Yervoy (ipilimumab)

Line(s) of Business:
HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date:
10/01/2015
Current Effective Date:
01/01/2018

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- Yervoy is indicated for the treatment of unresectable or metastatic melanoma
- Yervoy is indicated for the 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

Compendial Uses[2]

- Adjuvant treatment as a high-dose single agent for stage III disease or for nodal recurrence following surgery (eg, lymph node dissection/excision)
- Unresectable or metastatic melanoma
  - First-line therapy, in combination with nivolumab (Opdivo)
  - Second-line or subsequent therapy (if not previously used) for disease progression in patients with performance status (PS) 0-2, as a single agent or in combination with nivolumab
  - Following maximum clinical benefit from BRAF targeted therapy in patients with PS 0-2, as a single agent or in combination with nivolumab
  - Re-induction therapy as a single agent or in combination with nivolumab in patients with PS 0-2 who experienced disease control during prior Yervoy therapy and no residual toxicity but subsequently experience disease progression/relapse more than 3 months after treatment discontinuation
  - Central nervous system (CNS) metastases if active against primary tumor (melanoma) for recurrent disease as a single agent
- Small cell lung cancer
  - Subsequent therapy for patients with PS 0-2 in combination with nivolumab for
    - Relapse within 6 months of complete/partial response or stable disease with initial treatment
    - Primary progressive disease

B. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review:

- For initial therapy, current oncology notes, clinical notes (including previous treatment history), and any pertinent pathology reports and/or imaging studies supporting the diagnosis of melanoma
- For continuation of adjuvant therapy for melanoma or for small cell lung cancer, documentation demonstrating lack of disease recurrence or progression on therapy (e.g, clinical notes, laboratory tests, and any pertinent pathology reports and/or imaging studies)

C. PRESCRIBER RESTRICTION

Yervoy must be recommended by an oncologist.

D. CRITERIA FOR APPROVAL

1. Unresectable or Metastatic Melanoma

Initial authorization of 16 weeks may be granted for the treatment of unresectable or metastatic melanoma when the following criteria are met:

a. Yervoy is used for first-line therapy, second-line/subsequent therapy for disease progression, or for therapy following maximum clinical benefit from BRAF targeted therapy
b. Yervoy is used as monotherapy or in combination with nivolumab (Opdivo)

2. Melanoma Brain Metastases

Initial authorization of 16 weeks may be granted for the treatment of melanoma brain metastases when the following criteria are met:

a. Yervoy is used for recurrent disease
b. Yervoy is used as monotherapy

3. Adjuvant Treatment of Cutaneous Melanoma

Initial authorization of 3 months may be granted for the adjuvant treatment of cutaneous melanoma when the following criteria are met:

a. Yervoy will be used following surgery (eg, lymph node dissection, complete resection of nodal recurrence)
b. Member has cutaneous melanoma with positive lymph nodes or nodal recurrence

4. Small cell lung cancer

Initial authorization of 3 months may be granted for the treatment of small cell lung cancer when the following criteria are met:

a. Yervoy will be used following as subsequent systemic therapy for relapsed or primary progressive disease
b. Yervoy is used in combination with nivolumab (Opdivo)

E. CONTINUATION OF THERAPY

1. Unresectable or Metastatic Melanoma

Authorization of 1 additional course (16 weeks) may be granted for the treatment of unresectable or metastatic melanoma when ALL of the following criteria are met:

a. Member has received no more than 1 previous course (16 weeks) of total lifetime therapy with Yervoy.

b. Member had disease progression or relapse on Yervoy after disease control of at least 3 months duration

2. Adjuvant Treatment of Melanoma and Small Cell Lung Cancer

a. No previous authorization/precertification:
All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.

b. Reauthorization:
Authorization of 3 months may be granted to members requesting authorization for continuation of therapy if Yervoy was previously authorized by HMSA/CVS and there is no evidence of disease recurrence or progression.

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

1. Yervoy [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2017.
2. The NCCN Drugs & Biologics Compendium © 2017 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 21, 2017.

Document History

10/01/2015	Original effective date
01/2016	Added new combination (label update)

12/13/2016	Annual review
06/2017	Annual review
01/01/2018	Revision effective date