

COMPENDIA TRANSPARENCY TRACKING FORM

DATE: February 21, 2024

OFF-LABEL ID #: 1349

DRUG NAME: Sunitinib Malate

OFF-LABEL USE: Malignant tumor of thyroid gland Locally advanced or metastatic, progressive, refractory to radioactive iodine

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, 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)]

EVIDENCE CONSIDERED:

*to meet requirements 2 and 4

CITATION	LITERATURE CODE
Ravaud, A, dela Fouchardiere, C, Caron, P, et al: A multicenter phase II study of sunitinib in patients with locally advanced or metastatic differentiated, anaplastic or medullary thyroid carcinomas: mature data from the THYSU study. Eur J Cancer May 2017; Vol 76, pp. 110-117. Pubmed ID: 28301826	S
Carr, LL, Mankoff, DA, Goulart, BH, et al: Phase II study of daily sunitinib in FDG-PET-positive, iodine-refractory differentiated thyroid cancer and metastatic medullary carcinoma of the thyroid with functional imaging correlation. Clin Cancer Res Nov 01, 2010; Vol 16, Issue 21; pp. 5260-5268. Pubmed ID: 20847059	S
Bikas, A, Kundra, P, Desale, S, et al: Phase 2 clinical trial of sunitinib as adjunctive treatment in patients with advanced differentiated thyroid cancer. Eur J Endocrinol Mar 2016; Vol 174, Issue 3; pp. 373-380. Pubmed ID: 26671977	2
Atallah, V, Hocquet, A, Do Cao, C, et al: Activity and safety of sunitinib in patients with advanced radioiodine refractory thyroid carcinoma: a retrospective analysis of 57 patients. Thyroid Aug 2016; Vol 26, Issue 8; pp. 1085-1092. Pubmed ID: 27370404	S
Ravaud, A, de la Fouchardiere, C, Asselineau, J, et al: Efficacy of sunitinib in advanced medullary thyroid carcinoma: intermediate results of phase II THYSU. Oncologist 2010; Vol 15, Issue 2; pp. 212-214. Pubmed ID: 20189981	4
Sousa Santos, F, Joana Santos, R, and Leite, V: Sorafenib and sunitinib for the treatment of metastatic thyroid cancer of follicular origin: a 7-year single-centre experience. Eur Thyroid J Oct 2019; Vol 8, Issue 5; pp. 262-267. Pubmed ID: 31768337	2
Su, Jingyang, Lu, J, Zhang, J, et al: A meta-analysis of the efficacy and toxicity of tyrosine kinase inhibitors in treating patients with different types of thyroid cancer: how to choose drugs appropriately. Curr Opin Oncol Mar 01, 2023; Vol 35, Issue 2; pp. 132-144. Pubmed ID: 36721897	1
Filetti, S, Durante, C, Hartl, D, et al: Thyroid cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Dec 01, 2019; Vol 30, Issue 12; pp. 1856-1883. Pubmed ID: 31549998	4
Haugen, BR, Alexander, EK, Bible, KC, et al: 2015 American Thyroid Association Management Guidelines for Adult Patients with Thyroid Nodules and Differentiated Thyroid Cancer: The American Thyroid Association Guidelines Task Force on Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid Jan 2016; Vol 26, Issue 1; pp. 1-133. Pubmed ID: 26462967	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
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
MERATIVE MICROMEDEX	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	The use of Sunitinib in patients with malignant tumors of the thyroid gland in these small studies, showed decent overall survival and favorable progression free survival. The high degree of neutropenia and other adverse effects needs to be considered before therapy begins.	
Todd Gersten	Effective	Class I: Recommended	Across several trials of varying design, Sunitinib has demonstrated clinically important improvements in efficacy and survivorship endpoints in a disease with limited therapeutic options.	
Warren Brenner	Evidence is Inconclusive	Class III: Not Recommended	I think similar to pazopanib this agent has activity based on this data but i do not believe it would change standard of care with either lenvatinib or sorafenib. The lenvatinib trial data is a larger study and PFS and RR higher than this agent therefore do not believe we need another "me to drug" in this space	

