TRUVEN HEALTH ANALYTICS

COMPENDIA TRANSPARENCY TRACKING FORM

DRUG: Nilotinib

INDICATION: Gastrointestinal stromal tumors, advanced, resistant to or intolerant of imatinib and sunitinib

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, R, 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
Reichardt,P., et al: Phase III study of nilotinib versus best supportive care with or without a TKI in patients with gastrointestinal stromal tumors resistant to or intolerant of imatinib and sunitinib. Annals of Oncology 2012; Vol 23, Issue 7; pp. 1680-1687.	Study methodology comments: This was an open-label randomized trial. 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.	
Montemurro,M., et al: Nilotinib in the treatment of advanced gastrointestinal stromal tumours resistant to both imatinib and sunitinib. European Journal of Cancer Sep 2009; Vol 45, Issue 13; pp. 2293-2297.		3
Kim,K.-P., et al: Nilotinib in patients with GIST who failed imatinib and sunitinib: Importance of prior surgery on drug bioavailability. Cancer Chemotherapy and Pharmacology 2011; Vol 68, Issue 2; pp. 285-291.		3
Cauchi,C., et al: Evaluation of nilotinib in advanced GIST previously treated with imatinib and sunitinib. Cancer Chemotherapy and Pharmacology 2012; Vol 69, Issue 4; pp. 977-982		3
Sawaki,A., et al: Phase 2 study of nilotinib as third-line therapy for patients with gastrointestinal stromal tumor. Cancer Oct 15, 2011; Vol 117, Issue 20; pp. 4633-4641.		3

Bamboat,Z.M. and DeMatteo,R.P.: Updates on the Management of Gastrointestinal Stromal Tumors. Surgical Oncology Clinics of North America 2012; Vol 21, Issue 2; pp. 301-316.		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
Margi Schiefelbein, PA	None	Edward P. Balaban, DO	None
Stacy LaClaire, PharmD	None	Jeffrey F. Patton, MD	None
Felicia Gelsey, MS	None	John M. Valgus, PharmD	None
		Thomas McNeil Beck, MD	None
		Jeffrey A. Bubis, DO	Other payments: Dendreon

ASSIGNMENT OF RATINGS:

*to meet requirement 4

	EFFICACY	STRENGTH OF RECOMMENDATION	COMMENTS	STRENGTH OF EVIDENCE
MICROMEDEX	---			B
Edward P. Balaban, DO	Evidence is inconclusive	Class IIb - Recommended, In Some Cases	It is intriguing, however data and statistical analysis is somewhat confounding. Would agree with authors of proposed manuscript that “further evaluation of nilotinib in a well-defined population of patients is warranted.”	N/A
Jeffrey F. Patton, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Post-hoc analysis suggests efficacy but needs prospective validation.	N/A
John M. Valgus, PharmD	Ineffective	Class III - Not Recommended	This trial confirms prior data that nilotinib does not appear effective in this setting. Primary outcomes not reached and surrogate endpoints not validated.	N/A
Thomas McNeil Beck, MD	Evidence favors efficacy	Class IIb - Recommended, In Some Cases	Effective for a small group of patients	N/A
Jeffrey A. Bubis, DO	Effective	Class I - Recommended	Overall survival benefit.	N/A