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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 10/27/16

PACKET: 1374

DRUG: Sodium Ferric Gluconate Complex

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
Bastit L, et al. Randomized, multicenter, controlled trial comparing the efficacy and safety of darbepoetin alpha administered every 3 weeks with or without intravenous iron in patients with chemotherapy-induced anemia. Journal of Clinical Oncology 2008;26(10):1611–8.		S
Henry DH, et al. Intravenous ferric gluconate significantly improves response to epoetin alfa versus oral iron or no iron in anemic patients with cancer receiving chemotherapy. Oncologist 2007;12(2):231–42.		S

Pedrazzoli P, et al. Randomized trial of intravenous iron supplementation in patients with chemotherapy-related anemia without iron deficiency treated with darbepoetin alpha. Journal of Clinical Oncology 2008;26(10):1619–25.		S
Steensma DP, et al. Phase III, randomized study of the effects of parenteral iron, oral iron, or no iron supplementation on the erythropoietic response to darbepoetin alfa for patients with chemotherapy-associated anemia. Journal of Clinical Oncology 2011;29(1):97–105		S
Henry,D.H., Dahl,N.V., and Auerbach,M.A.: Thrombocytosis and venous thromboembolism in cancer patients with chemotherapy induced anemia may be related to ESA induced iron restricted erythropoiesis and reversed by administration of IV iron. Am J Hematol Mar 2012; Vol 87, Issue 3; pp. 308-310.		1
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	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases		B
John D Roberts	Effective	Class IIa: Recommended, In Most Cases	In patients with anemia attributed to chemotherapy without evidence of iron deficiency, addition of sodium ferric gluconate complex to erythropoiesis-stimulating agents modestly increases hemoglobin response. Sodium ferric gluconate complex probably is more effective than oral agents.	N/A

Jeffrey Klein	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	The combination of IV sodium ferric gluconate complex with an erythpoeitin agent showed an increased hemoglobin response in some trials over oral iron products. Another trial showed no benefit in using the IV iron product over an oral iron product or even a placebo. It seems that evidence is not decisive with this particular combination.	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