TRUVEN HEALTH ANALYTICS™
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 11/8/16

PACKET: 1377

DRUG: Febuxostat

USE: Increased uric acid level in patients receiving chemotherapy and at intermediate to high risk of tumor lysis syndrome, 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: C, S *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)]

TRUVEN HEALTH ANALYTICS™
an IBM Company

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Spina,M., Pristupa,A.S., Montesinos,P., et al: FLORENCE: a randomized, double-blind, phase III pivotal study of febuxostat versus allopurinol for the prevention of tumor lysis syndrome (TLS) in patients with hematologic malignancies at intermediate to high TLS risk. Annals of Oncology Oct 2015; Vol 26, Issue 10; pp. 2155-2161.	Comments: This was an international, multicenter, double-blind, randomized comparative trial. Overall, this study was at low risk of biases associated with lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with random sequence generation and allocation concealment was unclear and not discussed in the paper.	S
Tamura,K., Kawai,Y., Kiguchi,T., et al: Efficacy and safety of febuxostat for prevention of tumor lysis syndrome in patients with malignant tumors receiving chemotherapy: a phase III, randomized, multi-center trial comparing febuxostat and allopurinol. Int J Clin Oncol Mar 26, 2016.	Comments: This was a multicenter, open-label, randomized, noninferiority trial. Overall, this study was at low risk of biases associated with 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
Criscuolo,M., Fianchi,L., Dragonetti,G., et al: Tumor lysis syndrome: Review of pathogenesis, risk factors and management of a medical emergency. Expert Review of Hematology Feb 2016; Vol 9, Issue 2; pp. 197-208.		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 IIb: Recommended, In Some Cases		B
John D Roberts	Effective	Class IIb: Recommended, In Some Cases	Febuxostat likely is as effective as allopurinol in preventing tumor lysis syndrome in patients at risk and receiving chemotherapy. Rasburicase is as effective or more effective than allopurinol. In most cases any one of these agents is likely to be effective, and choice may be based upon other considerations.	N/A

Richard LoCicero	Effective	Class IIb: Recommended, In Some Cases	Febuxostat has been shown in randomized trials to be at least as effective and safe as Allopurinol (the current standard of care) for prevention of tumor lysis syndrome. The strength of recommendation is limited due to minimal advantage of Febuxostat over the standard of care, Allopurinol. Its role may be limited to those cases in which Allopurinol is contraindicated or not otherwise available.	N/A
Jeffrey Klein	Effective	Class I: Recommended	The use of febuxostat to reduce uric acid level and ultimately prevent tumor lysis syndrome in patients receiving chemotherapy is very effective. When compared to allopurinol, febuxostat reduced uric acid levels faster. Febuxostat is safe but carries a higher price tag than the traditional allopurinol. It would be interesting to see if febuxostat can delay or eliminate the use of rasburicase.	N/A