UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Votrient

Program	Prior Authorization
Medication	Votrient™ (pazopanib)
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

Votrient™ (pazopanib) is a multi-tyrosine kinase inhibitor indicated for the treatment of advanced renal cell carcinoma and advanced soft tissue sarcoma in patients who have received prior chemotherapy. The efficacy of Votrient for the treatment of patients with adipocytic soft tissue sarcoma or gastrointestinal stromal tumors has not been demonstrated.[1] Additionally, the National Cancer Comprehensive Network (NCCN) recommends use of Votrient in treatment of medullary, follicular, Hürthle cell and papillary thyroid carcinomas; ovarian cancer; and uterine sarcoma.[2]

2. Coverage Criteria:

A. Renal Cell Carcinoma (RCC)

1. Initial Authorization

a. **Votrient** will be approved based on **both** of the following criterion:

(1) Diagnosis of renal cell carcinoma (RCC)

-AND-

(2) **One** of the following:

(a) Disease is relapsed

-OR-

(b) **Both** of the following:

i. Medically or surgically unresectable tumor
ii. Diagnosis of Stage IV disease

Authorization will be issued for 12 months.

2. Reauthorization

a. Votrient will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

B. Soft Tissue Sarcoma (STS)

1. Initial Authorization

a. **Votrient** will be approved based on **one** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Angiosarcoma
(b) Pleomorphic rhabdomyosarcoma
(c) Retroperitoneal/Intra-abdominal of nonliposarcomal origin with disease that is unresectable or progressive
(d) Soft Tissue Sarcoma of the Extremity/Superficial Trunk or Head/Neck, of nonliposarcomal origin, with disease that is synchronous stage IV or recurrent and has disseminated metastases

-OR-

(2) **Both** of the following:

(a) Diagnosis of progressive gastrointestinal stromal tumors (GIST)

-AND-

(b) History of failure, contraindication, or intolerance to **one** of the following:

i. Gleevec (imatinib)
ii. Sutent (sunitinib)
iii. Stivarga (regorafenib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

C. Thyroid Carcinoma (off-label)

1. Initial Authorization

a. **Votrient** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of **one** of the following:

i. Follicular carcinoma
ii. Hürthle cell carcinoma
iii. Papillary carcinoma

-AND-

(b) **One** of the following:

i. Unresectable recurrent disease
ii. Persistent locoregional disease
iii. Metastatic disease

-AND-

(c) **One** of the following:

i. Patient has symptomatic disease
ii. Patient has progressive disease

-AND-

(d) Disease is refractory to radioactive iodine treatment

-OR-

(2) **All** of the following:

(a) Diagnosis of medullary carcinoma

-AND-

(b) **One** of the following:

i. Disease is progressive
ii. Disease is symptomatic with distant metastases

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following:

i. Caprelsa (vandetanib)
ii. Cometriq (cabozantinib)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

D. Uterine Sarcoma (off-label)

1. Initial Authorization

a. **Votrient** will be approved based on the following criterion:

(1) Diagnosis of uterine sarcoma

Authorization will be issued for 12 months.

2. Reauthorization

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on

Votrient therapy

Authorization will be issued for 12 months.

E. Ovarian Cancer (off-label)

1. Initial Authorization

a. **Votrient** will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Epithelial Ovarian Cancer
(b) Fallopian Tube Cancer
(c) Primary Peritoneal Cancer

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. Disease is stage II-IV

-AND-

ii. Patient is in complete remission following primary treatment

-OR-

(b) **Both** of the following:

i. **One** of the following:

1. Disease is persistent
2. Disease is recurrent

-AND-

ii. **One** of the following:

1. Used as a single agent

-OR-

2. **Both** of the following:

i. Disease is platinum resistant

-AND-

ii. Used in combination with weekly paclitaxel

Authorization will be issued for 12 months.

2. Reauthorization

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

3. References:

1. Votrient [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 13, 2017.

Program	Prior Authorization –Votrient (pazopanib)
Change Control	
Date	Change
9/2014	New guideline
7/2016	Updated clinical criteria to align with Employer and Individual notification policy and updated policy to new template
7/2017	Annual review with no changes to coverage criteria. Updated references.
11/2017	Updated criteria to align with NCCN recommendation for recurrent or persistent ovarian cancer. Removed criteria for dermatofibrosarcoma protuberans since it is no longer NCCN

	recommended. Updated references.