CVS/caremark

PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**VOTRIENT**
(generic)	**(pazopanib)**
Status: CVS/caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 547-A***

FDA-APPROVED INDICATIONS[1]

Votrient is indicated for the treatment of:

1. Advanced renal cell carcinoma (RCC)
2. Advanced soft tissue sarcoma (STS) in patients who have received prior chemotherapy

COMPENDIAL USES[2]

1. Relapsed or surgically unresectable RCC
2. Uterine sarcoma
3. Soft tissue sarcoma of one of the following subtypes:
   - Gastrointestinal stromal tumors (GIST)
   - Angiosarcoma
   - Pleomorphic rhabdomyosarcoma
   - Retroperitoneal/intra-abdominal sarcoma
   - Extremity/superficial trunk sarcoma
4. Papillary, Hürthle cell, or follicular thyroid carcinoma:
   - Unresectable recurrent or persistent locoregional disease
   - Distant metastatic disease
5. Medullary thyroid carcinoma:
   - Progressive disease
   - Symptomatic distant metastatic disease
6. Metastatic dermatofibrosarcoma protuberans (DFSP)

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of renal cell carcinoma? [If no, skip to question 3.]	Yes	No
2	Is the disease relapsed or unresectable? [No further questions.]	Yes	No
3	Does the patient have a diagnosis of soft tissue sarcoma? [If no, skip to question 6.]	Yes	No
4	Is the diagnosis adipocytic soft tissue sarcoma? [If yes, no further questions.]	Yes	No
5	Is the soft tissue sarcoma subtype ANY of the following: a) gastrointestinal stromal tumor (GIST), b) angiosarcoma, c) pleomorphic rhabdomyosarcoma, d) retroperitoneal/intra-abdominal sarcoma, or e) extremity/superficial trunk sarcoma? [No further questions.]	Yes	No
6	Does the patient have a diagnosis of thyroid carcinoma? [If no, skip to question 11.]	Yes	No
7	Does the disease express any of the following histologies? 1) Follicular, 2) Hurthle cell, or	Yes	No

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	3) Papillary [If no, skip to question 9.]		
8	Is the disease unresectable or metastatic? [No further questions.]	Yes	No
9	Does the disease express medullary histology? [If no, no further questions.]	Yes	No
10	Does the patient have progressive or metastatic disease? [No further questions.]	Yes	No
11	Does the patient have a diagnosis of dermatofibrosarcoma protuberans? [If no, skip to question 13.]	Yes	No
12	Is the disease metastatic? [No further questions.]	Yes	No
13	Does the patient have a diagnosis of uterine sarcoma?	Yes	No

Guidelines for Approval							
Duration of Approval				12 months			
Set 1: RCC		Set 2: STS		Set 3: Follicular, papillary, or Hurthle cell thyroid carcinoma		Set 4: Medullary thyroid carcinoma	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	None	3	1	6	1	6	1
2		5	4	7	3	9	3
				8		10	7

Set 5: DFSP		Set 6: Uterine sarcoma	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
11	1	13	1
12	3		3
	6		6
			11

Internal Use Only – Mapping Instructions		
	Yes	No
1.	Go to 2	Go to 3
2.	Approve, 12 months	Deny
3.	Go to 4	Go to 6
4.	Deny	Go to 5
5.	Approve, 12 months	Deny
6.	Go to 7	Go to 11
7.	Go to 8	Go to 9
8.	Approve, 12 months	Deny
9.	Go to 10	Deny
10.	Approve, 12 months	Deny
11.	Go to 12	Go to 13
12.	Approve, 12 months	Deny

Internal Use Only – Mapping Instructions		
	Yes	**No**
13.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Votrient [package insert]. Research Triangle Park, NC: GlaxoSmithKline; August 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 28, 2016. https://www.nccn.org/professionals/drug_compendium/content/contents.asp.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (AC) 10/2009
Revised:	GY 04/2010, KR 10/2011, KP 09/2012 (CMS); KP 07/2012; LD 06/2013 (CMS); AS 09/2013 (per CMS); AS 10/2013, TS 08/2014 (CMS); TS 06/2014, 08/2015 (CMS); ST 08/2015, 06/2016 (CMS), PK 07/2017 (CMS), 12/2017
Reviewed:	CDPR/WLF 10/2009; KP 05/2010, 08/2011, 05/2012, 08/2012; DNC 07/2013, MCM 08/2014, ADA 08/2015, ME 08/2016, SD 03/2017
External Review:	11/2009; 10/2010, 11/2011, 12/2012, 09/2013, 09/2014, 09/2015, 09/2016