TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Exemestane

INDICATION: Prevention of invasive breast cancer in postmenopausal women at increased 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: **A, C, 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
Goss,p.E., et al: Exemestane for Breast-Cancer Prevention in Postmenopausal Women. N Engl J Med Jun 04, 2011; Vol E Pub, p. 1.	Study methodology comments: This was a rigorously designed randomized, double-blind, placebo-controlled, multicenter trial with many strengths. Many potential confounding factors were controlled through the study design, statistical analyses, and eligibility criteria. Additional strengths of the study included: 1) defined primary and secondary outcomes; 2) conducted power analysis; 3) provided 95% confidence intervals; 4) conducted analyses on the intent-to-treat population; 5) had both inclusion and exclusion criteria; and 6) all mammograms and radiographic reports were reviewed centrally. Weaknesses of the study included: 1) possible selection bias since subjects were not recruited randomly or consecutively; 2) event rate was low; and 3) partial explanation of method of randomization.	S
Richardson H, et al: The National Cancer Institute of Canada clinical Trials Group MAP.3 trial: an international breast cancer prevention trial. Curr Oncol 2007; 14(3):89-96.	Study methodology comments: This is an abstract.	S
Exemestane for primary prevention of breast cancer in postmenopausal women: NCIC CTG MAP.3—A randomized, placebo-controlled clinical trial. 2011 ASCO abstract.		3
Bevers,T.B., et al: Breast cancer risk reduction. JNCCN Journal of the National Comprehensive Cancer Network 2010; Vol 8, Issue 10; pp. 1112-1146.		4
Cuzick,J., et al: Preventive therapy for breast cancer: A consensus statement. The Lancet Oncology 2011; Vol 12, Issue 5; pp. 496-503.		4

Goss,p.E., et al: National Cancer Institute of Canada Clinical Trials Group MAR3 trial: Evaluation of exemestane to prevent breast cancer in postmenopausal women. Clinical Breast Cancer 2007; Vol 7, Issue 11; pp. 895-900.		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)

TRUVEN HEALTH ANALYTICS

CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	James E. Liebmann, MD	None
Felicia Gelsey, MS	None	Thomas McNeil Beck, MD	None
		Gerald J. Robbins, MD	None
		Jeffrey A. Bubis,DO	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Edward P. Balaban,DO	Effective	Class I: Recommended	I believe the recently released data makes this drug another preventative alternative.	N/A
James E. Liebmann, MD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases		N/A
Thomas McNeil Beck, MD	Effective	Class I: Recommended	Evidence of efficacy is strong.	N/A
Gerald J. Robbins, MD	Effective	Class IIa: Recommended, In Most Cases	While effective with reduced toxicity, the number of women that are treated to see benefit remains high.	N/A
Jeffrey A. Bubis,DO	Effective	Class I: Recommended	The data speaks for itself. Recurrence rate decreases with the drug.	N/A