TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Cisplatin

INDICATION: Triple negative breast cancer

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, 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)]

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EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Fan,Y., et al: Docetaxel-cisplatin might be superior to docetaxel-capecitabine in the first-line treatment of metastatic triple-negative breast cancer. Annals of Oncology 2013; Vol 24, Issue 5; pp. 1219-1225	Study methodology comments: This was a prospective, open-label, randomized phase II clinical trial. Overall, this study was at low risk for most of the key risk of bias criteria which included lack of blinding (for objective outcome only), 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. There may be high risk of bias for the more subjective outcome of tumor response.	S
Frasci,G., et al: Preoperative weekly cisplatin-epirubicin-paclitaxel with G-CSF support in triple-negative large operable breast cancer. Ann Oncol Jul 2009; Vol 20, Issue 7; pp. 1185-1192.	Study methodology comments: This was an open-label, single-arm phase II clinical trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for objective outcomes. All subjects were included in the analyses. The results should be interpreted with caution since the study lacked a control group.	S
Torrisi,R., et al: Tailored preoperative treatment of locally advanced triple negative (hormone receptor negative and HER2 negative) breast cancer with epirubicin, cisplatin, and infusional fluorouracil followed by weekly paclitaxel. Cancer Chemotherapy and Pharmacology 2008; Vol 62, Issue 4; pp. 667-672.	Study methodology comments: This was an open-label, single-arm phase II clinical trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for outcomes. All but one subject were included in the analyses. The results should be interpreted with caution since the study lacked a control group.	S
Silver,D.P., et al: Efficacy of neoadjuvant cisplatin in triple-negative breast cancer. Journal of Clinical Oncology Mar 01, 2010; Vol 28, Issue 7; pp. 1145-1153.	Study methodology comments: This was an open-label, single-arm phase II clinical trial. There was low risk of bias associated with selection of cohorts and assessment of outcomes. Data was gathered prospectively for outcomes. All but one subject were included in the analyses. The results should be interpreted with caution since the study lacked a control group.	S

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Baselga,J., Gomez,P., Greil,R., et al: Randomized phase II study of the anti-epidermal growth factor receptor monoclonal antibody cetuximab with cisplatin versus cisplatin alone in patients with metastatic triple-negative breast cancer. J Clin Oncol Jul 10, 2013; Vol 31, Issue 20; pp. 2586-2592		1
Hurley,J., et al: The use of neoadjuvant platinum-based chemotherapy in locally advanced breast cancer that is triple negative: Retrospective analysis of 144 patients. Breast Cancer Research and Treatment 2013; Vol 138, Issue 3; pp. 783-794.		3
Halim,A. and Wahba,H.: Cisplatin-ifosfamide combination chemotherapy in metastatic triple-negative, anthracycline- and taxane-pretreated breast cancer patients; a Phase II study. Journal of B.U.ON. Apr 2012; Vol 17, Issue 2; pp. 254-258.		1
Koshy,N., et al: Cisplatin-gemcitabine therapy in metastatic breast cancer: Improved outcome in triple negative breast cancer patients compared to non-triple negative patients. Breast Jun 2010; Vol 19, Issue 3; pp. 246-248.		3
Ozkan,M., et al: Gemcitabine and cisplatin combination chemotherapy in triple negative metastatic breast cancer previously treated with a taxane/anthracycline chemotherapy; Multicenter experience. Neoplasma 2012; Vol 59, Issue 1; pp. 38-42.		3

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Tariq,K., Rana,F., Samiian,L., et al: Efficacy of neoadjuvant cisplatin and oral capecitabine in triple-negative breast cancers: A pilot study. Clinical Advances in Hematology and Oncology 2013; Vol 11, Issue 5; pp. 291-295.		1
Goel,A.K., Nandy,M., and Sharma,G.: Cisplatin as neoadjuvant chemotherapy in triple negative breast cancer: Exciting early results. Indian Journal of Medical and Paediatric Oncology Jul 2010; Vol 31, Issue 3; pp. 122-124.		4
Isakoff,S.J., et al: TBCRC009: A multicenter phase II study of cisplatin or carboplatin for metastatic triple-negative breast cancer and evaluation of p63/p73 as a biomarker of response. Journal of Clinical Oncology 2011; Vol 29, Issue 15 SUPPL. 1	Abstract	3
Alvarado,M et al: Phase II open, single-arm trial: Cisplatin combined with paclitaxel and doxorubicin in operable or locally advanced triple-negative breast cancer. Journal of Clinical Oncology 2011; Vol 29, Issue 15 SUPPL. 1	Abstract	3
Wang,Z., et al: Highly effective of gemcitabine and cisplatin (GP) as first-line combination therapy in patients with triple-negative metastatic breast cancer: Final report of a phase II trial. Cancer Research Dec 15, 2011; Vol 71, Issue 24 SUPPL. 3	Abstract	3

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az-Correa,E., Singh,C., and Pereira,R.: Neoadjuvant chemotherapy (NAC) consisting in dose-dense doxorubicin plus cyclophosphamide followed by cisplatin plus taxane for locoregional advanced triple-negative breast cancer (LATNBC). Journal of Clinical Oncology 2011; Vol 29, Issue 15 SUPPL. 1	Abstract	3

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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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	Thomas McNeil Beck, MD	None
Felicia Gelsey, MS	None	Thomas A. Marsland, MD	None
		Jeffrey A. Bubis, DO	Dendreon: Other payments
		Keith A. Thompson, MD	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 does favor efficacy in triple negative breast cancer. However, studies are single ARM Phase ll without control ARMS limiting a more broad general recommendation.	N/A
Thomas McNeil Beck, MD	Evidence favors efficacy	Class IIa - Recommended, In Most Cases	Evidence of benefit is strong in non-controlled studies.	N/A
Thomas A. Marsland, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Although not level l evidence, several Phase ll and other studies suggest significant activity in triple negative breast cancer. This is supported also by my own personal experience with platinum in TNBC over the years.	N/A
Jeffrey A. Bubis, DO	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Larger trials are needed in both the neoadjuvant and metastatic settings, but in general, the use of this agent is reasonable. Consideration of potential toxicity of the agent needs to be given lacking larger data sets.	N/A

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Keith A. Thompson, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	None	N/A

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