplatin
- Carmustine $\leq$ 250 mg/m^2
- Clofarabine
- Cyclophosphamide $\leq$ 1500mg/m^2
- Cytarabine >200mg/m^2
- Dactinomycin
- Daunorubicin
- Dinutuximab
- Doxorubicin <60 mg/m^2
- Epirubicin $\leq$ 90 mg/m^2
- Idarubicin
- Ifosfamide <2 g/m^2 per dose
- Interferon alfa $\geq$ 10 million IU/m^2
- Irinotecan
- Melphalan
- Methotrexate $\geq$250 mg/m^2
- Oxaliplatin
- Temozolomide
- Trabectedin

QUANTITY LIMIT: One 10mg syringe per 7 days (56 syringes/12month authorization) *based on FDA Max dosing*

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Sustol (granisetron ER) will be considered medically necessary for the Medicare line of business when the following criteria are met:

- Medical record documentation that Sustol is being used for the prevention of acute or delayed nausea and vomiting associated with initial or repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone

OR

- Medical record documentation that Sustol is being used for prevention of acute or delayed chemotherapy induced nausea and vomiting from low, or minimally emetogenic chemotherapy for members who have a treatment failure or contraindication to ondansetron **AND**
- Medical record documentation that Sustol is being given in combination with dexamethasone.

The following antineoplastic agents are considered MODERATELY emetogenic (not a complete list):

- Aldesleukin >12-15 million IU/m^2
- Amifostine >300 mg/m^2
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Carboplatin
- Carmustine $\leq$ 250 mg/m^2
- Clofarabine
- Cyclophosphamide $\leq$ 1500mg/m^2
- Cytarabine >200mg/m^2
- Dactinomycin
- Daunorubicin
- Dinutuximab
- Doxorubicin <60 mg/m^2
- Epirubicin $\leq$ 90 mg/m^2
- Idarubicin
- Ifosfamide <2 g/m^2 per dose
- Interferon alfa $\geq$ 10 million IU/m^2
- Irinotecan
- Melphalan
- Methotrexate $\geq$250 mg/m^2
- Oxaliplatin
- Temozolomide
- Trabectedin

QUANTITY LIMIT: One 10mg syringe per 7 days (56 syringes/12 month authorization) *based on FDA Max dosing*

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease

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: 1/17/17

Revised: 9/7/23 (LOB carve out, Medicaid business segment)

Reviewed: 10/31/17, 9/28/18, 9/27/19, 9/10/20, 9/8/21, 9/7/22