Oral Oncology Agents

Agent	Quantity Limit	Indication	PA Criteria
Afinitor 2.5 mg (everolimus)	1/qd	Renal cell carcinoma	1.Diagnosis of renal cell carcinoma and 2.Prior treatment with Sutent (sunitinib) or 3.Prior treatment with Nexavar (sorabfenib) (Can utilize Auto PA)
Afinitor 5 mg.	1/qd	Renal cell carcinoma	See above
Afinitor 7.5mg.	1/qd	Renal cell carcinoma	See above
Afinitor 10 mg.	1/qd	Renal Cell carcinoma	See above
Caprelsa 100 mg. (vandetanib)	2/qd	Treatment of medullary thyroid cancer that cannot be removed by surgery or that has spread to other parts of the body.	
Caprelsa 300 mg. (vandetanib)	1/qd	Treatment of medullary thyroid cancer that cannot be removed by surgery or that has spread to other parts of the body.	
Erivedge (vismodegib)	1 qd	Treatment of adults with metastatic basal cell carcinoma (BCC) or locally advanced BCC that has recurred following surgery or who are not candidates for surgery or radiation therapy	
Gleevec 100 mg. (imatinib)	3/qd	Treatment of some forms of adult and pediatric chronic myelogenous leukemia (CML), and for the treatment of a rare form of cancer called gastrointestinal stromal tumor (GIST)	
Gleevec 400 mg.	2/qd	Treatment of some forms of adult and pediatric chronic myelogenous leukemia (CML), and for the treatment of a rare form of cancer called gastrointestinal stromal tumor (GIST)	
Iressa 250 mg. (gefitinab)	1/qd	Indicated for monotherapy for the continued treatment of locally advanced or metastatic non-small cell lung cancer	

		after failure of both platinum- based and docletaxol chemotherapies	
Jakafi 5 mg., 10 mg, 15 mg, 20 mg, and 25 mg. (ruxolitinib)	2/qd	Indicated for treatment of patients with intermediate or high-risk myelofibrosis, including primary myelofibrosis, post–polycythemia vera myelofibrosis and post–essential thrombocythemia myelofibrosis	
Nexavar 200 mg. (sorafenib)	4/qd	Indicated for the treatment of unresectasble hepatocarcinoma or advance renal cell carcinoma	
Sprycel 20 mg. (dazatinib) Max dose: Chronic Phase 100 mg daily Accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL: 140 mg once daily.	2/qd	Indicated for the reatment of newly diagnosed Philadelphia-chromosome positive chronic myeloid leukemia (Ph+CML) in chronic phase. Treatment of adults with chronic, accelerated or myeloid or lymphoid blast phase chronic myeloid leukemia (CML) with resistance or intolerance to prior therapy including Gleevec® (imatinib). Treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia with resistance	
Sprycel 50 mg.	1 qd		
Sprycel 70 mg.	1/qd		
Sprycel 80 mg.	1/qd		
Sprycel 100 mg.	1/qd		
Sprycel 140 mg.	1/qd		
Sutent 12.5 mg (sunitib)	2/qd	Indicated for the treatment of advanced renal cell carcinoma, treatment of gastrointestinal stromal tumor (GIST)after disease progression on or intolerance to imanitib mesylate, and for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease.	
Sutent 25 mg	1/qd		
Sutent 50 mg.	1/qd	See above	
Tarceva 25 mg. (erlotinib)	1/qd	Indicated for the maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, treatment of patients with locally	

		advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen. and in combination with gemcitabine is indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer	
Tarceva 100 mg.			
Tarceva 150 mg.			
Tasigna 150 mg, 200 mg. (nilotinib)	4/day	indicated for the treatment of adult patients with newly diagnosed Philadelphia chromosome—positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The effectiveness of TASIGNA is based on major molecular response and cytogenetic response rates. and indicated for the treatment of chronic phase and accelerated phase Philadelphia chromosome—positive chronic myeloid leukemia (Ph+ CML) in adult patients resistant or intolerant to prior therapy that included imatinib. The effectiveness of TASIGNA is based on hematologic and cytogenetic response rates	
Tykerb	6/day	Indicated in combination with:capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab.or letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated.	
Votrient (pazpapnib)	4/day	Indicated for advanced renal cell carcinoma	Approved for diagnosis of advance renal cell carcinoma (Can utilize Auto PA)
Xalkori 200 mg, (crizotinib)	2/qd	Indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an	

		FDA-approved test.	
Xalkori 250 mg. (crizotinib)	2/qd	Treatment of locally advanced or metastatic non-small cell lung cancer.	
Zelboraf 240 mg. (vemurapanib)	6/qd	Indicated for the treatment for BRAF mutation-positive metastatic melanoma	
Zytiga 250 mg. (abiraterone)	4/day	Indicated for use in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel.	

Recommendation to the DUR Board is to add dosing limits (per manufacturer's recommendations) and prior authorization criteria is FDA approved diagnosis.