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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 9/16/16

PACKET: 1365

DRUG: Fosaprepitant Dimeglumine

USE: Prophylaxis, chemotherapy-induced nausea and vomiting in patients receiving cisplatin-based chemotherapy; prophylaxis, radiation-induced nausea and vomiting

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
Ruhlmann CH., et al. Efficacy and safety of fosaprepitant for the prevention of nausea and emesis during 5 weeks of chemoradiotherapy for cervical cancer (the GAND-emesis study): a multinational, randomised, placebo-controlled, double-blind, phase 3 trial. Lancet Oncol. 2016 Apr;17(4):509-18.	Comments: This was an international, double-blind, placebo-controlled, randomized phase 3 trial. 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
Navari RM., et al. Olanzapine versus fosaprepitant for the prevention of concurrent chemotherapy radiotherapy-induced nausea and vomiting. J Community Support Oncol. 2016 Apr;14(4):141-7.	Comments: This was a multi-site, double-blind, randomized phase 3 trial. Overall, this study was at low risk for most of the key risk of bias criteria which included random sequence generation, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with allocation concealment was unclear and not discussed in the paper.	S
Herrstedt,J., et al: 2016 Updated MASCC/ESMO Consensus Recommendations: Prevention of Nausea and Vomiting Following High Emetic Risk Chemotherapy. Support.Care Cancer Jul 22, 2016.		S

Becker-Schiebe,M. and Hoffmann,W.: Antiemetic prophylaxis with fosaprepitant in chemoradiotherapy of cervical cancer: Results of a randomized, double-blind phase III study (GAND-emesis study). Onkologe Jun 01, 2016; Vol 22, Issue 6; pp. 426-427.	Abstract	4
Ruhlmann,C.H. and Herrstedt,J.: New treatments on the horizon for chemoradiotherapy-induced nausea and vomiting. Expert Opinion on Pharmacotherapy 2016; Vol 17, Issue 12; pp. 1623-1629.		4
Schwartzberg,L.: Progress in chemoradiotherapy-induced nausea and vomiting. Lancet Oncol Apr 01, 2016; Vol 17, Issue 4; pp. 412-413.		4

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.

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	In a study of patients receiving pelvic chemoradiotherapy, the addition of fosaprepitant to palonosetron and dexamethasone modestly improved control of nausea and vomiting. In a study of patients receiving head and neck or esophageal chemoradiotherapy, olanzapine had effects similar to fosaprepitant but with moderately better control of nausea.	N/A

Jeffrey Klein	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	The addition of Fosaprepitant to a regimen consisting of dexamethasone and palonosetron is effective in one study to decrease risk of emesis and delayed emesis in patients receiving chemotherapy and/or radiation. In another head to head study the addition of Fosaprepitant was not as effective as olanzapine in controlling overall nausea and was quite more expensive. It seems that there might be a role for Fosaprepitant but that role must be considered by the practitioner more in depth.	N/A
Richard LoCicero	Effective	Class I: Recommended	Fosaprepitant is an established therapy for cisplatin-based chemotherapy-induced nausea and vomiting. It also has established efficacy and safety when given concurrently with radiation.	N/A