

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 9/6/2018

PACKET: 1692

DRUG: Naldemedine

USE: Opioid-induced constipation in patients with cancer

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 *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
Katakami N et al. Randomized Phase III and Extension Studies of Naldemedine in Patients With Opioid-Induced Constipation and Cancer. J Clin Oncol. 2017 Dec 1;35(34):3859-3866.	Comments: This was a multicenter randomized, double-blind, placebo-controlled phase IIb study that evaluated naldemedine 0.1, 0.2, or 0.4 mg compared to placebo for 14 days. Key bias criteria evaluated were (1) random sequence generation of randomization; (2) lack of allocation concealment, (3) lack of blinding, (4) incomplete accounting of patients and outcome events, and (5) selective outcome reporting bias. The study was at low risk of bias for these key criteria, and no additional biases were identified.	S
Katakami,N., Oda,K., Tauchi,K., et al: Phase IIb, Randomized, Double-Blind, Placebo-Controlled Study of Naldemedine for the Treatment of Opioid-Induced Constipation in Patients With Cancer. J Clin Oncol Jun 10, 2017; Vol 35, Issue 17; pp. 1921-1928.		2

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
Felicia Gelsey, MS	None		
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.
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ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	Effective	Class I: Recommended		B
John D Roberts	Effective	Class I: Recommended	A single randomized trial showed robust efficacy in patients with cancer and opioid induced constipation.	N/A
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Naldemedine to treat opioid induced constipation in cancer patients showed a good degree of effectiveness but only as a short term treatment. Patients treated with longer durations exhibited a greater degree of GI related adverse effects, most notably diarrhea. Naldemedine did not impede the analgesic effects of opioids as well	N/A
Richard LoCicero	Effective	Class I: Recommended	Naldemedine is FDA approved for treatment of opioid-induced constipation. There is now phase III data demonstrating its efficacy and safety in cancer patients as well.	N/A