

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: April 27, 2024

OFF-LABEL ID #: 2673

DRUG NAME: Olanzapine

OFF-LABEL USE: Malignant cachexia

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, E, 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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Sandhya L, Devi Sreenivasan N, Goenka L, Dubashi B, Kayal S, Solaiappan M, Govindarajalou R, Kt H, Ganesan P. Randomized Double-Blind Placebo-Controlled Study of Olanzapine for Chemotherapy-Related Anorexia in Patients With Locally Advanced or Metastatic Gastric, Hepatopancreaticobiliary, and Lung Cancer. J Clin Oncol. 2023 May 10;41(14):2617-2627. doi: 10.1200/JCO.22.01997. Epub 2023 Mar 28. PMID: 36977285.	S
Navari RM, Brenner MC. Treatment of cancer-related anorexia with olanzapine and megestrol acetate: a randomized trial. Support Care Cancer. 2010 Aug;18(8):951-6. doi: 10.1007/s00520-009-0739-7. Epub 2009 Sep 11. PMID: 19756773.	S
Navari RM, Pywell CM, Le-Rademacher JG, White P, Dodge AB, Albany C, Loprinzi CL. Olanzapine for the Treatment of Advanced Cancer-Related Chronic Nausea and/or Vomiting: A Randomized Pilot Trial. JAMA Oncol. 2020 Jun 1;6(6):895-899. doi: 10.1001/jamaoncol.2020.1052. PMID: 32379269	1
Roeland, EJ, Bohlke, K, Baracos, VE, et al: Cancer Cachexia: ASCO Guideline Rapid Recommendation Update. J Clin Oncol Sep 01, 2023; Vol 41, Issue 25; pp. 4178-4179. Pubmed ID: 37467399	S

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)

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	None		
		John D Roberts	None
		Jeffrey Klein	None
		Richard LoCicero	Incyte Corporation Local PI for REVEAL. Study is a multicenter, non-interventional, non-randomized, prospective, observational study in an adult population for patients who have been diagnosed with clinically overt PV and are being followed in either community or academic medical centers in the US who will be enrolled over a 12-month period and observed for 36 months.

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of low dose Olanzapine with or without Megesterol acetate appears to be effective in treating cachexia in oncology patients. Modest weight gain was noted. The adverse effects from Olanzapine needs to be considered.	
Todd Gersten	Effective	Class I: Recommended	Across several clinical trials spanning more than a decade, olanzapine consistently improves appetite and allows for weight gain in advanced cancer patients.	

Warren Brenner	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	I think that the addition of olanzapine to MA appears much more effective with little additional toxicity. I see no downside but only reason I used evidence favors efficacy and class IIa recommended is based on relatively small study size and data restriction to GI and lung cancer patients so not sure how it would translate to other cancers	
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