TRUVEN HEALTH ANALYTICS

## COMPENDIA TRANSPARENCY TRACKING FORM

**DRUG:** Olanzapine

**INDICATION:** Chemotherapy-induced nausea and vomiting, moderately and/or highly emetogenic chemotherapy; Prophylaxis

| COMPENDIA TRANSPARENCY REQUIREMENTS | |
|---|---|
| 1 | Provide criteria used to evaluate/prioritize the request (therapy) |
| 2 | Disclose evidentiary materials reviewed or considered |
| 3 | Provide names of individuals who have substantively participated in the review or disposition of the request and disclose their potential direct or indirect conflicts of interest |
| 4 | Provide meeting minutes and records of votes for disposition of the request (therapy) |

**EVALUATION/PRIORITIZATION CRITERIA:** **C, L**
*to meet requirement 1

| CODE | EVALUATION/PRIORITIZATION CRITERIA |
|---|---|
| **A** | Treatment represents an established standard of care or significant **advance** over current therapies |
| **C** | **Cancer** or cancer-related condition |
| **E** | Quantity and robustness of **evidence** for use support consideration |
| **L** | **Limited** alternative therapies exist for condition of interest |
| **P** | **Pediatric** condition |
| **R** | **Rare** disease |
| **S** | **Serious**, life-threatening condition |

**Note: a combination of codes may be applied to fully reflect points of consideration [eg, therapy may represent an advance in the treatment of a life-threatening condition with limited treatment alternatives (ASL)]**

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## EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

| CITATION | STUDY-SPECIFIC COMMENTS | LITERATURE CODE |
|---|---|---|
| Navari,R.M., Gray,S.E., and Kerr,A.C.: Olanzapine versus aprepitant for the prevention of chemotherapy-induced nausea and vomiting: a randomized phase III trial. The Journal of Supportive Oncology Sep 2011; Vol 9, Issue 5; pp. 188-195. | Study methodology comments:<br>This was an open-label, randomized-controlled trial. Overall, this study had a crucial limitation for one criterion sufficient to lower ones confidence in the estimate effect. There was potentially high bias for lack of blinding since this was an open-label trial that assessed subjective outcomes. There was low risk of bias for random sequence generation, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with allocation concealment could not be assessed due to insufficient information about this process. | S |
| Tan,L., Liu,J., Liu,X., et al: Clinical research of Olanzapine for prevention of chemotherapy-induced nausea and vomiting. J Exp Clin Cancer Res 2009; Vol 28, p. 131. | Study methodology comments:<br>This was an open-label, randomized-controlled trial. Overall, this study had a crucial limitation for one criterion sufficient to lower ones confidence in the estimate effect. There was potentially high bias for lack of blinding since this was an open-label trial that assessed subjective outcomes. There was low risk of bias for random sequence generation, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with allocation concealment could not be assessed due to insufficient information about this process. | S |
| Navari,R.M., Einhorn,L.H., Passik,S.D., et al: A phase II trial of olanzapine for the prevention of chemotherapy-induced nausea and vomiting: a Hoosier Oncology Group study. Support Care Cancer Jul 2005; Vol 13, Issue 7; pp. 529-534. | | 3 |
| Navari,R.M., Einhorn,L.H., Loehrer,P.J.,Sr., et al: A phase II trial of olanzapine, dexamethasone, and palonosetron for the prevention of chemotherapy-induced nausea and vomiting: a Hoosier oncology group study. Support Care Cancer Nov 2007; Vol 15, Issue 11; pp. 1285-1291. | | 3 |

| | | |
|---|---|---|
| Passik,S.D., Kirsh,K.L., Theobald,D.E., et al: A retrospective chart review of the use of olanzapine for the prevention of delayed emesis in cancer patients. J Pain Symptom Manage May 2003; Vol 25, Issue 5; pp. 485-488. | | 3 |
| Basch,E., Hesketh,P.J., Kris,M.G., et al: Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. Journal of Oncology Practice Nov 2011; Vol 7, Issue 6; pp. 395-398. | | 4 |
| Licup,N., Baumrucker,S., Licup,Nerissa, et al: Olanzapine for nausea and vomiting. [Review]. American Journal of Hospice & Palliative Medicine Sep 2010; Vol 27, Issue 6; pp. 432-434. | | 4 |
| Navari,R., Gray,S., and Kerr,A.: Olanzapine versus aprepitant for the prevention of chemotherapy induced nausea and vomiting: A randomized Phase III trial. Psycho-Oncology Feb 2012; Vol 21 SUPPL. 1, pp. 111-112. | Abstract | 3 |

**Literature evaluation codes: S = Literature selected; 1 = Literature rejected = Topic not suitable for scope of content; 2 = Literature rejected = Does not add clinically significant new information; 3 = Literature rejected = Methodology flawed/Methodology limited and unacceptable; 4 = Other (review article, letter, commentary, or editorial)**

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## CONTRIBUTORS:

*to meet requirement 3

| PACKET PREPARATION | DISCLOSURES | EXPERT REVIEW | DISCLOSURES |
|---|---|---|---|
| Margi Schiefelbein, PA | None | Thomas McNeil Beck, MD | None |
| Stacy LaClaire, PharmD | None | John M. Valgus, PharmD | None |
| Felicia Gelsey, MS | None | James E. Liebmann, MD | None |
| | | Gerald J. Robbins, MD | None |
| | | Keith A. Thompson, MD | None |

## ASSIGNMENT OF RATINGS:

*to meet requirement 4

| | EFFICACY | STRENGTH OF RECOMMENDATION | COMMENTS | STRENGTH OF EVIDENCE |
|---|---|---|---|---|
| **MICROMEDEX** | --- | --- | | B |
| Thomas McNeil Beck, MD | Evidence is inconclusive | Class III - Not Recommended | Efficacy based on highly subjective outcomes | N/A |
| John M. Valgus, PharmD | Evidence is inconclusive | Class IIb - Recommended, In Some Cases | The Tan study did not compare olanzapine to standard of care. The Navari study is confounded by a lack of randomization in a blinded setting which allows bias to be entered into the design. | N/A |
| James E. Liebmann, MD | Evidence favors efficacy | Class IIb - Recommended, In Some Cases | Two randomized trials have shown that olanzapine is more effective than decadron in preventing delayed nausea and vomiting and more effective than aprepitant in preventing delayed nausea in patients receiving highly emetogenic chemotherapy. Olanzapine does not require several days of steroids and may be particularly attractive for patients with Diabetes. | N/A |

| | | | | |
|---|---|---|---|---|
| Gerald J. Robbins, MD | Evidence favors efficacy | Class IIb - Recommended, In Some Cases | Category B evidence and subjective criteria, but pharmacologic rationale for use exists. Was consistent in both studies. | N/A |
| Keith A. Thompson, MD | Evidence favors efficacy | Class IIb - Recommended, In Some Cases | None | N/A |