

# Pharmacy

## PRIOR AUTHORIZATION FORM

For Prior Authorization, please fax to: (877) 974-4411 toll free, or (616) 942-8206

This form applies to:  Commercial Plan  Medicaid Plan  Medicare Plan

# Yervoy<sup>®</sup> (ipilimumab)

**URGENT** (life threatening)

**Non-Urgent** (standard review)

A claim involving "urgent care" applies when then standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

### Member Information

Member Name:	Member No.:
DOB:	Gender:
Member's PCP:	

### Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

\_\_\_\_\_  
Provider Signature

\_\_\_\_\_  
Date

### PRODUCT INFORMATION

- Yervoy<sup>®</sup> 50 mg/10 mL vial  
 Yervoy<sup>®</sup> 200 mg/40 mL vial

**Dose:**  3 mg/kg IV q 3 weeks x 4 doses

\_\_\_\_\_

**Start Date:** \_\_\_\_\_

**Patient's Weight:** \_\_\_\_\_

Note: Authorization, when given, will be for 16 weeks from the start date of the first infusion. The authorization will expire after the administration of 4 doses or 16 weeks, whichever occurs earlier.

### BILLING INFORMATION

#### Place of administration:

- Provider's Office  
 Outpatient Infusion Center  
 Center Name: \_\_\_\_\_  
 Home Infusion  
 Agency Name: \_\_\_\_\_

#### Billing Options:

- Physician buy and bill  
 Preferred Specialty Vendor  
 Other: \_\_\_\_\_

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**PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION**

Authorization for Yervoy (ipilmumab) requires the following information to certify:

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**Authorization for Yervoy<sup>®</sup> requires:**

1. Diagnosis of unresectable or metastatic melanoma.
2. Agreement to permanently discontinue Yervoy<sup>®</sup> if the patient experiences any severe adverse reactions.
3. Prescriber must communicate directly, face-to-face, with patient to provide both verbal and printed materials regarding the safety risks associated with the use of Yervoy<sup>®</sup>.

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**PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION**

Authorization for Yervoy<sup>®</sup> (ipilimumab) requires the following information to certify:

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**A. What is the patient's diagnosis?**

- a.  Unresectable or metastatic melanoma
- b.  Other: \_\_\_\_\_

ICD Code: \_\_\_\_\_

Rationale for use: \_\_\_\_\_

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

**B. In the event the patient experiences a severe or life-threatening adverse reaction to Yervoy, prescriber agrees to permanently discontinue the drug.**

- Yes
- No (authorization will not be given)

**Severe or life-threatening adverse reactions, including any of the following:**

- Colitis with abdominal pain, fever, ileus, or peritoneal signs; increase in stool frequency (7 or more over baseline), stool incontinence, need for intravenous hydration for more than 24 hours, gastrointestinal hemorrhage, and gastrointestinal perforation
- Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >5 times the upper limit of normal or total bilirubin >3 times the upper limit of normal
- Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations
- Severe motor or sensory neuropathy, Guillain-Barré syndrome, or myasthenia gravis
- Severe immune-mediated reactions involving any organ system (eg, nephritis, pneumonitis, pancreatitis, non-infectious myocarditis)
- Immune-mediated ocular disease that is unresponsive to topical immunosuppressive therapy

**C. Prescriber has communicated verbally with the patient through direct, face-to-face communication and has provided printed materials regarding the safety risks associated with the use of Yervoy<sup>®</sup> (materials available through the manufacturer's Risk Evaluation & Mitigation Strategy (REMS) program).**

- Yes
- No (authorization will not be given)

## WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY<sup>®</sup> can result in severe and fatal immune-mediated adverse reactions due to T-cell activation and proliferation. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY<sup>®</sup>.

Permanently discontinue YERVOY<sup>®</sup> and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests and thyroid function tests at baseline and before each dose.

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### PRIORITY MEDICARE PLANS (Part B Only)

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**Note:** Priority Health Medicare applies CMS national and local coverage determination criteria when available for Part B drugs. If no national determination criteria or local coverage determination criteria is available for the state in which the member is receiving the services, the above prior authorization criteria must be met.

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### FOR MEDICARE ONLY (Part D Only)

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If none of the above precertification criteria is applicable to this member, please check off which, if any, of the following apply:

1.  All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects
2.  The number of doses available under a dose restriction for the prescription drug:
  - a.  Has been ineffective in the treatment of the enrollee's disease or medical condition, or
  - b.  Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
3.  The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
  - a.  Has been ineffective in the treatment of the enrollee's disease or medical condition, or
  - b.  Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
  - c.  Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.
4.  None of the above apply

**\*\*If you selected 1, 2, or 3 above, supporting evidence/documentation is required for review. If no supporting evidence/documentation is provided, this request will not be approved.**

\*\*\* All fields must be complete and legible for Prior Authorization Review\*\*\*

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**YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**