IBM Watson Health

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 3/25/2020

PACKET: 1971

DRUG: Anastrozole

USE: Malignant tumor of ovary; Recurrent, estrogen- or progesterone-receptor positive, in postmenopausal women

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, R, 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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Kok, PS, Beale, P, O'Connell, RL, et al: PARAGON (ANZGOG-0903): a phase 2 study of anastrozole in asymptomatic patients with estrogen and progesterone receptor-positive recurrent ovarian cancer and CA125 progression. J Gynecol Oncol Sep 2019; Vol 30, Issue 5; p. e86.	This study was part of the PARAGON basket trial, an exploratory single-arm phase II trial that investigated anastrozole therapy in patients with ER+ and/or PR+ recurrent/metastatic gynecological cancers. This trial specifically includes the subset of patients who were asymptomatic and had CA125 progression. There was low risk of bias associated with selection of cohorts and assessment of outcomes. All subjects were included in the analyses. A major caveat is that the study lacked a control group.	S
Bonaventura, A, O'Connell, RL, Mapagu, C, et al: Paragon (ANZGOG-0903): phase 2 study of anastrozole in women with estrogen or progesterone receptor-positive platinum-resistant or -refractory recurrent ovarian cancer. Int J Gynecol Cancer Jun 2017; Vol 27, Issue 5; pp. 900-906.	This study was part of the PARAGON basket trial, an exploratory single-arm phase II trial that investigated anastrozole therapy in patients with ER+ and/or PR+ recurrent/metastatic gynecological cancers. This trial specifically includes the subset of patients with platinum-resistant/refractory recurrent ovarian cancer. There was low risk of bias associated with selection of cohorts and assessment of outcomes. All subjects were included in the analyses. A major caveat is that the study lacked a control group.	S
Tang, M, O'Connell, RL, Amant, F, et al: PARAGON: A Phase II study of anastrozole in patients with estrogen receptor-positive recurrent/metastatic low-grade ovarian cancers and serous borderline ovarian tumors. Gynecol Oncol Sep 2019; Vol 154, Issue 3; pp. 531-538.	This study was part of the PARAGON basket trial, an exploratory single-arm phase II trial that investigated anastrozole therapy in patients with ER+ and/or PR+ recurrent/metastatic gynecological cancers. This trial specifically includes the subset of patients who had low-grade ovarian cancers and serous borderline ovarian tumors. There was low risk of bias associated with selection of cohorts and assessment of outcomes. All subjects were included in the analyses. A major caveat is that the study lacked a control group.	S

Langdon, SP, Gourley, C, Gabra, H, et al: Endocrine therapy in epithelial ovarian cancer. Expert Rev Anticancer Ther Feb 2017; Vol 17, Issue 2; pp. 109-117.		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
Megan Smith	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
IBM MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of anastrozole in ovarian cancer patients who are ER+ or PR + demonstarted some degree of efficacy to delay progression of the disease and /or delay need for chemotherapy. Theses studies were small and most patients did eventually progress within 6 months.	

John Roberts	Evidence is Inconclusive	Class III: Not Recommended	In 3 single arm trials in 3 different, distinct groups of women with persistent ovarian cancer following prior treatment, responses to anastrozole were uncommon and toxicity was moderate. Meaningful benefit seems unlikely. Stable disease is not a reliable sign of benefit in single arm studies due to patient selection bias and lack of a control.	
Richard LoCicero	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Phase II trials have demonstrated efficacy of anastrazole for the treatment of recurrent ER+/PR+ ovarian cancer. Lack of control group limits strength of recommendation. No unexpected toxicities were observed.	