Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 24.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Aloxi (Palonosetron)

I. Policy:
Aloxi (Palonosetron)

II. Purpose/Objective:
To provide a policy of coverage regarding Aloxi (Palonosetron)

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:
Aloxi (Palonosetron) is a 5-HT3 antagonist indicated for the prevention of chemotherapy induced nausea and vomiting.

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

Aloxi (Palonosetron) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when all of the following criteria are met:

1. **PREVENTION OF ACUTE NAUSEA AND VOMITING**
   - Medical record documentation that Aloxi is being used for prevention of chemotherapy induced nausea or vomiting from low, or minimally, emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to Granisetron (Kytril) or Ondansetron (Zofran). Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of efficacy; **OR**
   - Medical record documentation that Aloxi is being used for prevention of acute and/or delayed nausea or vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy OR acute nausea or vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

   AND
   - If a brand drug is being requested when a therapeutically equivalent generic drug exists:
     - Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
     - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

The following antineoplastic agents are considered MODERATELY emetogenic (refer to NCCN for complete list):
- Aldesleukin >12-15 million IU/m^2
- Amifostine >300 mg/m^2
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Clofarabine
- Cyclophosphamide ≤1500mg/m^2
- Cytarabine >200mg/m^2
- Dinutuximab
- Idarubicin
- Interferon alfa ≥10 million IU/m^2
- Melphalan
- Temozolomide

The following antineoplastic agents are considered HIGHLY emetogenic (refer to NCCN for complete list):
- AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide
- Carboplatin
- Carmustine
- Cisplatin
- Cyclophosphamide at doses >1500 mg/m^2
- Dacarbazine
- Dactinomycin
- Daunorubicin
- Doxorubicin
- Epirubicin
- Ifosfamide
- Irinotecan
- Mechlorethamine
- Methotrexate at doses $\geq$ 250mg/m^2
- Oxaliplatin
- Streptozotocin
- Trabectedin

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.

Aloxi (Palonosetron) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. **PREVENTION OF ACUTE NAUSEA AND VOMITING**
   - Medical record documentation that Aloxi is being used for prevention of chemotherapy induced nausea or vomiting from low, or minimally, emetogenic cancer chemotherapy for members who have a treatment failure or contraindication to antiemesis regimens recommended by National Comprehensive Cancer Network (NCCN) for low emetogenic risk chemotherapy regimens, including but not limited to Granisetron (Kytril) or Ondansetron (Zofran). Treatment failure is defined as an allergy, intolerable side effects, significant drug-drug interactions, or lack of efficacy; **OR**
   - Medical record documentation that Aloxi is being used for prevention of acute and/or delayed nausea or vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy OR acute nausea or vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy.

The following antineoplastic agents are considered MODERATELY emetogenic (refer to NCCN for complete list):

- Aldesleukin >12-15 million IU/m^2
- Amifostine >300 mg/m^2
- Arsenic trioxide
- Azacitidine
- Bendamustine
- Busulfan
- Clofarabine
- Cyclophosphamide ≤1500mg/m^2
- Cytarabine >200mg/m^2
- Dinutuximab
- Idarubicin
- Interferon alfa ≥10 million IU/m^2
- Melphalan
- Temozolomide

The following antineoplastic agents are considered HIGHLY emetogenic (refer to NCCN for complete list):

- AC combination defined as any chemotherapy regimen that contains an anthracycline and cyclophosphamide
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- Carmustine
- Cisplatin
- Cyclophosphamide at doses >1500 mg/m^2
- Dacarbazine
- Dactinomycin
- Daunorubicin
- Doxorubicin
- Epirubicin
- Ifosfamide
- Irinotecan
- Mechlorethamine
- Methotrexate at doses $\geq$ 250mg/m^2
- Oxaliplatin
- Streptozotocin
- Trabectedin

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: 10/27/03

Revised: 5/05 (grammatical) 7/07 (removed prior auth); 7/12 (re-establish policy and prior auth), 1/26/15 (removed "contraindications"), 3/24/15 (formatting, criteria, authorization duration, references), 7/19/16 (added moderate criteria), 1/29/18 (updated drug lists), 2/27/18 (per DHS), 10/4/23 (LOB carve out, Medicaid business segment, added generic drug language)

Reviewed: 6/06, 2/14, 1/26/15, 3/24/15, 3/31/16, 5/16/17, 10/31/18, 10/25/19, 10/20/20, 10/5/21 (formatting), 10/5/22