COMPENDIA TRANSPARENCY TRACKING FORM

DATE: February 20, 2024

OFF-LABEL ID #: 2646

DRUG NAME: Pazopanib Hydrochloride

OFF-LABEL USE: Malignant tumor of thyroid gland Differentiated, 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
Bible, KC, Menefee, ME, Lin, C-C, et al: An International Phase 2 Study of Pazopanib in Progressive and Metastatic Thyroglobulin Antibody Negative Radioactive Iodine Refractory Differentiated Thyroid Cancer. Thyroid Sep 2020; Vol 30, Issue 9; pp. 1254-1262. Pubmed ID: 32538690	S
Bible,K.C., Suman,V.J., Molina,J.R., et al: Efficacy of pazopanib in progressive, radioiodine-refractory, metastatic differentiated thyroid cancers: Results of a phase 2 consortium study. The Lancet Oncology Oct 2010; Vol 11, Issue 10; pp. 962-972. Pubmed ID: 20851682	2
de la Fouchardiere, C, Godbert, Y, Dalban, C, et al: Intermittent versus continuous administration of pazopanib in progressive radioiodine refractory thyroid carcinoma: Final results of the randomised, multicenter, open-label phase II trial PAZOTHYR. Eur J Cancer Nov 2021; Vol 157, pp. 153-164. Pubmed ID: 34509954	2
Sherman, EJ, Harris, J, Bible, KC, et al: Radiotherapy and paclitaxel plus pazopanib or placebo in anaplastic thyroid cancer (NRG/RTOG 0912): a randomised, double-blind, placebo-controlled, multicentre, phase 2 trial. Lancet Oncol Feb 2023; Vol 24, Issue 2; pp. 175-186. Pubmed ID: 36681089	1
Bible, KC, Kebebew, E, Brierley, J, et al: 2021 American Thyroid Association Guidelines for Management of Patients with Anaplastic Thyroid Cancer. Thyroid Mar 2021; Vol 31, Issue 3; pp. 337-386. Pubmed ID: 33728999	4
Bible, KC, Kebebew, E, Brierley, J, et al: Correction to: 2021 American Thyroid Association Guidelines for Management of Patients with Anaplastic Thyroid Cancer: American Thyroid Association Anaplastic Thyroid Cancer Guidelines Task Force by Bible et al. Thyroid 2021;31(3):337-386; DOI: 10.1089/thy.2020.0944. Thyroid Oct 2021; Vol 31, Issue 10; pp. 1606-1607. Pubmed ID: 34694915	4
Boucher, A, Ezzat, S, Hotte, S, et al: Canadian consensus statement on the management of radioactive iodine-resistant differentiated thyroid cancer. Oral Oncol Oct 2021; Vol 121, p. 105477.	4
Fugazzola, L, Elisei, R, Fuhrer, D, et al: 2019 European Thyroid Association Guidelines for the Treatment and Follow-Up of Advanced Radioiodine-Refractory Thyroid Cancer. Eur Thyroid J Oct 2019; Vol 8, Issue 5; pp. 227-245. Pubmed ID: 31768334	4
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
Hamidi, S, Hofmann, M-C, Iyer, PC, et al: Review article: new treatments for advanced differentiated thyroid cancers and potential mechanisms of drug resistance. Front Endocrinol (Lausanne) Jun 26, 2023; Vol 14, p. 1176731. Pubmed ID: 37435488	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 IIa: Recommended, in Most Cases		B
Jeffrey Klein	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	The use of Pazopanib in patients with malignant tumors of thyroid gland showed good efficacy in this small study. Patients tested were refractory to radioactive iodine. Good progression free survival, and overall survival was demonstrated.	
Todd Gersten	Evidence Favors Efficacy	Class IIa: Recommended, in Most Cases	Although the evidence/data is limited to a single arm study of just 60 patients, pazopanib demonstrated clinically meaningful improvements in disease control in a population with limited treatment options.	

Warren Brenner	Evidence is Inconclusive	Class III: Not Recommended	In this setting we have FDA approved options particularly with lenvatinib showing efficacy in a phase III randomized clinical trial with what appears to be a more effective agent with better RR ancf PFS understanding the limitations of cross trial comparisons - therefore this small study would not change management options and I do not believe would change our management options - I would not pursue a larger phase III trial given the proven effectiveness of lenvatinib	