DESCRIPTION: Yervoy is a recombinant, human monoclonal antibody that acts by binding to cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4). This prevents CTLA-4 from interacting with its ligands, CD80/CD86, and subsequently enhances T-cell activation and proliferation.

INDICATION(S): Ipilimumab is indicated for the treatment of unresectable or metastatic melanoma

Also, Ipilimumab is adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy. Dosing is 3 mg/kg administered intravenously over 90 minutes every 3 weeks for a total of 4 doses.

REASONS FOR PA:
- ✗ Cost
- ☐ Potential for misuse
- ✗ Toxicity

CRITERIA for APPROVAL:
1. Patient has unresectable or metastatic melanoma OR
2. As adjuvant treatment of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.
3. Patient is 18 years of age or older
4. Baseline liver function tests performed (AST, ALT, total bilirubin)
5. Baseline thyroid function tests performed (TSH)
6. Dosing:
   a. For unresectable or metastatic melanoma: 3 mg/kg IV every 3 weeks for a total of 4 doses
   b. For adjuvant melanoma: 10 mg/kg IV every 3 weeks for a total of 4 doses, followed by 10 mg/kg every 12 weeks up to 3 years or until documented disease recurrence or severe adverse reactions

REASONS for DENIAL of BENEFIT:
1. Patient does not meet above criteria
2. Patient has a known allergy to ipilimumab or any other component of Yervoy

RENEWAL CRITERIA:
1. Patient is responding to treatment without disease progression
2. Liver function tests and thyroid function tests are performed prior to renewal

BENEFIT APPROVAL:
Initial approval: 8 weeks (2 doses)
Renewal approval period: Additional 8 weeks (2 doses), if therapy has proven to be beneficial

References: Yervoy (ipilimumab) prescribing information. Princeton, NJ: Bristol-Myers Squibb; October 2015