TRUVEN HEALTH ANALYTICS™
an IBM Company

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 3/27/2017

PACKET: 1344

DRUG: Risedronate Sodium

USE: Prophylaxis Osteopenia, Secondary to androgen-deprivation therapy in patients with prostate 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, 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)]

TRUVEN HEALTH ANALYTICS™
an IBM Company

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Choo,R., et al: Randomized, double-blinded, placebo-controlled, trial of risedronate for the prevention of bone mineral density loss in nonmetastatic prostate cancer patients receiving radiation therapy plus androgen deprivation therapy. Int J Radiat Oncol Biol Phys Apr 01, 2013; Vol 85, Issue 5; pp. 1239-1245.	Comments: This was a randomized, double-blind, placebo-controlled trial. Due to the results of an interim analysis, the study was terminated early after enrolling 104 patients. Overall, this study was at low risk of biases associated with poor random sequence generation, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with lack of allocation concealment was unclear and not discussed in the paper.	S
Taxel,P., et al: Risedronate prevents early bone loss and increased bone turnover in the first 6 months of luteinizing hormone-releasing hormone-agonist therapy for prostate cancer. BJU Int Nov 2010; Vol 106, Issue 10; pp. 1473-1476.	Comments: This was a randomized, double-blind, placebo-controlled 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

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 IIa: Recommended, In Most Cases		B
John D Roberts	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	In two small trials, evidence that risedronate prevents osteopenia induced by androgen deprivation therapy concurrent with radiation for the treatment of prostate cancer was mixed. Risedronate might be considered for patients known to be at risk for osteopenic fracture. There are other agents that might be more effective.	N/A

Jeffrey Klein	Evidence Favors Efficacy	Class I: Recommended	The prophylaxis use of risedronate to prevent bone loss in patients receiving androgen deprivation therapy (for prostate cancer) showed significant results in a 6 month to 2 year time frame. The studies were small and adverse effects were minimal. Oral risedronate posed an advantage over similar IV therapies. The studies did not indicate if these patients were taking calcium/vitamin D supplements.	N/A
Richard LoCicero	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	Weekly risedronate has been shown to improve bone mineral density in men with prostate cancer receiving androgen-deprivation therapy. Treatment was associated with acceptable toxicity.	N/A