Renal cell carcinoma (RCC) is the most common form of kidney cancer representing approximately 90% of cases. Approximately 30% of patients present with metastatic disease, 25% with locally advanced disease, and 45% with localized disease. Treatment of RCC is dependent on tumor type and disease stage. Surgical resection is currently the only effective treatment for localized RCC. Primary treatment involves removal of the entire kidney, adrenal gland, and some surrounding fatty tissue and nearby lymph nodes. Smaller renal cell tumors are treated by performing a partial nephrectomy. Radiation therapy may be used to treat RCC either prior to or following surgical procedures. It may be used as the main form of treatment for those patients too fragile to undergo surgery, although it is not routinely recommended due to poor response rates. Treatment of metastatic RCC involves the use of immunotherapy with interleukin-2 and interferon-alpha, alone or in combination with chemotherapy.

Sorafenib is a multiple kinase inhibitor indicated for the treatment of advanced (metastatic) RCC. Sorafenib works by inhibiting cancer cell proliferation by blocking angiogenesis (the formation of new blood vessels) in tumors. Progression free survival (PFS) is currently used as the predictor of clinical benefit in cancer clinical trials. In one clinical study, the median PFS for patients randomized to sorafenib was 167 days compared to 84 days in those given placebo. Another study showed PFS to be 163 days in patients treated with sorafenib and 41 days in patients treated with placebo.

Sorafenib is also used to treat hepatocellular carcinoma (HCC). Hepatocellular carcinoma (HCC) is the most common form of liver cancer representing approximately 90% of cases. No standard medication options exist for HCC and treatment is limited to surgical resection and liver transplantation. Only about 15% of patients receive benefit from these invasive procedures. Clinical studies such as the Sorafenib HCC Assessment Randomized Protocol (SHARP) revealed significant improvement in overall survival (OS) versus placebo. The median OS for patients randomized to sorafenib was 10.7 months versus 7.9 months in those given placebo. It also significantly prolonged time to progression (TTP) versus placebo. The median TTP for sorafenib was 5.5 months compared to 2.8 months in those given placebo.

The recommended dose of sorafenib is 400 mg as two 200 mg tablets twice daily. If the dose needs to be reduced or discontinued due to side effects, it should be restarted at 400 mg once daily. If side effects continue, a single dose of 400 mg every other day should be given. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. The most common adverse events reported with sorafenib are hand-foot skin reaction, diarrhea, rash/desquamation, fatigue, alopecia, and nausea/vomiting.

Sorafenib is currently being investigated for the treatment of various other forms of cancer including metastatic colorectal and breast cancers, advanced soft tissue sarcomas, and unresectable Stage III or IV melanoma.

**What it costs**

<table>
<thead>
<tr>
<th>Dosing</th>
<th>AWP per 200 mg tablet</th>
<th>Cost per month (30 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg (2 tablets) twice daily without food</td>
<td>$58.67</td>
<td>$7041</td>
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</table>

**Rationale for prior authorization**

To reduce exposure to cost associated with the treatment of other cancers for which the effectiveness of sorafenib is not known.

**Benefit design**

Coverage is determined through prior authorization for every claim AND Coverage is provided for a quantity sufficient for dosing up to 800mg per day.

**Prior authorization criteria**

- Coverage is provided for the treatment of advanced renal cell carcinoma.
- Coverage is provided for the treatment of hepatocellular carcinoma.
- Coverage duration: coverage is provided for 6 months at a dose of up to 800 mg per day.
- Coverage is renewable for up to 3 months in the absence of disease progression.

**References**
