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: 11/01/2018**
Policy Number: PA.CP.PMN.11	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Oral Antiemetics (5-HT3 Antagonists)	**HC Approval Date:**

Type of Submission – Check all that apply:

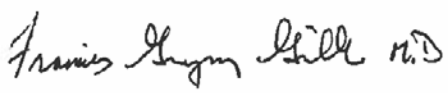
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***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:

This policy is being retired and replaced by and split into the following policy(s):

- **PA.CP.PMN.45 Ondansetron (Zuplenz)**
- **PA.CP.PMN.141 Dolasetron (Anzemet)**
- **PA.CP.PMN.74 Granisetron (Kytril, Sancuso)**

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Oral Antiemetics (5-HT3 Antagonists)

Reference Number: PA.CP.PMN.11
Effective Date: 01/18
Last Review Date: 11/16

Coding Implications
Revision Log

Description
The following oral antiemetics are serotonin 5-hydroxytryptamine, type 3 (5-HT3) receptor antagonists requiring prior authorization: dolasetron (Anzemet®), granisetron (Kytril®), netupitant/ palonosetron (Akynzeo®), and ondansetron (Zuplenz®).

FDA approved indication
- Treatment of chemotherapy-induced nausea/vomiting
- Prophylaxis of chemotherapy-induced nausea/vomiting
- Prophylaxis of radiation-induced nausea/vomiting (Kytril and Zuplenz only)
- Prophylaxis of postoperative nausea/vomiting (Zuplenz only)

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that 5-HT3 receptor antagonist oral antiemetics are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chemotherapy/Radiation Induced Nausea and Vomiting (must meet all)**:**
1. Prescribed for the prevention/treatment of chemotherapy or radiation induce nausea/vomiting;
2. Failure of ondansetron at maximum indicated doses, unless member has contraindication(s) or intolerance to ondansetron;
3. Requested dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: projected course of chemo/radiation therapy up to 72 hours after completion of chemo/radiation therapy

B. Postoperative Nausea/Vomiting (must meet all)**:**
1. Prescribed for prevention/treatment of postoperative nausea/vomiting;
2. Failure of ondansetron trial at maximum indicated doses, unless member has contraindication(s) or intolerance to ondansetron;
3. Requested dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: 3 days

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

II. Continued Therapy

A. Chemotherapy/Radiation Induced Nausea and Vomiting (must meet all)**:**

1. Documentation that member is currently receiving chemotherapy/radiation therapy;
2. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
3. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

Approval duration: projected course of chemo/radiation therapy up to 72 hours after completion of chemo/radiation therapy

B. Postoperative Nausea and Vomiting – reauthorization is not permitted

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: duration of request or 3 month (whichever is less)

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

IV. Appendices/General Information

Appendix A: Abbreviation Key

5-HT3: serotonin 5-hydroxytryptamine, type 3

V. Dosage and Administration

Drug	Recommended Dosage	Maximum Dose
Anzemet (dolasetron)	100 mg tablet by mouth within 1 hour before chemotherapy	100 mg/dose by mouth
Akynzeo (netupitant; palonosetron)	1 capsule by mouth as a single dose approximately 60 minutes prior to chemotherapy	1 capsule (netupitant 300 mg; palonosetron 0.5 mg) by mouth as a single dose
Kytril (granisetron)	1 mg by mouth twice daily on days of chemotherapy administration	2 mg by mouth
Zuplenz (ondansetron)	8 mg by mouth twice daily or 24 mg by mouth once given 30 minutes before administration	24 mg/day by mouth

VI. Product Availability

Drug	Availability
Anzemet (dolasetron)	100 mg, 500 mg tablet
Akynzeo (netupitant; palonosetron)	300 mg/0.5mg capsule
Kytril (granisetron)	1 mg tablet
Zuplenz (ondansetron)	4 mg, 8 mg oral soluble film

VII. References

1. Clinical Pharmacology. Tampa, FL: Gold Standard; 2008. Available at www.clinicalpharmacology.com. Accessed August 24, 2016.
2. Zuplenz Prescribing Information. Portland, OR: Galena Biopharma, Inc.; September 2014. Available at http://zuplenz.com. Accessed August 2016.
3. Akynzeo Prescribing Information. Woodcliff Lake, NJ: Eisai Inc.; December 2015. Available at https://www.akynzeo.com. Accessed August 2016.
4. Anzemet Prescribing Information. Bridgewater, NJ: Sanofi-Aventis; September 2014. Available at https://dailymed.nlm.nih.gov. Accessed August 2016.
5. Granisetron Prescribing Information. Columbus, OH: Roxane Laboratories, Inc.; August 2014. Available at https://dailymed.nlm.nih.gov. Accessed August 2016.
6. Basch E, Prestrud AA, Hesketh PJ et al. Antiemetics: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2011 Nov 1;29(31):4189-98. doi: 10.1200/JCO.2010.34.4614. Epub 2011 Sep 26.
7. Prevention and Treatment of Postoperative Nausea and Vomiting. *American Journal of Health-System Pharmacy*. 2005; 62(12):1247-1260. Accessed on Medscape. http://www.medscape.com/viewarticle/506997.
8. Guidelines for Antiemetic Treatment of Chemotherapy-Induced Nausea and Vomiting: Past, Present, and Future Recommendations. *The Oncologist*, Vol. 12, No. 9, 1143-1150, September 2007; doi:10.1634/theoncologist.12-9-1143. http://theoncologist.alphamedpress.org/cgi/content/full/12/9/1143.

Reviews, Revisions, and Approvals	Date	Approval Date