TRUVEN HEALTH ANALYTICS™
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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 7/31/2017

PACKET: 1469

DRUG: Abiraterone Acetate

USE: Hormone sensitive prostate cancer, newly diagnosed, metastatic, high-risk, in combination with prednisone and androgen-deprivation therapy

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, 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
Fizazi,K., Tran,N., Fein,L., et al: Abiraterone plus prednisone in metastatic, castration-sensitive prostate cancer. N.Engl.J Med Jun 04, 2017; Vol Epub,	Comments: This was an international, phase 3, double-blind, placebo-controlled, randomized trial that was conducted at 235 sites in 34 countries. As a result of the findings at the time of the interim analysis, the independent data and safety monitoring committee unanimously recommended on January 12, 2017, that the trial be unblinded to allow crossover among the patients in the placebo group to receive abiraterone. 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	Effective	Class I: Recommended		B
John D Roberts	Effective	Class I: Recommended	A well done industry sponsored trial demonstrated improvement in multiple clinical outcomes including survival with the addition of abiraterone/prednisone to androgen-deprivation therapy in men with newly diagnosed, metastatic, high-risk prostate cancer.	N/A

Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	The use of abiraterone in combination with prednisone and androgen deprivation therapy proved to be effective. Increased overall survival and progression free survival in patients with prostate cancer were seen. Another benefit was delaying PSA progression. The incidence and severity of hypertension and hypokalemia needs to be considered before and during treatment.	N/A
Richard LoCicero	Effective	Class I: Recommended	Clinical trial data supports the use of abirateone (+prednisone) in combinationwith androgen-deprivation therapy in newly diagnosed metastatic hormone sensitive prostate cancer. Its efficacy was confirmed in a double-blind, placebo-controlled trial establishing a significant survival benefit compared to placebo.	N/A