CVS/caremark

PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**NEXAVAR**
(generic)	**(sorafenib)**
Status: CVS/caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 417-A***

FDA-APPROVED INDICATIONS[1]

Nexavar is indicated for the treatment of patients with:

1. Advanced renal cell carcinoma
2. Unresectable hepatocellular carcinoma
3. Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioiodine treatment

COMPENDIAL USES[2]

1. Relapsed or surgically unresectable RCC
2. Osteosarcoma
3. Soft tissue sarcoma subtypes:
   - Angiosarcoma
   - Desmoid tumors (aggressive fibromatosis)
   - Gastrointestinal stromal tumors (GIST)
4. Medullary thyroid carcinoma:
   - Progressive disease
   - Symptomatic distant metastatic disease
5. Acute myeloid leukemia

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 thyroid carcinoma? [If no, skip to question 8.]	Yes	No
4	Does the disease express papillary, Hurthle cell, or follicular histology? [If no, skip to question 6.]	Yes	No
5	Is the disease unresectable or metastatic? [No further questions.]	Yes	No
6	Does the disease express medullary histology? [If no, no further questions.]	Yes	No
7	Does the patient have progressive or metastatic disease? [No further questions.]	Yes	No
8	Does the patient have a diagnosis of gastrointestinal stromal tumor? [If no, skip to question 10.]	Yes	No
9	Has the disease progressed after imatinib, sunitinib, or regorafenib?	Yes	No

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	[No further questions.]		
10	Does the patient have a diagnosis of angiosarcoma? [If yes, no further questions.]	Yes	No
11	Does the patient have a diagnosis of desmoid tumors (aggressive fibromatosis)? [If yes, no further questions.]	Yes	No
12	Does the patient have a diagnosis of osteosarcoma? [If yes, no further questions.]	Yes	No
13	Does the patient have a diagnosis of hepatocellular carcinoma? [If yes, no further questions.]	Yes	No
14	Does the patient have a diagnosis of acute myeloid leukemia? [If no, no further questions.]	Yes	No
15	Is the disease relapsed or refractory? [If no, no further questions.]	Yes	No
16	Is the disease FLT3-ITD mutation-positive?	Yes	No

Guidelines for Approval			
Duration of Approval		**12 months**	
Set 1: RCC		**Set 2: Thyroid carcinoma, differentiated**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	3	1
2		4	
		5	
Set 3: Thyroid carcinoma, medullary		**Set 4: GIST**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
3	1	8	1
6	4	9	3
7			
Set 5: Angiosarcoma		**Set 6: Desmoid tumors**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
10	1	11	1
	3		3
	8		8
			10
Set 7: Osteosarcoma		**Set 8: HCC**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
12	1	13	1
	3		3
	8		8
	10		10
	11		11
			12
Set 9: AML			
Yes to question(s)	**No to question(s)**		

14	1
15	3
16	8
	10
	11
	12
	13

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 8
4	Go to 5	Go to 6
5	Approve, 12 months	Deny
6	Go to 7	Deny
7	Approve, 12 months	Deny
8	Go to 9	Go to 10
9	Approve, 12 months	Deny
10	Approve, 12 months	Go to 11
11	Approve, 12 months	Go to 12
12	Approve, 12 months	Go to 13
13	Approve, 12 months	Go to 14
14	Go to 15	Deny
15	Go to 16	Deny
16	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.Nexavar [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; November 2013.
2.The NCCN Drugs & Biologic 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:	UM Development (NB) 01/2006
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Reviewed:	CDPR/MM 01/2006; WLF 02/2007, 01/2008, 03/2008, 06/2009; KP 05/2010, 09/2010, 08/2011, 08/2012; DNC 07/2013, MCM 08/2014, KJC 01/2015, ADA 08/2015, DNC 08/2016, SD 03/2017
External Review:	04/2006, 06/2007, 07/2008, 08/2009, 10/2010, 11/2011, 12/2012, 09/2013, 09/2014, 01/2015, 09/2015, 09/2016