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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 2/13/2017

PACKET: 1410

DRUG: Fulvestrant

USE: Malignant tumor of breast Locally advanced or metastatic, First-line endocrine 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: A, C, E *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
Howell,A., Robertson,J.F.R., Abram,P., et al: Comparison of fulvestrant versus tamoxifen for the treatment of advanced breast cancer in postmenopausal women previously untreated with endocrine therapy: A multinational, double-blind, randomized trial. Journal of Clinical Oncology 2004; Vol 22, Issue 9; pp. 1605-1613.	Comments: This was a multicenter, double-blind, randomized, phase 3, noninferiority trial. Overall, this study was at low risk of biases associated with poor random sequence generation, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with poor allocation concealment was unclear and not discussed in the paper.	3
Robertson,J.F., Bondarenko,I.M., Trishkina,E., et al: Fulvestrant 500 mg versus anastrozole 1 mg for hormone receptor-positive advanced breast cancer (FALCON): an international, randomised, double-blind, phase 3 trial. Lancet Nov 28, 2016	Comments: This was a phase 3, randomized, double-blind, double-dummy, international 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
Robertson John,F.R., Llombart-Cussac,Antonio, Rolski,Janusz, et al: Activity of fulvestrant 500 mg versus anastrozole 1 mg as first-line treatment for advanced breast cancer: results from the FIRST study. Journal of clinical oncology - official journal of the American Society of Clinical Oncology Sep 20, 2009; Vol 27, Issue 27; pp. 4530-4535.	Comments: This was a phase II, open-label, randomized, multicenter, noninferiority trial. Overall, this study was at low risk of biases associated with lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with poor random sequence generation and poor allocation concealment was unclear and not discussed in the paper.	S

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Robertson JF, Lindemann JP, Llombart-Cussac A, et al: Fulvestrant 500 mg versus anastrozole 1 mg for the first-line treatment of advanced breast cancer: follow-up analysis from the randomized 'FIRST' study. Breast Cancer Res Treat. 2012 Nov;136(2):503-11.		S
Ellis,M.J. and Rukazenkov,Y.: Fulvestrant 500 mg Versus Anastrozole 1 mg for the First-Line Treatment of Advanced Breast Cancer: Overall Survival Analysis From the Phase II FIRST Study. Journal of Clinical Oncology Nov 10, 2015; Vol 33, Issue 32; pp. 3781-3787		S
Martin,M., Tarruella Cobo,S.L., and Gilarranz,Y.J.: Endocrine therapy for hormone treatment-naive advanced breast cancer. Breast Aug 01, 2016; Vol 28, pp. 161-166		4
Reinert,T. and Barrios,C.H.: Definition of first-line endocrine therapy for hormone receptor-positive advanced breast cancer. Journal of Clinical Oncology Jun 01, 2016; Vol 34, Issue 16; pp. 1959-1960.		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)

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CONTRIBUTORS:

*to meet requirement 3

PACKET PREPARATION	DISCLOSURES	EXPERT REVIEW	DISCLOSURES
Felicia Gelsey, MS	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
MICROMEDEX	Effective	Class I: Recommended		B
John D Roberts	Effective	Class I: Recommended	Fulvestrant has been shown active and as or more effective anastrozole with a similar side effect profile.	N/A
Jeffrey Klein	Evidence Favors Efficacy	Class I: Recommended	The use of Fulvestrant as first line endocrine therapy in malignant breast cancer (hormone receptor receptor positive) demonstrates a superior efficacy with OS and PFS. Theses studies compared fulvestrant to the benchmark agent anastrazole. Fulvestrant is given as an IM 500mg injection monthly typically while anastrazole is given orally, and costs might play a role for some patients as well. This may limit fulvestrants' use somewhat.	N/A

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Richard LoCicero	Effective	Class I: Recommended	Randomized clinical trials have demonstrated that fulvestrant is as effective or more effective that an aromatase inhibitor as first-line endocrine therapy for post-menopausal women with locally advanced or metastatic breast cancer. Treatment also has acceptable toxicity.	N/A

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