POLICY NUMBER UM ONC_1195	SUBJECT Votrient™ (pazopanib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
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	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 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	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

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.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand name drugs.
2. **Advanced/Metastatic Renal Cell Carcinoma**
    a. NOTE: The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway for first line advanced/metastatic clear cell renal cell carcinoma, for IMDC Good Risk (Favorable Risk) Disease is Votrient (pazopanib).
    b. IMDC criteria: Please see table 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. NOTE: Votrient (pazopanib) is PREFERRED in subsequent setting for any IMDC risk clear cell RCC per NCH pathway & NCH Policy (if not used in first line).

d. Pazopanib use is supported as a single agent, for first line therapy of recurrent/metastatic renal cell carcinoma (predominantly clear cell histology) **AND** IMDC Criteria Favorable Risk Disease.

e. Pazopanib use is supported as a single agent, for subsequent line therapy for recurrent/metastatic renal cell carcinoma (predominantly clear cell histology) regardless of IMDC Risk Category.

f. Pazopanib use is supported, as a single agent, for first line/subsequent line therapy for metastatic/recurrent renal cell carcinoma of predominantly Non-Clear cell histology.

3. Advanced Soft Tissue Sarcoma

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

III. EXCLUSION CRITERIA

1. The member has stage I-III RCC.
2. Votrient (pazopanib) is being used concurrently with other chemotherapy.
3. Member has disease progression while taking Votrient (pazopanib).
4. Dosing exceeds single dose limit of Votrient (pazopanib) 800 mg.
5. Do not exceed 120 (200 mg) tablets/month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Votrient prescribing information. Novartis Pharmaceuticals Corporation East Hanover, New Jersey 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.

3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.