TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Cisplatin

INDICATION: Malignant tumor of thyroid gland, Advanced, in combination with doxorubicin

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, 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
Shimaoka K., et al: A randomized trial of doxorubicin versus doxorubicin plus cisplatin in patients with advanced thyroid carcinoma. Cancer Nov 01, 1985; Vol 56, Issue 9; pp. 2155-2160.	Study methodology comments: This was a randomized, open-label, multicenter, comparative trial that should be interpreted with caution. A major caveat of the study was the absence of a power analysis. As a result, the statistically nonsignificant findings should be interpreted with caution. Additional weaknesses included 1) open-label design without the use of independent reviewers; 2) did not present 95% confidence intervals; 3) possible selection bias since subjects were not recruited randomly or in a consecutive manner; and 4) provided only a partial explanation of method of randomization. Strengths included 1) confirmed diagnosis; 2) had inclusion and exclusion criteria; 3) defined response; and 4) controlled for the effect of confounding factors on outcomes.	S
De,Besi P., et al: Combined chemotherapy with bleomycin, adriamycin, and platinum in advanced thyroid cancer. J Endocrinol Invest Jun 1991; Vol 14, Issue 6; pp. 475-480.	Study methodology comments: This was an open-label time-series trial that should be interpreted with caution. A major weakness of the study was the absence of a control group. Additional weaknesses included 1) open-label design without the use of independent reviewers; 2) absence of a power analysis; and 3) did not present 95% confidence intervals. Strengths included 1) confirmed diagnosis; 2) had inclusion and exclusion criteria; 3) defined response; 4) reduced selection bias by recruiting consecutively presenting patients; 5) all histologic sections were reviewed by one pathologist; 6) controlled for the effect of some potential confounding factors; and 7) the use of a within-subject design to control for confounding effects of patient characteristics.	1
Williams SD., Birch R., and Einhorn L.H.: Phase II evaluation of doxorubicin plus cisplatin in advanced thyroid cancer: a Southeastern Cancer Study Group Trial. Cancer Treat Rep Mar 1986; Vol 70, Issue 3; pp. 405-407	Study methodology comments: This was an open-label time-series trial that should be interpreted with caution. A major weakness of the study was the absence of a control group. Additional weaknesses included 1) open-label design without the use of independent reviewers; 2) absence of a power analysis; 3) possible selection bias since subjects were not recruited randomly or in a consecutive manner; and 4) did not examine the effect of potential confounding factors on outcomes. Strengths included 1) confirmed diagnosis; 2) had inclusion and exclusion criteria; 3) defined response; 4) presented 95% confidence intervals; and 5) the use of a within-subject design to control for confounding effects of patient characteristics.	S

De,Crevoisier R., et al: Combined treatment of anaplastic thyroid carcinoma with surgery, chemotherapy, and hyperfractionated accelerated external radiotherapy. Int J Radiat Oncol Biol Phys Nov 15, 2004; Vol 60, Issue 4; pp. 1137-1143.	Study methodology comments: This was an open-label time-series trial that should be interpreted with caution. A major weakness of the study was the absence of a control group. Additional weaknesses included 1) open-label design without the use of independent reviewers; 2) absence of a power analysis; and 3) no inclusion or exclusion criteria. Strengths included 1) confirmed diagnosis; 2) defined response; 3) reduced selection bias by recruiting consecutively presenting patients; 4) used a single pathologist to review histologic slides; 5) controlled for the effect of potential confounding factors on outcomes; 6) presented 95% confidence intervals; and 7) the use of a within-subject design to control for confounding effects of patient characteristics.	S
Busnardo B., et al: A multimodality therapeutic approach in anaplastic thyroid carcinoma: study on 39 patients. J Endocrinol Invest Dec 2000; Vol 23, Issue 11; pp. 755-761.	Study methodology comments: This was a case series study that should be interpreted with much caution. Weaknesses included 1) open-label design without the use of independent reviewers; 2) did not examine the effect of potential confounding factors on outcomes; 3) no inclusion or exclusion criteria; and 4) no controls. Strengths included 1) confirmed diagnosis; 2) defined response; and 3) reduced selection bias since subjects were recruited in a consecutive manner.	3
Intensive chemotherapy for anaplastic thyroid carcinoma: combination of cisplatin, doxorubicin, etoposide and peplomycin with granulocyte granulocyte colony-stimulating factor support. Chemotherapy Committee, The Japanese Society of Thyroid Surgery. Japanese Journal of Clinical Oncology Oct 1995; Vol 25, Issue 5; pp. 203-207.	Study methodology comments: This was an open-label time-series trial that should be interpreted with much caution. A major weakness of the study was the absence of a control group which would have controlled for many potential confounds. Additional weaknesses included 1) open-label design without the use of independent reviewers; 2) did not examine the effect of potential confounding factors on outcomes; 3) no exclusion criteria; 4) absence of a power analysis; 5) did not present 95% confidence intervals; and 6) possible selection bias since subjects were not recruited in a random or consecutive manner. Strengths included 1) had inclusion criteria; 2) defined response; and 3) the use of a within-subject design to control for confounding effects of patient characteristics.	1
Vrbic S., et al: Therapy of stage IV B anaplastic thyroid carcinoma: single institution experience. J BUON. Jan 2009; Vol 14, Issue 1; pp. 41-44.	Study methodology comments: This was a cohort study that should be interpreted with caution. Weaknesses included 1) open-label design without the use of independent reviewers; 2) did not examine the effect of potential confounding factors on outcomes; 3) no inclusion or exclusion criteria; 4) no controls; 5) absence of a power analysis; and 6) possible selection bias since subjects were not recruited in a random or consecutive manner. Strengths included 1) confirmed diagnosis; 2) defined response; 3) defined primary endpoint; and 4) presented 95% confidence intervals.	S
Kanaseki T., et al: A case of anaplastic thyroid carcinoma surviving disease free for over 2 years. Auris, Nasus, Larynx Apr 1999; Vol 26, Issue 2; pp. 217-220.		3

Basu S.: Combination of Cisplatin, Bleomycin and 5 Fluorouracil in a case of advanced primary squamous cell carcinoma of the thyroid grand. Journal of Experimental and Clinical Cancer Research Dec 01, 1995; Vol 14, Issue 4; pp. 363-364.		3
Muggia F, et al: Phase I study of amifostine (A) as a cytoprotector of the gemcitabine/cisplatin (GP) combination. European Journal of Cancer Oct 2001; Vol 37, Issue Supplement 6; p. S71.		3
Chou T, et al. ETOPOSIDE AND CISPLATIN (EP) COMBINATION CHEMOTHERAPY FOR ANAPLASTIC THYROID CARCINOMA (RETROSPECTIVE STUDY). 1998 ASCO abstract.		3
Rovere,R.K.: Treatment of recurrent thyroid cancers - Is there a light in the horizon?. Current Opinion in Oncology May 01, 2008; Vol 20, Issue 3; pp. 245-248.		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
Amy Hemstreet, PharmD	None	Keith A. Thompson, MD	None
Stacy LaClaire, PharmD	None	James E. Liebmann, MD	None
Felicia Gelsey, MS	None	Susan Goodin, PharmD	None
		Thomas McNeil Beck, MD	None
		Edward P. Balaban, DO	None

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---	---	None	B
Keith A. Thompson, MD	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	None	N/A
James E. Liebmann, MD	Evidence Is Inconclusive	Class IIb: Recommended In Some Cases	The articles included in this packet, as well as other studies not included, show modest activity for Cisplatin (at best) in thyroid cancer. The honest truth, of course, is that there is no truly effective chemotherapy for metastatic thyroid cancer. However, platinum has some activity and can be considered in what are usually desperate cases.	N/A
Susan Goodin, PharmD	Evidence Favors Efficacy	Class IIb: Recommended, In Some Cases	None	N/A
Thomas McNeil Beck, MD	Evidence is Inconclusive	Class IIb: Recommended, In Some Cases	Small studies; no control; insignificant benefit;	N/A
Edward P. Balaban, DO	Evidence is Inconclusive	Class III: Not Recommended	Can't be recommended until there is more data. Very toxic!	N/A