PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Sorafenib Preferred Specialty Management Policy
- Nexavar® (sorafenib tablets – Bayer/Onyx, generic)

REVIEW DATE: 07/05/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sorafenib, a kinase inhibitor, is indicated for the treatment of the following:[1-2]
- **Differentiated thyroid carcinoma**, locally recurrent or metastatic, progressive disease that is refractory to radioactive iodine treatment.
- **Hepatocellular carcinoma** that is unresectable.
- **Renal cell carcinoma** that is advanced.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Sorafenib Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Oncology – Sorafenib Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for 1 year.

Documentation: Documentation is required for use of Nexavar as noted in the criteria as **[documentation required]**. Documentation may include, but is not

limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Preferred Products: generic sorafenib tablets
Non-Preferred Products: Nexavar

Oncology – Sorafenib non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Nexavar	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Oncology – Sorafenib Prior Authorization Policy* criteria; AND **B)** Patient has tried generic sorafenib tablets **[documentation required]**; AND **C)** Patient cannot continue to use the Preferred medication due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient has met the standard *Oncology – Sorafenib Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B) and/or (1C) above for brand Nexavar: approve generic sorafenib tablets.

REFERENCES

1. Nexavar® tablets [prescribing information]. Wayne, NJ: Bayer; July 2020.
2. Sorafenib tablets [prescribing information]. Princeton, NJ: Dr. Reddy's; April 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/13/2022
Annual Revision	No criteria changes.	07/05/2023