Drug Policy:

Votrient™ (pazopanib)

POLICY NUMBER UM ONC_1195	SUBJECT Votrient™ (pazopanib)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
DATES COMMITTEE REVIEWED 01/04/12, 01/08/13, 01/06/14, 06/10/15, 06/28/17, 07/26/17, 07/03/18, 06/12/19, 12/11/19, 06/10/20, 05/12/21, 11/15/21, 05/11/22, 01/11/23, 01/10/24, 01/08/25	APPROVAL DATE January 08, 2025	EFFECTIVE DATE January 31, 2025	COMMITTEE APPROVAL DATES 01/04/12, 01/08/13, 01/06/14, 06/10/15, 06/28/17, 07/26/17, 07/03/18, 06/12/19, 12/11/19, 06/10/20, 05/12/21, 11/15/21, 05/11/22, 01/11/23, 01/10/24, 01/08/25	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Evolent Specialty Services Clinical Guideline Review Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses clinical guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this clinical guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their plan customer service representative for specific coverage information.

I. PURPOSE

To define and describe the accepted indications for Votrient (pazopanib) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The member has not experienced disease progression on the requested medication AND
2. The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
3. Additional medication(s) are not being added to the continuation request.

B. Renal Cell Carcinoma

1. Votrient (pazopanib) may be used in members with recurrent/metastatic renal cell carcinoma for ANY of the following clinical settings:
   a. As a single agent for first line therapy and IMDC Criteria Favorable Risk Disease OR
   b. As a single agent for subsequent line therapy, regardless of IMDC Risk category.

   IMDC criteria: Please see table below (Reference below)

CRITERIA= Assign 1 point for each	**RISK CATEGORIES= RISK SCORE**
Time to systemic treatment less than 1 year from diagnosis	Favorable Risk = 0
Performance Status < 80% Karnofsky Scale	Intermediate Risk = 1-2
Hemoglobin < LLN; <12 g/dL	Poor Risk= 3-6
Calcium > ULN; > 12 mg/dL	
Neutrophils > ULN	
Platelets > ULN	

C. Soft Tissue Sarcoma

1. Palliative therapy for recurrent or metastatic soft tissue sarcoma as a single agent, as subsequent line therapy.

III. EXCLUSION CRITERIA

A. The member has stage I-III RCC, soft tissue sarcoma, or gastrointestinal stromal tumors.

B. Votrient (pazopanib) is being used concurrently with other anticancer therapy.

C. Member has disease progression while taking Votrient (pazopanib).

D. Dosing exceeds single dose limit of Votrient (pazopanib) 800 mg.

E. Do not exceed 120 (200 mg) tablets/month.

F. Investigational use of Votrient (pazopanib) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
   1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
   2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
   3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.

4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. CODING INFORMATION

HCPCS Code	Description
J8999	pazopanib

V. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

VI. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VII. ATTACHMENTS

A. None

VIII. REFERENCES

A. Votrient prescribing information 2024. Novartis Pharmaceuticals Corporation East Hanover, New Jersey

B. Heng DY, Xie W, Regan MM, Warren MA, Golshayan AR, Sahi C, Eigl BJ, Ruether JD, Cheng T, North S, Venner P, Knox JJ, Chi KN, et al. Prognostic factors for overall survival in patients with metastatic renal cell carcinoma treated with vascular endothelial growth factor-targeted agents: results from a large, multicenter study. *J Clin Oncol*. 2009; 27:5794–9. 10.1200/JCO.2008.21.4809.

C. Clinical Pharmacology Elsevier Gold Standard 2025.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2025.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2025.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2025.

G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

H. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.