

Federal Employee Program.

#### **5-HT3 ANTAGONISTS**

Aloxi injection (palonosetron)
Anzemet\* tablets (dolasetron)

Granisetron injection, granisetron tablets, Sancuso patch, Sustol injection (granisetron)
Ondansetron 16mg tablets\*, Ondansetron 24mg tablets, Zofran, Zuplenz oral film\*

(ondansetron)

\* Prior authorization for certain formulations applies only to formulary exceptions due to being a non-covered medication.

# RATIONALE FOR INCLUSION IN PA PROGRAM

## **Background**

Selective 5-hydroxytryptamine 3 (5-HT3) receptor antagonists are antinauseant and anti-emetic agents with little or no affinity for other serotonin receptors, making them very useful in the treatment of nausea and vomiting. Often, these agents are used in the treatment of nausea and vomiting associated with chemotherapy in the treatment of cancer, as many of these 5-HT3 receptors are located centrally in the chemoreceptor trigger zone. 5-HT3 receptors are also located peripherally on vagal nerve terminals as well as on enteric neurons in the GI tract. When activated, they stimulate GI secretions and vagal afferent discharge, which induces vomiting. 5-HT3 antagonists block this from occurring (1).

### **Regulatory Status**

FDA-approved indications:

- Aloxi, Anzemet, Granisetron, Kytril, Sancuso, Sustol, Zofran, and Zuplenz are serotonin-3
  (5-HT3) receptor antagonists indicated for the prevention and/or treatment of nausea and
  vomiting in patients receiving moderately and/or highly emetogenic chemotherapy or postoperative nausea and vomiting (2 -10).
- Ondansetron 24mg tablets are indicated for the prevention of nausea and vomiting in patients receiving highly emetogenic chemotherapy (11).

Off-label use of ondansetron for the treatment of nausea and vomiting of pregnancy during the first trimester did not increase the risk of specific birth defects (12).

# Summary

Selective 5-hydroxytryptamine 3 (5-HT3) receptor antagonists are antinauseant, and anti-emetic agents with little or no affinity for other serotonin receptor, making them very useful in the treatment of nausea and vomiting. Often, these agents are used in the treatment of nausea and vomiting



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associated with chemotherapy in the treatment of cancer (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of 5-HT3 antagonists while maintaining optimal therapeutic outcomes.

### References

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