merative

Micromedex

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: June 26, 2023

OFF-LABEL ID #: 2579

DRUG NAME: Abiraterone Acetate

OFF-LABEL USE: Malignant tumor of prostate; Nonmetastatic, high-risk, in combination with 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, A *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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Kanesvaran, R, Castro, E, Wong, A, et al: Pan-Asian adapted ESMO Clinical Practice Guidelines for the diagnosis, treatment and follow-up of patients with prostate cancer. ESMO Open Aug 2022; Vol 7, Issue 4; p. 100518.	S
Rajwa, P, Pradere, B, Gandaglia, G, et al: Definitive Local Treatment in Nonmetastatic Unfavourable Prostate Cancer: A Systematic Review and Meta-analysis. Eur Urol Jul 2022; Vol 82, Issue 1; pp. 82-96.	S
Attard G, Murphy L, Clarke NW, et al; (STAMPEDE) investigators. Abiraterone acetate and prednisolone with or without enzalutamide for high-risk non-metastatic prostate cancer: a meta-analysis of primary results from two randomised controlled phase 3 trials of the STAMPEDE platform protocol. Lancet. 2022 Jan 29;399(10323):447-460. Epub 2021 Dec 23. PMID: 34953525; PMCID: PMC8811484.	S
Lowrance 2023	2

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
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
MERATIVE MICROMEDEX	Effective	Class I: Recommended		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Abiraterone with androgen deprivation therapy(enzalutamide) in non-metastatic prostate cancer patients demonstrated a much higher level of progression free survival than without the Abiraterone. The incidence of adverse effects with this combination does need to be considered.	
Richard LoCicero	Effective	Class I: Recommended	Two phase III trials evaluated the addition of abiraterone to androgen deprivation therapy in non-metastatic, high risk prostate cancer after definitive surgery +/- radiation therapy. In a meta-analysis, the 6 year metastasis-free survival was 82% in the group that received abiraterone and 69% in the group that did not. Unexpected toxicity was not observed.	

Todd Gersten	Effective	Class I: Recommended	The available evidence strongly supports that the addition of 2 years of abiraterone to androgen deprivation therapy (ADT) in men with high-risk non-metastatic prostate cancer significantly lengthened the time to development of metastatic disease and improved length of life.	