COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Anastrozole

INDICATION: Prevention of breast cancer in postmenopausal women at high risk

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, 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

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Cuzick,J., et al: Anastrozole for prevention of breast cancer in high-risk postmenopausal women (IBIS-II): an international, double-blind, randomised placebo-controlled trial. Lancet Mar 22, 2014; Vol 383, Issue 9922; pp. 1041-1048.	This was a randomized, double-blind, placebo-controlled trial. Overall, this study was at low risk for most of the key risk of bias criteria which included random sequence generation, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated lack of allocation concealment was unclear and not discussed in the paper.	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)

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CONTRIBUTORS:
*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	Thomas McNeil Beck, MD	None
Felicia Gelsey, MS	None	James E. Liebmann, MD	None
		Keith A. Thompson, MD	None
		John M. Valgus, PharmD	None

ASSIGNMENT OF RATINGS:
*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban, DO	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Data is beginning to increase regarding anastrozole positive effect in this population. Particularly ER+ lesions	N/A
Thomas McNeil Beck, MD	Effective	Class I: Recommended	An effective therapy for high risk women	N/A

James E. Liebmann, MD	Effective	Class IIa: Recommended, In Most Cases	The ISIS 2 trial was a well conducted trial performed by the same group that did the largest European placebo-controlled trial of tamoxifen for breast cancer prevention. The results of the trial are believable and consistent with the reduction of contralateral breast cancer risk demonstrated in the ATAC trial and the reduction of breast cancer risk seen with exemestane in the MAP.3 trial. The major caveat ot the routine use of either aromatase inhibitor for breast cacner prevention is that neither has been directly studied against tamoxifen for this indication. However, anastrozole or exemestane are reasonable options for postmenopausal women who are at high risk of breast cancer who wish to lower their risk. Women with normal or high bone density, a history of deep vein thrombosis, or a personal or family history of uterine cancer may be particularly good candidates for an aromatase inhibitor as opposed to tamoxifen.	N/A
Keith A. Thompson, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A
John M. Valgus, PharmD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	Data is favorable for anastrozole in the prevention setting for high risk patients. Unknown efficacy and safety compared to other options for chemoprevention though with shorter follow up. Preliminary results are favorable though.	N/A