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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 10/27/16

PACKET: 1388

DRUG: Iron Dextran

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: A, C, E *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
Mhaskar,R., et al: The role of iron in the management of chemotherapy-induced anemia in cancer patients receiving erythropoiesis-stimulating agents. Cochrane Database Syst Rev 2016; Vol 2016, Issue 2; p. CD009624.	Comments: This was a Cochrane systematic review which included randomized controlled trials comparing 'iron plus ESA' or 'iron alone' versus 'ESA alone' in people with CIA. Eight randomized trials were included. The risk of bias tool was used to assess the quality of the included trials. Overall, the risk of bias was judged to be moderate for selection bias and detection bias and low for attrition bias, reporting bias, and other potential sources of bias. This systematic review conducted a comprehensive literature search and provided information on eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used.	S
Auerbach, M, et al: Darbepoetin alfa 300 or 500 mug once every 3 weeks with or without intravenous iron in patients with chemotherapy-induced anemia. American journal of hematology Sep 2010; Vol 85, Issue 9; pp. 655-663.		S
Auerbach,M., et al: Intravenous iron optimizes the response to recombinant human erythropoietin in cancer patients with chemotherapy-related anemia: a multicenter, open-label, randomized trial. J Clin Oncol Apr 01, 2004; Vol 22, Issue 7; pp. 1301-1307.		S
Shord,S.S., Hamilton,Jr, and Cuellar,S.: Parenteral iron with erythropoiesis-stimulating agents for chemotherapy-induced anemia. Journal of Oncology Pharmacy Practice 2008; Vol 14, Issue 1; pp. 5-22.		4

Gafter-Gvili,A., Steensma,D.P., and Auerbach,M.: Should the ASCO/ASH Guidelines for the use of intravenous iron in cancer- and chemotherapy-induced anemia be updated?. J Natl.Compr.Canc.Netw. May 2014; Vol 12, Issue 5; pp. 657-664.		4
Rizzo,J.D., et al: Use of epoetin and darbepoetin in patients with cancer: 2007 American Society of Hematology/American Society of Clinical Oncology clinical practice guideline update. Blood Jan 01, 2008; Vol 111, Issue 1; pp. 25-41.		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
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 IIa: Recommended, In Most Cases**		B
John D Roberts	Effective	Class IIa: Recommended, In Most Cases	In patients with anemia attributed to chemotherapy, addition of iron dextran to erythropoiesis-stimulating agents modestly increases hemoglobin response. In patients without iron deficiency, iron dextran probably is more effective than oral agents.	N/A
Jeffrey Klein	Effective	Class I: Recommended	The use of iron dextran concurrently with an erythropoetin stimulating agent significantly improves the hemoglobin response than without iron dextran. The iron infusion did carry a minimal risk for anaphylaxis but was extremely well tolerated. Other favorable results were decrease RBC transfusions, lower doses of the erythpoetin needed, and an improved quality of life.	N/A

Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Clinical trial date supports the use of iron supplementation in combination with erythropoiesis-stimulating agents for management of anemia due to chemotherapy. There is insufficient or conflicting data with respect to oral vs. IV iron therapy. Therefore, in patients intolerant of oral iron therapy, IV iron therapy can be appropriate.	N/A