COMPENDIA TRANSPARENCY TRACKING FORM

DATE: July 2, 2024

OFF-LABEL ID #: 2734

DRUG NAME: Sunitinib Malate

OFF-LABEL USE: Paraganglioma Metastatic, progressive

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 *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
Baudin, E, Goichot, B, Berruti, A, et al: Sunitinib for metastatic progressive phaeochromocytomas and paragangliomas: results from FIRSTMAPPP, an academic, multicentre, international, randomised, placebo-controlled, double-blind, phase 2 trial. Lancet Mar 16, 2024; Vol 403, Issue 10431; pp. 1061-1070. Pubmed ID: 38402886	S
Taieb, D, Nolting, S, Perrier, ND, et al: Management of phaeochromocytoma and paraganglioma in patients with germline SDHB pathogenic variants: an international expert Consensus statement. Nat Rev Endocrinol Mar 2024; Vol 20, Issue 3; pp. 168-184. Pubmed ID: 38097671	S
Garcia-Carbonero, R, Matute Teresa, F, Mercader-Cidoncha, E, et al: Multidisciplinary practice guidelines for the diagnosis, genetic counseling and treatment of pheochromocytomas and paragangliomas. Clin Transl Oncol Oct 2021; Vol 23, Issue 10; pp. 1995-2019. Pubmed ID: 33959901	2
Fassnacht, M, Assie, G, Baudin, E, et al: Adrenocortical carcinomas and malignant phaeochromocytomas: ESMO-EURACAN Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol Nov 2020; Vol 31, Issue 11; pp. 1476-1490. Pubmed ID: 32861807	2

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 IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Sunitinib in previously treated metastatic paraganglioma patients, showed a higher degree of progression free survival over placebo in 12 months. The true benefit might be seen with patients who have a specific biomarker present. The degree of asthenia with sunitinib need to be considered.	
Todd Gersten	Evidence Favors Efficacy	Class IIb: Recommended, in Some Cases	Sunitinib has demonstrated disease responsiveness and control, with a trend towards improving overall survivorship, versus placebo. This remains an option for patients who are unable to receive other treatments including chemotherapy and/or radioligand therapy.	

Warren Brenner	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	feasibility of a randomized phase II trial in an ultra rare malignancy and as expected took a long time of 7 years to accrue less than 100 patients. However having said that the groups seem well balanced and I think the use of a placebo arm was appropriate as there are no standard of care therapies in this disease. Although there was no survival differences possibly due at least partially to cross over effect there was improvement ins PFS and RR although QOL scores were equivalent at 12 months. The PFS benefit and improvement in pain scores is clinically useful albeit many patients had side effects with sunitinib requiring dose modification with this agent which is expected. I assigned an efficacy rating favoring efficacy and class 2a recommendation due to the other options that have come to light since this study was conducted that may offer patients alternative treatment options, the lack of OS difference and no difference in QOL scores despite improvement in RR and PFS. It also difficult to determine efficacy difference between paraganglioma and phaeochromocytoma (no data or forest plots available for review to differentiate between the 2 types of cancer)	