

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: PROCHLORPERAZINE

INDICATION: Radiotherapy-induced nausea and vomiting, 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: A, C

*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	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
<p>Priestman,T.J., Roberts,J.T., and Upadhyaya,B.K.: A prospective randomized double-blind trial comparing ondansetron versus prochlorperazine for the prevention of nausea and vomiting in patients undergoing fractionated radiotherapy. Clin Oncol (R Coll Radiol) 1993; Vol 5, Issue 6; pp. 358-363.</p>	<p>Study methodology comments: This double-blind, randomized-controlled, comparative trial had limitations for one or more criteria sufficient to substantially lower ones confidence in the estimate of effect. The risk potential bias that could result from not rigorously implementing random sequence generation, allocation concealment, and blinding of participants and outcome assessors was unclear due to the lack of information on these methods. The risk of potential bias associated with attrition and reporting was deemed low.</p>	<p>S</p>
<p>Berry,G.H., Duncan,W., and Bowman,C.M.: The prevention of radiation sickness. Report of a double blind random clinical trial using prochlorperazine and metopimazine. Clin Radiol Oct 1971; Vol 22, Issue 4; pp. 534-537.</p>		<p>3</p>
<p>Ungerleider,J.T., et al: Tetrahydrocannabinol vs. prochlorperazine. The effects of two antiemetics on patients undergoing radiotherapy. Radiology Feb 1984; Vol 150, Issue 2; pp. 598-599.</p>		<p>3</p>
<p>None Listed: Radiation-induced emesis: a prospective observational multicenter Italian trial. The Italian Group for Antiemetic Research in Radiotherapy. Int J Radiat Oncol Biol Phys Jun 01, 1999; Vol 44, Issue 3; pp. 619-625.</p>		<p>1</p>

<p>Basch,E., et al: Antiemetics: american society of clinical oncology clinical practice guideline update. J Clin Oncol Nov 01, 2011; Vol 29, Issue 31; pp. 4189-4198</p>		<p>4</p>
<p>Ward,H.W.: Metoclopramide and prochlorperazine in radiation sickness. Br Med J Apr 07, 1973; Vol 2, Issue 5857; p. 52.</p>		<p>4</p>

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
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	Thomas McNeil Beck, MD	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
		Jeffrey F. Patton, MD	None
		Gerald J. Robbins, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	ASCO's recommendation would state that 5HT3 inhibitors are preferred in situations characterized as 'moderate emetic risk' as was the case in the Priestman article. However, dose of prochlorperazine was higher than that referred to in ASCO guideline. Although Priestman's experience shows efficacy, more data is needed!	N/A
Thomas McNeil Beck, MD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Ondansetron has a long history of relative safety and efficacy in the management of nausea/emesis related to oncology treatments.	N/A

James E. Liebmann, MD	Ineffective	Class III - Not Recommended	The ASCO guidelines clearly recommend 5-HT3 antagonists for prophylaxis of radiation-induced nausea and vomiting. Note that the NCCN guidelines also recommend this. The Priestman trial showed that prochlorperazine is inferior to ondansetron for prophylaxis. Prochlorperazine may be useful for treatment failures, but is not adequate for prophylaxis.	N/A
Jeffrey F. Patton, MD	Evidence is inconclusive	Class III - Not Recommended	None	N/A
Gerald J. Robbins, MD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	The articles included do not directly address prochlorperazine prophylaxis reliably. This would require placebo. However, guidelines offer it as an option in "rescue" for minimal risk and advise "rescue" be continued "prophylactic" for rest of course. Also, there were people who had ADR to ondansetron where it would be useful.	N/A