TRUVEN HEALTH ANALYTICS™

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: March 28, 2016

PACKET: 1279

DRUG: Docetaxel

USE: Hormone sensitive prostate cancer, Metastatic, in combination with androgen-deprivation 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: 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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	STUDY-SPECIFIC COMMENTS	LITERATURE CODE
Tucci M et al. Addition of Docetaxel to Androgen Deprivation Therapy for Patients with Hormone-sensitive Metastatic Prostate Cancer: A Systematic Review and Meta-analysis. Eur Urol. 2015 Sep 25. pii: S0302-2838(15)00907-0.	This was a systematic review. This systematic review conducted a comprehensive literature search and provided information on eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used. Assessment of the methodological quality of the studies was limited to evaluating the randomization process. According to the authors, the quality of randomization process was judged adequate in all three trials.	S
Vale,C.L., Burdett,S., Rydzewska,L.H.M., et al: Addition of docetaxel or bisphosphonates to standard of care in men with localised or metastatic, hormone-sensitive prostate cancer: A systematic review and meta-analyses of aggregate data. The Lancet Oncology 2015	This was a systematic review. The risk of bias tool was used to assess the quality of the included trials. According to the authors, the overall risks of bias were low for all the studies. This systematic review conducted a comprehensive literature search and provided information on eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used.	2
Abdel-Rahman,O.: Combined Chemohormonal Strategy in Hormone-Sensitive Prostate Cancer: A Pooled Analysis of Randomized Studies. Clinical Genitourinary Cancer 2015	This was a systematic review. This systematic review conducted a comprehensive literature search and provided information on eligibility criteria, study characteristics, and heterogeneity. The appropriate statistical tests were used. The authors did not discuss the methodological quality of the studies.	2
Parker,C., Gillessen,S., Heidenreich,A., et al: Cancer of the prostate: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Sep 2015; Vol 26 Suppl 5, pp. v69-v77.		S

James,N.D., Sydes,M.R., Clarke,N.W., et al: Addition of docetaxel, zoledronic acid, or both to first-line long-term hormone therapy in prostate cancer (STAMPEDE): survival results from an adaptive, multiarm, multistage, platform randomised controlled trial. Lancet Dec 21, 2015		S
James,N.D., Spears,M.R., Clarke,N.W., et al: Survival with newly diagnosed metastatic prostate cancer in the docetaxel era: Data from 917 patients in the control arm of the STAMPEDE Trial (MRC PR08, CRUK/06/019). European Urology Jun 01, 2015; Vol 67, Issue 6; pp. 1028-1038.		1
Sweeney,C.J., Chen,Y.H., Carducci,M., et al: Chemohormonal therapy in metastatic hormone-sensitive prostate cancer. New England journal of medicine Aug 20, 2015; Vol 373, Issue 8; pp. 737-746.		S
Gravis,G., Fizazi,K., Joly,F., et al: Androgen-deprivation therapy alone or with docetaxel in non-castrate metastatic prostate cancer (GETUG-AFU 15): a randomised, open-label, phase 3 trial. Lancet Oncol Feb 2013; Vol 14, Issue 2; pp. 149-158.		S

Sweeney,C.J.: ECOG: CHAARTED--ChemoHormonal therapy versus androgen ablation randomized trial for extensive disease in prostate cancer. Clin Adv Hematol Oncol Aug 2006; Vol 4, Issue 8; pp. 588-590.		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 I: Recommended		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, In Most Cases	It appears that adding docetaxel to androgen-deprivation therapy results in a significant overall survival benefit when compared to treatment without docetaxel. Some factors need to be considered: Pts must be fit, and have a high tumor burden. Six cycles are needed for optimum response. The incidence of adverse effects, most notably neutropenia can affect quality of life and need to be managed in a timely manner (g-csf treatment). Docetaxel can have a synergistic effect when added, and can quite possibly help with androgen-deprivation therapy resistance.	N/A
Richard LoCicero	Effective	Class I: Recommended	Large randomized clinical trials have established a survival advantage of the addition of Taxotere to androgen-deprivation therapy in metastatic hormone-sensitive prostate cancer.	N/A
John D Roberts	Effective	Class I: Recommended	Two of three randomized trials and a literature based meta-analysis show a statistically and clinically significant survival advantage to the addition of docetaxel to androgen deprivation therapy in men with metastatic (image(s) positive) disease. This recommendation is for fit men (Karnofsky PS 70 or higher; ECOG PS 0-1) of any age. Concurrent daily prednisone or similar is not recommended. In these trials many patients were treated with concurrent myeloid growth factor, but the data necessary to make a recommendation for or against this practice largely were not collected.	N/A