Clinical Policy: Sorafenib (Nexavar)

Reference Number: ERX.SPA.13
Effective Date: 07.01.16
Last Review Date: 05.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sorafenib (Nexavar®) is a kinase inhibitor.

FDA Approved Indication(s)

Nexavar is indicated for the treatment of:

- Unresectable hepatocellular carcinoma (HCC)
- Advanced renal cell carcinoma (RCC)
- Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) refractory to radioactive iodine treatment

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Nexavar is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hepatocellular Carcinoma (must meet all)**:**

1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Confirmation of Child-Pugh class A or B7 status;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of advanced RCC;
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 per 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*

Approval duration:

Commercial – Length of Benefit
Medicaid – 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. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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 clinically significant adverse effects are experienced or both are contraindicated;*
   b. Clinical trials are not available or appropriate;

   **Prior authorization may be required for Caprelsa and Cometriq*
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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 or hematologist;
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 per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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;

**Prior authorization may be required for Nexavar and Afinitor*

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 per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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®, Stivarga®, and Qinlock™;*

   **Prior authorization may be required for imatinib, Sutent, Stivarga, and Qinlock*
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 per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

H. Ovarian Cancers (off-label) (must meet all)**:**

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is platinum-resistant (i.e., cancer returns less than 6 months after finishing platinum-based chemotherapy);
5. Disease is persistent or recurrent;
6. Prescribed in combination with topotecan;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 800 mg per 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

I. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or documentation supports that member is currently receiving Nexavar for a covered indication and has received this medication for at least 30 days;
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. New dose does not exceed 800 mg per day;
   b. New 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*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DTC: differentiated thyroid carcinoma
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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Caprelsa® (vandetanib)	MTC: 300 mg PO QD	300 mg/day
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
Qinlock™ (ripretinib)	GIST: 150 mg PO QD	150 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

V. Dosage and Administration

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

VI. Product Availability

Tablet: 200 mg

VII. References

1. Nexavar Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2020. Available at: http://labeling.bayerhealthcare.com/html/products/pi/Nexavar_PI.pdf. Accessed February 9, 2021.
2. National Comprehensive Cancer Network. Hepatobiliary Cancers Version 5.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed February 9, 2021.
3. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors (GISTs) Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf. Accessed February 9, 2021.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionlas/drug_compendium. Accessed February 9, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Increased continued approval duration from 6 months to 12 months. Split NCCN off-label uses into their own criteria sets per updated template.	04.17	05.17
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; added continuity of care statement; approval duration changed to length of benefit; references reviewed and updated.	01.17.18	05.18
2Q 2019 annual review: no significant changes; added hematologist prescriber option for AML; references reviewed and updated.	02.26.19	05.19
2Q 2020 annual review: added NCCN compendium-supported indication of epithelial ovarian cancers; added Medicaid line of business with 6/12 month approval durations; references reviewed and updated.	02.15.20	05.20
2Q 2021 annual review: clarified RCC criteria to be advanced RCC per PI; added requirement for Child-Pugh class A or B7 for HCC per NCCN; added hematologist specialty to acute myeloid leukemia indication; added requirement for disease progression to include Qinlock for GIST as 4th line therapy per off-label recommendation of NCCN category 2A; references reviewed and updated.	02.14.21	05.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.