Month/Year of Review: November 2014
PDL Classes: Antiemetics, Newer

Current Status of PDL Class:
- Preferred Agents: ONDANSETRON TAB RAPDIS/SOLUTION/TABLET
- Non-Preferred Agents: APREPITANT/FOSAPREPITANT (EMEND®), DOXYLAMINE SUCCINATE/PYRIDOXINE HCL (DICLEGIS®), DOLASETRON (ANZEMET®), GRANISETRON HCL, GRANISETRON TRANSDERMAL PATCH (SANCUSO®), ONDANSETRON ORAL FILM (ZUPLENZ®), PALONOSETRON (ALOXI®)

Previous Conclusions and Recommendation:
- In patients with post-operative nausea and vomiting (PONV) and chemotherapy induced nausea and vomiting (CINV):
  - Dolasetron, granisetron and ondansetron are equally effective in preventing nausea or vomiting.
  - There is evidence that palonsetron may be superior to other 5HT3 antagonists in the treatment of chemotherapy induced nausea and vomiting for moderately emetogenic chemotherapy and that ondansetron, dolasetron, and granisetron are equally effective.
- In patients with radiotherapy-induced nausea and vomiting (RINV):
  - Granisetron and ondansetron showed no difference in efficacy.
- In pregnant patients:
  - Ondansetron was not superior to promethazine for effectiveness, but was less sedating.
  - Long term studies show no difference in number of live births, proportion of infant deformities, and birth weight between ondansetron and the active control groups.
- Ondansetron is superior to granisetron for complete response rates in subpopulations based on a predisposition to nausea/vomiting such as motion sickness or previous treatment with emetogenic chemotherapy.
- There is low quality evidence that the combination of doxylamine/pyridoxine led to significantly greater improvement in nausea vomiting symptoms as compared with placebo (-4.8 PUQE score vs. -3.9; p=0.006) but insufficient comparative evidence compared to other available agents.

PA Criteria: Prior authorization is in place to: promote preferred drugs, reserve costly antiemetics for appropriate indications, restrict chronic use (> 3 days per week), and if chemotherapy is more frequent than once weekly, approve a quantity sufficient for three days beyond the duration of chemotherapy (Appendix 1).

Methods:
The DERP Scan was used to identify any new comparative research that has emerged since the last P&T review.¹

Conclusions and Recommendations:
- No further review or research needed.
- Evaluate comparative costs in executive session.
Appendix 1

Antiemetcs, New

Goal(s):
- Promote Preferred drugs.
- Reserve costly antiemetics for appropriate indications.
- Restrict chronic use (> 3 days per week).
- If chemotherapy is more frequent than once weekly, approve a quantity sufficient for three days beyond the duration of chemotherapy.

Length of Authorization: 3 days to 6 months (criteria specific)

Requires PA:
- Non-preferred drugs.

Preferred Alternatives: Preferred alternatives listed at: http://www.orpdl.org/

Check the Reason for PA:
- Non-preferred drugs will deny on initiation
- Preferred drugs will deny only when maximum dose exceeded (www.orpdl.org)

<table>
<thead>
<tr>
<th>HICL</th>
<th>Generic</th>
<th>Brand</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>025058</td>
<td>Aprepitant</td>
<td>Emend</td>
<td>3 doses/ 7 days</td>
</tr>
<tr>
<td>016576</td>
<td>Dolasetron</td>
<td>Anzemet</td>
<td>9 doses/ 7 days</td>
</tr>
<tr>
<td>007611</td>
<td>Granisetron</td>
<td>Kytril Tablets</td>
<td>6 doses / 7 days (30 ml liquid)</td>
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</tbody>
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Approval Criteria

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.</td>
<td>What is the diagnosis?</td>
<td>Record ICD9 code</td>
</tr>
<tr>
<td>2.</td>
<td>Is the drug requested preferred?</td>
<td>Yes: Go to #4</td>
</tr>
<tr>
<td>3.</td>
<td>Will the prescriber consider a change to a preferred product?</td>
<td>Yes: Inform provider of covered alternatives in class and dose limits. If dose &gt; limits, continue to #4.</td>
</tr>
</tbody>
</table>
4. Is client currently diagnosed with cancer AND receiving chemotherapy or radiation therapy more frequently than every 7 days?
   - **Yes**: Approve for 3 days past length of therapy (Chemo regimen more frequently than weekly)
   - **No**: Go to #5

5. Does client have refractory nausea that would require hospitalization or ER visits?
   - **Yes**: Go to #6
   - **No**: Go to #8

6. Has client tried and failed two conventional antiemetics, listed below?
   - **Yes**: Approve up to 6 months.
   - **No**: Go to #7

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
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<tbody>
<tr>
<td>Metoclopramide</td>
<td>Reglan</td>
</tr>
<tr>
<td>Prochlorperazine</td>
<td>Compazine</td>
</tr>
<tr>
<td>Promethazine</td>
<td>Phenergan</td>
</tr>
</tbody>
</table>

7. Does client have contraindications to conventional antiemetics, e.g. Allergy; or cannot tolerate?
   - **Yes**: Document reason and approve up to 6 months. (Contraindications to required alternative medications)
   - **No**: Pass to RPH; Go to #8

8. RPH only:
   All other indications need to be evaluated as to whether they are above the line or below the line.
   - Above: Deny, (Medical Appropriateness)
   - Below: Deny, (Not Covered by the OHP)

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P&T/DUR Action: 9/24/09 (DO/KK), 2/23/06, 2/24/04, 11/18/03, 9/9/03, 5/13/03, 2/11/03
Revision(s): 1/1/10, 7/1/06, 3/20/06, 6/30/04 (added aprepitant), 3/1/04 (removed injectables), 6/19/03
Initiated: ?