TRUVEN HEALTH ANALYTICS™
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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 5/13/16

PACKET: 1280

DRUG: Anastrozole

USE: Intraductal carcinoma in situ of breast, as adjuvant therapy in postmenopausal women with hormone receptor-positive disease

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 *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
Ganz PA, et al. Patient-reported outcomes with anastrozole versus tamoxifen for postmenopausal patients with ductal carcinoma in situ treated with lumpectomy plus radiotherapy (NSABP B-35): A randomised, double-blind, phase 3 clinical trial. Lancet 2016; 387: 857–65	Comments: This was a multicenter, double-blind, randomized, comparative trial. 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
Margolese RG, et al. Anastrozole versus tamoxifen in postmenopausal women with ductal carcinoma in situ undergoing lumpectomy plus radiotherapy (NSABP B-35): a randomised, double-blind, phase 3 clinical trial. Lancet 2016; 387: 849–56.	Comments: This was a multicenter, double-blind, randomized, comparative trial. 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
Forbes JF et al. Anastrozole versus tamoxifen for the prevention of locoregional and contralateral breast cancer in postmenopausal women with locally excised ductal carcinoma in situ (IBIS-II DCIS): a double-blind, randomised controlled trial. Lancet 2016; 387: 866–73	Comments: This was an international, double-blind, randomized, comparative trial. 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

Jack Cuzick, et al. Anastrozole for prevention of breast cancer in high-risk postmenopausal women (IBIS-II): an international, double-blind, randomised placebo-controlled trial. Lancet 2014; 383: 1041–48.		1
Anastrozole provides alternative option for DCIS By: PATRICE WENDLING, Oncology Practice Digital Network June 2, 2015		4
Mitchell KB & Kuerer H. Ductal Carcinoma In Situ: Treatment Update and Current Trends. Curr Oncol Rep (2015) 17: 48		4
J Cuzick, et al. Abstract S3-01: Breast cancer prevention using anastrozole in postmenopausal women at high risk. Cancer Res 2013;73(24 Suppl): Abstract nr S3-01.	Abstract	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
Felicia Gelsey, MS	None		
Stacy LaClaire, PharmD	None		
Catherine Sabatos, PharmD	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.
		John D Roberts	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	**Effective**	**Class IIb: Recommended, In Some Cases**		A
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	The use of anastrozole vs tamoxifen in intraductal carcinoma in situ of breast showed some favorable gains with the anastrozole group. The main benefit of anastrozole (longer breast cancer free interval) was seen in patients< age 60 in two of the 3 studies. Unfortunately anastrozole has a distinct side effect profile that must be taken into consideration before initiating therapy.	N/A

Richard LoCicero	Effective	Class I: Recommended	NSABP B-35 was a multi-center, randomized, placebo-controlled trial that established anastrazole as equivalent to or better than tamoxifen as an adjuvant treatment for DCIS in post-menopausal women.	N/A
John D Roberts	Effective	Class IIb: Recommended, In Some Cases	Adjuvant hormonal therapy does not improve survival for post-menopausal women with ductal carcinoma in situ. It is an option for post-menopausal women with hormone receptor positive tumors who are willing to take for several years medicine, which often causes bothersome and rarely causes dangerous side effects, in order to avoid a small risk of a cancer recurrence that requires more treatment. Women who have chosen to take adjuvant hormonal therapy have the options of tamoxifen and anastrozole. Both are effective. Both occasionally cause bothersome and rarely cause dangerous side effects. Side effects differ between the two agents, and women might decide on one or the other on the basis the differences. Anastrozole may be more effective than tamoxifen in women under 60.	N/A