# Drug Policy:

# Votrient™ (pazopanib)

| POLICY NUMBER<br>UM ONC_1195 | SUBJECT<br>Votrient™ (pazopanib) | | DEPT/PROGRAM<br>UM Dept | PAGE 1 of 3 |
|---|---|---|---|---|
| DATES COMMITTEE REVIEWED<br>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 | APPROVAL DATE<br>January 10, 2024 | EFFECTIVE DATE<br>January 26, 2024 | COMMITTEE APPROVAL DATES<br>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 | |
| PRIMARY BUSINESS OWNER: UM | | COMMITTEE/BOARD APPROVAL<br>Utilization Management Committee | | |
| NCQA STANDARDS<br>UM 2 | | ADDITIONAL AREAS OF IMPACT | | |
| CMS REQUIREMENTS | STATE/FEDERAL REQUIREMENTS | | APPLICABLE LINES OF BUSINESS<br>Commercial, Exchange, Medicaid | |

## 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.
1. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
2. 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.
3. 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).
4. 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.
5. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
6. 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. MEDICATION MANAGEMENT

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

## V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

A. None

## VII. REFERENCES


A. Votrient prescribing information. Novartis Pharmaceuticals Corporation East Hanover, New Jersey 2022.

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 2023.

D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2023.

E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2023.

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.

I. NCQA UM 2023 Standards and Elements.