

Votrient[®] (pazopanib) (Oral)

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Date of Origin: 01/01/2012

Dates Reviewed: 12/2012, 11/2013, 08/2014, 07/2015, 07/2016, 08/2017, 07/2018

I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Votrient 200 mg tablet: 4 tablets per day

B. Max Units (per dose and over time) [Medical Benefit]:

- N/A

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient Age is 18 years and older; **AND**

Renal Cell Carcinoma †

- Must be used as a single agent; **AND**
- Patient has advanced disease †; **OR**
- Patient's disease must be relapsed **OR** surgically unresectable Stage IV; **AND**
 - Must be used as first line or subsequent therapy for clear cell histology; **OR**
 - Used as systemic therapy for non-clear cell histology.

Soft Tissue Sarcoma †

- Angiosarcoma
 - Must be used as a single agent for palliative therapy
- Gastrointestinal stromal tumors (GIST)
 - Patient has progressive disease and is no longer receiving benefit from any of the following: imatinib, sunitinib or regorafenib
- Retroperitoneal/Intra-abdominal

- Must be used as a single agent for palliative therapy; **AND**
- Disease must be unresectable or progressive of non-liposarcomal origin
- Rhabdomyosarcoma
 - Must be used as a single agent for palliative therapy
- Cancer of the extremity/Superficial Trunk, Head/Neck
 - Must be used as a single agent for palliative therapy; **AND**
 - Disease must be recurrent with disseminated metastases or synchronous stage IV of non-liposarcomal origin
- Patient has advanced disease †
 - Patient must have received prior chemotherapy

Uterine Sarcoma ‡

- Must be used as a single agent; **AND**
- Patient has recurrent or metastatic disease that has progressed following prior cytotoxic chemotherapy; **AND**
- Patient's disease is Stage II or later

Thyroid carcinoma ‡

- Medullary Carcinoma; **AND**
 - Patient has recurrent, or persistent distant metastatic disease; **AND**
 - Patient's disease is symptomatic or progressive; **AND**
 - Clinical trials, vandetanib, or cabozantinib are not available or appropriate treatment options; **OR**
 - Disease progressed on vandetanib or cabozantinib
- Follicular, Hürthle cell, or Papillary Cancer; **AND**
 - Disease is progressive and/or symptomatic iodine-refractory; **AND**
 - Clinical trials or other systemic therapies are not available or appropriate; **AND**
 - Patient has unresectable recurrent or persistent locoregional disease; **OR**
 - Patient has distant metastatic disease

Ovarian Cancer (Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer) ‡

- Patient's disease must be persistent disease or recurrent; **AND**
- Patient's disease is platinum-resistant; **AND**
- Must be given in combination with paclitaxel

† FDA-labeled indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: hepatotoxicity (severe changes in liver function tests); cardiac toxicity (QT prolongation, decreased LVEF); hemorrhagic events; arterial thromboembolic events; venous thrombotic events (VTE, PE); thrombotic microangiopathy; gastrointestinal perforation/fistula; severe and repeated proteinuria episodes; interstitial lung disease(ILD)/pneumonitis; reversible posterior leukoencephalopathy syndrome (RPLS); hypertension; impaired wound healing; hypothyroidism; infection, etc.

V. Dosage/Administration

Indication	Dose
All Indications	800mg daily without food (at least 1 hour before or 2 hours after a meal)

VI. Billing Code/Availability Information

HCPCS code:

- C9399: Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)
- J8999: Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

- Votrient 200 mg tablet – 00173-0804-xx

VII. References

1. Votrient [package insert]. Research Triangle Park, NC; GlaxoSmithKline; May 2017. Accessed June 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for pazopanib. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2018.
3. Sternberg CN, Szczylik C, Lee E, et al, “A Randomized, Double-Blind Phase III Study of Pazopanib in Treatment-Naive and Cytokine-Pretreated Patients With Advanced Renal Cell Carcinoma (RCC),” J Clin Oncol, 2009, 27(15s) [abstract 5021 from 2009 ASCO Annual Meeting].

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.A0	Gastrointestinal stromal tumor, unspecified site
C49.A1	Gastrointestinal stromal tumor of esophagus
C49.A2	Gastrointestinal stromal tumor of stomach
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C49.A9	Gastrointestinal stromal tumor of other sites
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen

ICD-10	ICD-10 Description
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C53.0	Malignant neoplasm of endocervix
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis

ICD-10	ICD-10 Description
C65.9	Malignant neoplasm of unspecified renal pelvis
C73	Malignant neoplasm of thyroid gland
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.528	Personal history of other malignant neoplasm of kidney
Z85.43	Personal history of malignant neoplasm of ovary
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC