RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Sutent (sunitinib malate) is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment (1).

Regulatory Status
FDA-approved indication: Sutent is a kinase inhibitor indicated for the treatment of patients with: (1)

1. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
2. Advanced renal cell carcinoma (RCC)
3. Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy
4. Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease

Off Label Uses: (2-4)

1. Recurrent chordoma
2. Relapsed or unresectable renal cell carcinoma
3. Neuroendocrine tumors
   a. Unresectable
   b. Metastatic disease
4. Soft tissue sarcoma
   a. Angiosarcoma
   b. Solitary fibrous tumor
   c. Hemangiopericytoma
   d. Alveolar Soft Part Sarcoma (ASPS)
5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
   a. Unresectable recurrent or persistent
   b. Distant metastatic disease
6. Medullary thyroid carcinoma
   a. Progressive disease
   b. Symptomatic distant metastatic disease
7. Thymic carcinoma
Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests should be obtained before initiation of Sutent, and it should be monitored at least 2 weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Temporarily hold and then reduce or permanently discontinue Sutent depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis. Sutent should be interrupted for grade 3 or 4 drug-related hepatic adverse events and discontinue if there is no resolution (1).

The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Summary
Sutent is a kinase inhibitor, designed to block enzymes that promote cancer growth. Sutent has been approved to treat gastrointestinal stromal tumors (GIST), renal cell carcinoma (RCC), neuroendocrine tumors, soft tissue sarcoma, thyroid carcinoma, thymic carcinoma or recurrent chordoma. Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests should be obtained before initiation of Sutent, and it should be monitored at least 2 weeks during the first 2 months of treatment. The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Sutent while maintaining optimal therapeutic outcomes.

References