RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Tecentriq is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma, metastatic non-small cell lung cancer (NSCLC), metastatic non-squamous NSCLC, small cell lung cancer, and triple-negative breast cancer. Urothelial carcinoma (also called transitional cell carcinoma) is the most common form of bladder cancer. Tecentriq is the first PD-L1 inhibitor that works by blocking the PD-L1 pathway which may help the body’s own immune system fight off the cancer cells (1).

Regulatory Status
FDA-approved indication: Tecentriq is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with: (1)

1. Locally advanced or metastatic urothelial carcinoma who:
   a. Are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 as determined by an FDA-approved test, or
   b. Are not eligible for any platinum-containing chemotherapy regardless of level of tumor PD-L1 expression, or
   c. Have disease progression during or following platinum-containing chemotherapy, or
   d. Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

2. Non-small cell lung cancer (NSCLC):
   a. In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment, of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations, or
   b. As a single agent, for adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq.

3. Locally Advanced or Metastatic Triple-Negative Breast Cancer (TNBC):
   a. In combination with paclitaxel protein-bound for the treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 as determined by an FDA-approved test.
4. Small cell lung cancer (SCLC):

Patients should be monitored for multiple immune-related conditions including: immune-related pneumonitis, immune-related hepatitis, immune-related colitis, immune-related endocrinopathies, immune-related pancreatitis, and immune-related myasthenic syndrome/myasthenia gravis, or meningoencephalitis. Additionally, patients should be monitored for the development of other conditions including ocular inflammatory toxicity, severe or life threatening infections, infusion reactions, and severe intestinal obstructions. Immune-mediated hepatitis occurred in patients receiving Tecentriq treatment. Liver test abnormalities also occurred in patients who received Tecentriq. Monitor patients for signs and symptoms of hepatitis. Liver function tests should be performed periodically during treatment with Tecentriq including bilirubin, ALT, and AST. Therapy with this agent should be withheld for the development of moderate conditions associated with treatment and permanently discontinued for severe conditions (1).

The safety and efficacy of Tecentriq in pediatric patients less than 18 years of age have not been established (1).

Summary
Tecentriq is a novel agent for the treatment of patients with locally advanced or metastatic urothelial carcinoma, metastatic non-small cell lung cancer, metastatic non-squamous NSCLC, small cell lung cancer, and triple-negative breast cancer. Tecentriq has been associated with many toxicities and patients should be monitored accordingly, as seriously adverse events occurred in 45% of patients in clinical trials. The safety and efficacy of Tecentriq in pediatric patients less than 18 years of age have not been established (1).

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

References