



Prior Authorization Approval Criteria

Yervoy (ipilimumab)

Generic name:	Ipilimumab
Brand name:	Yervoy
Medication class:	Antineoplastic agent; cytotoxic T-lymphocyte antigen 4 blocking antibody
FDA-approved uses:	Treatment of unresectable or metastatic melanoma
Available dosage forms:	50mg/10ml vial 200mg/40ml vial
Usual dose:	3mg/kg IV infusion over 90 minutes every 3 weeks for 4 cycles
Approximate cost: (based on AWP 2011)	\$30,000 per infusion
Duration of therapy:	16 weeks (maximum of 4 cycles)

Criteria for use (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed Stage III/IV unresectable or metastatic melanoma
- Life expectancy of at least 4 months
- Baseline liver function tests are obtained
 - Total bilirubin
 - AST
 - ALT
- Baseline thyroid function test is obtained
 - TSH

Criteria for continuation of therapy:

- Patient responding to treatment without disease progression
- Patient tolerating treatment
- Liver function and thyroid function are assessed before each cycle
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- Has not received the maximum of 4 cycles
- Each cycle must be given within 16 weeks of initiating the first cycle

Caution:

- Black box warning - Immune-mediated adverse reactions due to T-cell activation and proliferation

Monitoring:

- Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy at baseline and before each dose
- Evaluate clinical chemistries including liver functions tests and thyroid functions tests at

baseline and before each dose

Not approved if:

- Patient does not meet the above stated criteria

Special considerations:

- Approval will be for one cycle at a time
- One cycle consists of one infusion every 3 weeks

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 06/08/11