TRUVEN HEALTH ANALYTICS™
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COMPENDIA TRANSPARENCY TRACKING FORM

DATE: 4/26/17

PACKET: 1436

DRUG: Sunitinib Malate

USE: Renal cell carcinoma, high-risk, adjuvant 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, E, R, 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
Haas, NB et al. Adjuvant sunitinib or sorafenib for high-risk, non-metastatic renal-cell carcinoma (ECOG-ACRIN E2805): a double-blind, placebo-controlled, randomised, phase 3 trial. Lancet 2016; 387: 2008–16	Comments: This was an international, randomized, double-blind, phase 3 trial that included 226 sites. On Oct 16, 2014, the committee concluded that further blinded follow-up was highly unlikely to alter the evidence, and recommended that the study results be released. By this time, all patients had completed treatment. Follow-up for survival continued at time of publication. 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
A. Ravaud et al. Adjuvant Sunitinib in High-Risk Renal-Cell Carcinoma after Nephrectomy. N Engl J Med 2016;375:2246-54.	Comments: This was an international, randomized, double-blind, phase 3 trial that included 99 centers in 21 countries. Since there was a lower-than-expected rate of disease-free survival during the trial, the protocol was amended to specify that the final analysis would occur approximately 5 years after the last patient underwent randomization. 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 allocation concealment was unclear and not discussed in the paper.	S
Bex A et al. Updated European Association of Urology Guidelines Regarding Adjuvant Therapy for Renal Cell Carcinoma. Eur Urol. 2017 May;71(5):719-722.		S
Gyawali B and Ando Y. Adjuvant Sunitinib for high-risk resected renal cell carcinoma: a meta-analysis of ASSURE and S-TRAC trials. Ann Oncol. 2016 Dec 19.		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		
		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	Ineffective	Class lll: Not Recommended		B
John D Roberts	Ineffective	Class lll: Not Recommended	In two randomized trials adjuvant therapy with sunitinib following resection of renal cell carcinoma resulted in no improvement in overall survival and significant toxicity. Results with regard to disease free survival were discordant.	N/A
Jeffrey Klein	Ineffective	Class lll: Not Recommended	The use of sunitinib in post nephrectomy patients did not significantly show any disease free survival benefit. In addition the adverse effects from the product warranted dose reductions and discontinuation on a very wide scale.	N/A

Richard LoCicero	Ineffective	Class lll: Not Recommended	Two double-blind randomized clinical trials have evaluated the role for sunitinib as an adjuvant therapy for high-risk renal cell carcinoma after nephrectomy. Neither demonstrated an improved in overall survival. One showed improvement in progression free survival (PFS); one did not. Treatment was associated with toxicity including skin toxicity, HTN, fatigue and a lower QOL score compared to placebo.	N/A