Clinical Policy Title:	sorafenib
Policy Number:	RxA.237
Drug(s) Applied:	Nexavar®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of Child-Pugh Class A or B7 hepatocellular carcinoma;
2. Diagnosis meets one of the following (a, b, c, or d):
3. Member
   a. Unresectable disease and member is not a transplant candidate;
   b. Inoperable by performance status or comorbidity;
   c. Local disease or local disease with minimal extrahepatic disease only;
   d. Metastatic disease or extensive liver tumor burden;
4. Prescribed as single agent therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

B. Renal Cell Carcinoma (must meet all):
1. Diagnosis of advanced renal cell carcinoma;
2. Prescribed as single agent therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

C. Differentiated Thyroid Carcinoma (must meet all):
1. Diagnosis of DTC (includes Papillary, Follicular, Hürthle cell carcinoma)
2. Diagnosis meets one of the following (a or b):
   a. Unresectable locoregional recurrent or persistent disease;
   b. Distant metastatic disease;
3. Disease is refractory to radioactive iodine treatment.

Approval Duration
All Lines of Business (except Medicare): 12 months

D. Acute Myeloid Leukemia (off-label) (must meet all):
1. Diagnosis of relapsed or refractory acute myeloid leukemia;
2. Disease is FLT3-ITD mutation-positive;
3. Prescribed in one of the following ways (a or b):
   a. In combination with azacitidine or decitabine;

b. As a single agent for maintenance therapy in remission postallogeneic stem cell transplantation.

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Bone Cancer (off-label) (must meet all):
1. Diagnosis of bone cancer;
2. Medication is prescribed in one of the following ways (a or b):
   a. As second-line therapy as a single agent or in combination with everolimus for relapased/refractory or metastatic osteosarcoma;
   b. As single agent therapy for treatment of recurrent chordoma.

Approval Duration
All Lines of Business (except Medicare): 12 months

F. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer (off-label) (must meet all):
1. Diagnosis of one of the following (a, b, or c):
   a. Epithelial ovarian cancer;
   b. Fallopian tube cancer;
   c. Primary peritoneal cancer;
2. If platinum-resistant, prescribed in combination with topotecan for persistent disease or recurrence.

Approval Duration
All Lines of Business (except Medicare): 12 months

G. Medullary Thyroid Carcinoma (off-label) (must meet all):
1. Diagnosis of recurrent or persistent distant metastatic medullary thyroid carcinoma;
2. Member meets one of the following (a or b):
   a. Disease progression on vandetanib (Caprelsa) or cabozantinib (Cometriq), unless contraindicated or clinically significant adverse effects are experienced;
   b. Clinical trials are not available or appropriate.
   *Prior authorization may be required for vandetanib and/or cabozantinib

Approval Duration
All Lines of Business (except Medicare): 12 months

H. Myeloid/Lymphoid Neoplasms with Eosinophilia and FLT3 rearrangement (off-label) (must meet all):
1. Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and FLT3 rearrangement in blast or chronic phase.

Approval Duration
All Lines of Business (except Medicare): 12 months

I. Soft Tissue Sarcoma (off-label) (must meet all):
1. Diagnosis of one of the following soft tissue sarcomas (a, b, c, or d):
   a. Angiosarcoma as single agent therapy;
   b. Desmoid Tumors (aggressive fibromatosis) as single agent therapy;
   c. Solitary Fibrous Tumor/Hemangiopericytoma as single agent therapy;
   d. Gastrointestinal stromal tumors (GIST), unresectable or metastatic disease progression after single-agent therapy with imatinib, sunitinib and regorafenib.

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Bone Cancer Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Kidney Cancer Version 1.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August 28, 2024.
5. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed August 28, 2024.
6. National Comprehensive Cancer Network. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed August 28, 2024.
7. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 28, 2024.
8. National Comprehensive Cancer Network. Thyroid Carcinoma Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy updated. 1. Formatting updated. 2. Criteria for approval and continued approval updated. 3. Approval duration updated. Reference Updated	07/21/2020	09/14/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.5 was updated to include “Request is to be used as a component of repeating the initial successful induction regimen if late relapse (≥12 months since induction regimen) if not administered…”. 2. Initial Approval Criteria I.I.1.b was updated to include “…therapy for primary treatment or treatment of	07/13/2021	09/14/2021

gross residual disease (R2 resection) in abdominal wall tumors if time to response is more critical as a single agent (preferred) for (meets one of the following i, ii, or iii)". 3. Initial Approval Criteria I.I.1.b.i was updated to include "Ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid;". 4. Initial Approval Criteria I.I.1.b.ii was updated to include "Documented progression in anatomic location where progression would be morbid;". 5. Initial Approval Criteria I.I.1.b.iii was updated to include "No documented progression in anatomic location where progression would be morbid if concerns for morbidity or significant symptoms;". 6. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 7. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.B.1.: Updated indication from Diagnosis of relapsed or stage IV renal cell carcinoma to Diagnosis of advanced renal cell carcinoma. 2. Continued Therapy Approval Criteria II.A.1 was updated from Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in the policy to Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria for the covered indications and has	02/04/2022	04/18/2022

received this medication for at least 30 days. 3. Continued Therapy Approval Criteria II.A.2: updated to remove criteria for currently receiving medication and added to II.A.1. 4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.5 and I.C.5: Updated dosing criteria from dose does not exceed 800 mg/day to Request meets one of the following (a or b):* a. Dose does not exceed 800 mg/day. b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). *Prescribed regimen must be FDA-approved or recommended by NCCN. 2. Initial Approval Criteria, I.D.5: Updated to remove prior criteria pertaining to indication Acute Myeloid Leukemia "Request is to be used as a component of repeating the initial successful induction regimen if late relapse (≥ 12 months since induction regimen) if not administered continuously and not stopped due to development of clinical resistance." 3. Initial Approval Criteria, I.D.5.b: Updated to include new prescribing criteria, As a single agent for maintenance therapy for member in remission postallogeneic stem cell transplantation. 4. Initial Approval Criteria, I.I.1.b: Updated to remove "primary treatment or treatment of gross residual disease (R2 resection) in abdominal wall tumors if time to response is more critical as a single agent (preferred) for (meets one of the following i, ii, or iii):	12/27/2022	04/13/2023

i. Ongoing progression with potential morbidity or significant symptoms in anatomic location where progression would not be morbid; ii. Documented progression in anatomic location where progression would be morbid; iii. No documented progression in anatomic location where progression would be morbid if concerns for morbidity or significant symptoms;" 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	9/13/2024