

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Goserelin acetate

INDICATION: Post-chemotherapy ovarian failure prophylaxis, in patients with breast cancer receiving adjuvant anthracycline and cyclophosphamide-based therapy

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

*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
Badawy,A., Elnashar,A., El-Ashry,M., et al: Gonadotropin-releasing hormone agonists for prevention of chemotherapy-induced ovarian damage: prospective randomized study. Fertility & Sterility Mar 2009; Vol 91, Issue 3; pp. 694-697.	<u>Study methodology comments:</u> Overall, this study was at low risk for most of the key risk of bias criteria which included allocation concealment, lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with random sequence generation was unclear and not discussed in the paper.	S
Gerber,B., Von,Minckwitz G., Stehle,H., et al: Effect of luteinizing hormone-releasing hormone agonist on ovarian function after modern adjuvant breast cancer chemotherapy: the GBG 37 ZORO study. J Clin Oncol Jun 10, 2011; Vol 29, Issue 17; pp. 2334-2341.	<u>Study methodology comments:</u> This was a prospective, randomized, open-label, controlled, multicenter phase II study. Overall, this study was at low risk for most of the key risk of bias criteria which included lack of blinding, incomplete accounting of patients and outcome events, and selective outcome reporting. The risk of bias associated with random sequence generation and allocation concealment was unclear and not discussed in the paper.	S
Blumenfeld,Z.: ZORO study: discrepancy between the conclusion and the results. J Clin Oncol Aug 20, 2011; Vol 29, Issue 24; pp. 3340-3342.		4
Del,Mastro L., Catzeddu,T., Boni,L., et al: Prevention of chemotherapy-induced menopause by temporary ovarian suppression with goserelin in young, early breast cancer patients. Ann Oncol Jan 2006; Vol 17, Issue 1; pp. 74-78.		3
DelMastro,L.: Temporary ovarian suppression with goserelin and ovarian function protection in patients with breast cancer undergoing chemotherapy. Journal of Clinical Oncology Aug 20, 2011; Vol 29, Issue 24; pp. 3339-3340.		4

<p>Matsumoto,M., Miyauchi,M., Yamamoto,N., et al: Investigation of menstruation recovery after LH-RH agonist therapy for premenopausal patients with breast cancer. Breast Cancer 2000; Vol 7, Issue 3; pp. 237-240.</p>		<p>3</p>
<p>Potolog-Nahari,C., Fishman,A., and Cohen,I.: Protection of ovarian function and fertility using a combination of gonadotropin-releasing hormone (GnRH) agonist and GnRH antagonist during cancer treatment in young females. Gynecol Endocrinol May 2007; Vol 23, Issue 5; pp. 290-294.</p>		<p>3</p>
<p>Recchia,F., Sica,G., De,Filippis S., et al: Goserelin as ovarian protection in the adjuvant treatment of premenopausal breast cancer: a phase II pilot study. Anticancer Drugs Apr 2002; Vol 13, Issue 4; pp. 417-424.</p>		<p>3</p>
<p>Recchia,F., Saggio,G., Amiconi,G., et al: Gonadotropin-releasing hormone analogues added to adjuvant chemotherapy protect ovarian function and improve clinical outcomes in young women with early breast carcinoma. Cancer Feb 01, 2006; Vol 106, Issue 3; pp. 514-523.</p>		<p>3</p>
<p>Urruticoechea,A., Arnedos,M., Walsh,G., et al: Ovarian protection with goserelin during adjuvant chemotherapy for pre-menopausal women with early breast cancer (EBC). Breast Cancer Res Treat Aug 2008; Vol 110, Issue 3; pp. 411-416.</p>		<p>3</p>

<p>Wong,M., O'Neill,S., Walsh,G., et al: Goserelin with chemotherapy to preserve ovarian function in pre- menopausal women with early breast cancer: menstruation and pregnancy outcomes. Ann Oncol Sep 27, 2012; Vol E Pub, p. 1.</p>		<p>3</p>
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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
Margi Schiefelbein, PA	None	Thomas McNeil Beck, MD	None
Stacy LaClaire, PharmD	None	Jeffrey F. Patton, MD	None
Felicia Gelsey, MS	None	John M. Valgus, PharmD	None
		Thomas A. Marsland, MD	None
		Keith A. Thompson, MD	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---		B
Thomas McNeil Beck, MD	Evidence is inconclusive	Class III - Not Recommended	Evidence conflicting.	N/A
Jeffrey F. Patton, MD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	None	N/A
John M. Valgus, PharmD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	One study demonstrated significant difference vs placebo while another only demonstrated a trend towards benefit. Non-oncology studies also demonstrate benefit.	N/A
Thomas A. Marsland, MD	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	2 trials relatively small not comparable one just ER. One ER	N/A
Keith A. Thompson, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	None	N/A