ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Nexavar® (sorafenib) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit:

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Nexavar® (sorafenib)

Diagnosis (documentation supportive of diagnosis is required)

☐ Advanced Renal Cell Carcinoma
☐ Unresectable Hepatocellular Carcinoma
☐ Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment
☐ Other (please state): _____

Physician Specialty

☐ Oncology
☐ Other (please state): _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):	
Drug Name (Brand Name and Scientific Name)/Strength:	

Dose:	Route:	Frequency:
Quantity:	Number of Refills:	
Product will be delivered to: ☐ Patient's Home ☐ Physician Office		Other:
Prescriber or Authorized Signature:		Date:
Dispensing Pharmacy Name and Phone Number:		

☐ **Approved**	☐ **Denied**
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:	

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

Nexavar® (sorafenib)

CLASSIFICATION

- Antineoplastic Agent

DESCRIPTION

- Sorafenib is an inhibitor of multiple intracellular and cell surface kinases, inhibiting tumor growth and angiogenesis of human hepatocellular carcinoma and renal cell carcinoma.
- The most common adverse reactions (≥20%) include fatigue, weight loss, rash/desquamation, hand-foot skin reaction, alopecia, diarrhea, anorexia, nausea and abdominal pain.

Advanced hepatocellular carcinoma:

- Nexavar has produced few objective responses (partial responses, ~ 2%) in clinical trials, but it did significantly prolonged median overall survival and delayed time to radiologic progression in a phase 3, international, multicenter, randomized, double-blind, placebo-controlled [SHARP] trial (n=602).
- In the SHARP trial, patients with intermediate (17.5%) or advanced (82.5%) HCC and predominantly Child-Pugh class A status, who had received no prior systemic therapy for HCC were randomized to treatment with sorafenib 400mg orally twice daily (n=299) or placebo (n=303). A planned second interim analysis, requiring a statistical significance threshold level of p=0.0077 for the primary endpoint, resulted in closure of the trial due to a significant improvement (hazard ratio, 0.69; 95% CI, 0.55-0.87; p=0.001) in median overall survival in the sorafenib arm (10.7 months; 95% CI, 9.4-13.3 months) compared to the placebo arm (7.9 months; 95% CI, 6.8-9.1 months).

Advanced Renal Cell Carcinoma:

- When used in adults for first line-therapy, Nexavar did not demonstrate a significant difference in objective response rate when compared to Nexavar plus low-dose interferon alfa-2b in metastatic RCC in a phase 2 trial (n=80). In another phase 2 trial (n-189), Nexavar resulted in similar progression-free survival compared with interferon alfa-2a (IFN) in patients with advanced renal cell carcinoma (RCC). Some benefit was demonstrated with a sorafenib dose escalation to 600 milligrams twice daily or second-line sorafenib therapy after INF for those who had disease progression.
- In the TARGET study (phase 3, randomized, double-blind, placebo-controlled trial, n=903), oral sorafenib prolonged progression-free survival 5.5months vs. 2.8 months for placebo, in patients with advanced clear-cell RCC who had failed first-line therapy. For the patients who received oral sorafenib greater than 1 year, the median progression-free survival was 10.9 months. Treatment was associated with an increased risk of adverse events. Overall, 34% of patients (grade 3, 29%; grade 4, 5%) experienced a serious treatment-related adverse event including hand-foot skin reaction (grade 3 only, 7%), hypertension (grade 3, 5%; grade 4, 1%), diarrhea (grade 3 only, 2%), fatigue (grade 3 only, 2%), and weight loss (grade 3 only, 2%).

Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment:

- Sorafenib significantly improved progression-free survival time compared with placebo (10.8 vs 5.8 months) in a phase 3, randomized clinical trial in adults with locally recurrent or metastatic, progressive differentiated thyroid carcinoma refractory to radioactive iodine treatment (n=417); there was no significant difference in overall survival between the 2 groups.

- In 3 open-label, single-arm, phase 2 studies, oral sorafenib produced partial responses in 31% (8 of 26), 23% (7 of 30), and 15% (3 of 19) of patients with metastatic or unresectable thyroid cancer; nearly all patients had received prior radioactive iodine therapy. Toxicity included grade 4 myocardial infarction, pericardial effusion, reversible neutropenia, and grade 3 or 4 liver function test elevations.

FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Tier 3
Commercial Formulary: Tier 3
Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Nexavar® (sorafenib) meets the definition of **medical necessity** for all FDA approved indications not otherwise excluded from Part D, including the following:

- Treatment of patients with unresectable hepatocellular carcinoma.
- Treatment of patients with advanced renal cell carcinoma.
- Treatment of adults with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment.

Nexavar® (sorafenib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported including:
  - Advanced non-small cell lung cancer - use in combination with carboplatin and paclitaxel is contraindicated.

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION

Adult Dosing (safety and efficacy has not been determined for pediatric patient):

- **Unresectable Liver Carcinoma:** 400 mg ORALLY twice daily at least 1 hour before or 2 hours after eating; continue until patient no longer benefits or until unacceptable toxicity
- **Advanced Renal cell carcinoma:** 400 mg ORALLY twice daily at least 1 hour before or 2 hours after eating; continue until patient no longer benefits or until unacceptable toxicity
- **Malignant tumor of thyroid gland, Metastatic or locally advanced, refractory to radioactive iodine:** 400 mg orally twice daily, at least 1 hour before or 2 hours after eating. Continue treatment until the patient no longer benefits or until unacceptable toxicity occurs.

Dose adjustments:

- Management of adverse drug reactions may require temporary interruption and/or dose reductions. See prescribing information for dose modifications.
- Hepatic impairment: No dose adjustment necessary for mild to moderate hepatic impairment; sorafenib has not been studied in patients with severe (Child-Pugh C) hepatic impairment.
- Renal impairment: No adjustment is necessary for mild to moderate or severe renal impairment. Sorafenib has not been studied in patients on dialysis.

PRECAUTIONS

Contraindications:

- Combination with carboplatin and paclitaxel in patients with squamous cell lung cancer
- Severe hypersensitivity to sorafenib or any of its components

Precautions:

- Cardiac ischemia has been reported; consider temporary or permanent discontinuation.
- Concomitant use with gemcitabine and cisplatin in patients with squamous cell lung cancer is considered an unapproved use and is not recommended.
- Avoid concomitant use with strong CYP3A4 inhibitors, including carbamazepine, dexamethasone, phenobarbital, phenytoin, rifampin, rifabutin, and St. John's Wort.
- Avoid use if congenital long QT syndrome.
- Dermatologic toxicities, including cases of hand-foot skin reaction and rash, have been reported and may require supportive therapy, temporary interruption, dose modification, or permanent discontinuation depending on severity of the reaction.
- There are reported cases of gastrointestinal perforation, some not associated with apparent intraabdominal tumor. This warrants permanent discontinuation of sorafenib.
- Severe and fatal hemorrhage has occurred; may warrant permanent discontinuation of sorafenib for bleeding requiring medical intervention. Use local therapy for tracheal, bronchial, or esophageal infiltration prior to sorafenib in patients with differentiated thyroid carcinoma. May warrant permanent discontinuation for bleeding requiring medical intervention.
- Potentially severe or persistent hypertension has occurred. It may require temporary or permanent discontinuation and treatment with antihypertensive therapy. Monitoring recommended.
- Myocardial infarction has been reported; temporary or permanent discontinuation should be considered.
- Pregnancy category D for all trimesters. Avoid use as it is a known teratogen.
- QT/QTc interval prolongation has been reported; monitoring recommended in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, and in patients receiving other drugs known to prolong the QT interval. Temporary interruption may be necessary.
- Major surgical procedures while on sorafenib may increase the risk of wound healing complications; temporary interruption is recommended.
- Hepatitis, including hepatic failure and death, has been reported. Monitoring is recommended. Discontinuation of therapy may be necessary.
- TSH suppression may be impaired in patients with differentiated thyroid carcinoma; monitor and adjust thyroid replacement therapy if necessary.

Billing/Coding information

HCPCS Coding:

C9399	Unclassified drugs or biologicals (This code should only be used for drugs and biologicals that are approved by the FDA on or after January 1, 2004) (Hospital Outpatient Use ONLY)
J 8999	Prescription drug, oral, chemotherapeutic, Not otherwise specified

COST

- AWP (February 2012): Nexavar 200mg (120): $10,052.40
- AWP (January 2014): Nexavar 200mg (120): $12,630

COMMITTEE APPROVAL

- January 2006

GUIDELINE UPDATE INFORMATION

January 2006	Prior Authorization created
February 2012	Coverage Policy created
May 2014	Coverage Policy updated – new indication

REFERENCES

- DRUGDEX®, accessed 02/16/2011, 5/17/2014
- Product Information: Nexavar® (sorafenib), oral tablet. Bayer Healthcare Pharmaceuticals Inc. Wayne, NJ, 2011, 2013.