Yervoy (Ipilimumab) is an Antineoplastic Agent, Monoclonal Antibody.

Pre-Authorization Criteria:

VCHCP will authorize Yervoy (Ipilimumab) for FDA indicated treatment of unresectable or metastatic melanoma.

VCHCP requires that Yervoy be prescribed by an Oncologist.

Dosing: Adult

Melanoma, unresectable or metastatic: I.V.: 3 mg/kg every 3 weeks for 4 doses

Dosage Forms: U.S.

Injection, solution [preservative free]: Yervoy™: 5 mg/mL (10 mL, 40 mL) [contains polysorbate 80; derived from or manufactured using Chinese hamster ovary cells]

Administration

I.V.: Infuse over 90 minutes through a low protein-binding in-line filter. Flush with NS or D5W at the end of infusion

WARNINGS / PRECAUTIONS

Concerns related to adverse effects:

Immune-mediated adverse effects: [U.S. Boxed Warning]: Severe and fatal immune-mediated adverse effects due to T-cell activation and proliferation may occur. While any organ system may be involved, common severe effects include dermatitis (including toxic epidermal necrolysis), endocrine disorder, enterocolitis, hepatitis, and neuropathy. Reactions generally occur during treatment, although some reactions have occurred weeks to months after treatment discontinuation. Discontinue treatment (permanently) and initiate high-dose corticosteroid treatment for severe immune mediated reactions. Evaluate liver function and thyroid function tests at baseline and prior to each dose. Assess for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrine disorder at baseline and prior to each dose. Uncommon immune-mediated adverse effects
reported include hemolytic anemia, iritis, meningitis, nephritis, pericarditis, pneumonitis, and uveitis. Initiate prednisone 1-2 mg/kg/day (or equivalent) for severe reactions.

Dermatologic toxicity: Severe, life-threatening, or fatal dermatitis has been reported

Endocrine disorders: Severe or life-threatening endocrine disorders (hypopituitarism, adrenal insufficiency, hypogonadism and hypothyroidism) have been reported; may require hospitalization

Hepatotoxicity: Severe, life-threatening or fatal hepatotoxicity and immune-mediated hepatitis have been observed

Ophthalmic toxicity: Administer corticosteroid ophthalmic drops in patients who develop episcleritis, iritis, or uveitis; permanently discontinue ipilimumab if unresponsive to topical ophthalmic immunosuppressive treatments.

**DRUG Interactions**

Cardiac Glycosides: Antineoplastic Agents may decrease the absorption of Cardiac Glycosides. This may only affect digoxin tablets. **Exceptions:** Digitoxin. **Risk C: Monitor therapy**

Vitamin K Antagonists (eg, warfarin): Antineoplastic Agents may enhance the anticoagulant effect of Vitamin K Antagonists. Antineoplastic Agents may diminish the anticoagulant effect of Vitamin K Antagonists. **Risk C: Monitor therapy**

**REFERENCES**


Revision History:
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<td>Catherine Sanders, MD; Robert Sterling, MD</td>
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