Clinical Policy: Sorafenib (Nexavar)

Reference Number: PA.CP.PHAR.69
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

Description
Sorafenib (Nexavar®) is a kinase inhibitor.

FDA Approved Indication(s)
Nexavar (sorafenib) is indicated for the treatment of:
- Unresectable hepatocellular carcinoma (HCC);
- Advanced renal cell carcinoma (RCC);
- Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

Policy/Criteria
It is the policy of health plans affiliated with Pennsylvania Health and Wellness® that Nexavar is **medically necessary** when one of the following criteria is met:

I. Initial Approval Criteria

A. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of hepatocellular carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 800 mg/day.

Approval duration: 6 months

B. Renal Cell Carcinoma (must meet all):
1. Diagnosis of renal cell carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 800 mg/day.

Approval duration: 6 months

C. Differentiated Thyroid Carcinoma (must meet all)**:**
1. Diagnosis of DTC (includes papillary, follicular, Hürthle cell carcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is refractory to radioactive iodine treatment;
5. Disease is locally recurrent or metastatic, and progressive;
6. Dose does not exceed 800 mg/day.

Approval duration: 6 months

D. Medullary Thyroid Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of medullary thyroid carcinoma (MTC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Member meets one of the following (a or b):
   a. Disease progression on Caprelsa®* or Cometriq®*, unless contraindicated or clinically significant adverse effects are experienced;
   b. Clinical trials are not available or appropriate;

   **Prior authorization is required for Caprelsa and Cometriq*
5. 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*).

Approval duration: 6 months

E. Acute Myeloid Leukemia (off-label) (must meet all)**:**
1. Diagnosis of relapsed or refractory acute myeloid leukemia;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is FLT3-ITD mutation-positive;
5. Prescribed in combination with azacitidine or decitabine;
6. 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*).

Approval duration: 6 months

F. Bone Cancer (off-label) (must meet all)**:**
1. Diagnosis of one of the following bone cancers (a or b):
   a. Osteosarcoma, and Nexavar will be used for second-line therapy as a single agent or in combination with Afinitor®;
   b. Chordoma, and Nexavar will be used as single agent therapy for treatment of recurrent disease;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. 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*).

Approval duration: 6 months

G. 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);
   c. Solitary Fibrous Tumor/Hemangiopericytoma as single-agent therapy;
   d. Gastrointestinal stromal tumors (GIST) with disease progression after single-agent therapy with imatinib*, Sutent® or Stivarga®;
2. Prescribed by or in consultation with an oncologist;

3. Age ≥ 18 years;
4. 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 (*prescriber must submit supporting evidence*).

Approval duration: 6 months

H. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. Dose does not exceed 800 mg/day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DTC: differentiated thyroid carcinoma
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
MTC: medullary thyroid carcinoma
RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Caprelsa (vandetanib)	MTC: 300 mg PO QD	300 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cometriq (cabozantinib)	MTC: 140 mg PO QD	180 mg/day
imatinib (Gleevec®)	Soft Tissue Sarcoma: 400 mg PO QD	800 mg/day
Sutent (sunitinib)	Soft Tissue Sarcoma: 37.5 to 50 mg PO QD	50 mg/day
Stivarga (regorafenib)	Soft Tissue Sarcoma: 160 mg PO QD	160 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known severe hypersensitivity to sorafenib or any other component of Nexavar
  - Nexavar use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer
- Boxed warning(s): none reported

Appendix D: General Information

- NCCN Compendium include sorafenib with a 2A recommendation in the following conditions: acute myeloid leukemia, bone cancer (chordoma, osteosarcoma), soft tissue sarcoma, and medullary thyroid carcinoma

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
HCC, RCC, thyroid cancer	400 mg PO BID	800 mg/day

V. Product Availability

Tablet: 200 mg

VI. References

1. Nexavar Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; December 2018. Available at: http://labeling.bayerhealthcare.com/html/products/pi/Nexavar_PI.pdf. Accessed February 26, 2019.
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed February 26, 2019.
3. National Comprehensive Cancer Network. Bone Cancer Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed February 26, 2019.

4. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed February 26, 2019.
5. National Comprehensive Cancer Network. Kidney Cancer Version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 26, 2019.
6. National Comprehensive Cancer Network. Soft Tissue Sarcoma 2.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed February 26, 2019.
7. National Comprehensive Cancer Network. Thyroid Carcinoma 3.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 26, 2019.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: Added age; added NCCN compendium use for solitary fibrous tumor/hemangiopericytoma; summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	01.17.18	04.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	04/2019	