COMPENDIA TRANSPARENCY TRACKING FORM

DATE: July 2, 2024

OFF-LABEL ID #: 2697

DRUG NAME: Sunitinib Malate

OFF-LABEL USE: Pheochromocytoma 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 pheochromocytoma patients, showed a favorable degree of progression free survival over placebo in a 12 month period. The true benefit might be seen with patients who have a specific biomarker present. The degree of asthenia with sunitinib needs 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	This was a well conducted phase II randomized trial in a ultra rare malignancy for which there are no standard therapeutic options outside of nuclear therapy and some cytotoxic chemotherapy. The study was well balanced between the active study group and the placebo group including good balance between prior therapies, germline SFHB mutations and metastatic sites of disease. Study appeared effective in pheochromocytoma with improved RR and PFS. I rated is aas favors efficacy and gave a class IIA recommendation. The reason for this includes the positives as listed above but negatives which led to class IIA rather than class I is the number of patients(78 - understandable in a rare cancer), prolonged time to recruit, no improvement in OS(understanding cross over effect) and side effects of study and QOL were the same at 12 months(not improved in study group despite improved pFS and RR). I also gave a class IIA recommendation due to the other rx options that have become available since the study started recruitment.	