CLINICAL MEDICATION POLICY	
Policy Name:	Yervoy® (ipilimumab)
Policy Number:	MP-013-MC-OH
Responsible Departments:	Medical Management, Medical Policy, Clinical Pharmacy
Provider Notice Date:	04/1/2017
Original Effective Date:	05/01/2017
Annual Approval Date:	03/15/2018
Revision Date:	N/A
Products:	Ohio Medicare Assured
Application:	All participating and nonparticipating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Gateway Health℠ (Gateway) clinical medication policy is intended to serve only as a general reference resource regarding payment and coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Gateway Health℠ may provide coverage under the medical or pharmacy benefits of the Company's Medicare products for medically necessary administration of Yervoy® (Ipilimumab).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

PROCEDURES

Gateway Health ℠ considers ipilimumab (Yervoy) medically necessary for the treatment of melanoma when the following criteria are met:

1. Coverage may be provided when the diagnosis is unresectable or metastatic melanoma and the following criteria are met:
   A. The patient is age 18 years or older; AND
   B. Treatment is prescribed by an oncologist/hematologist; AND
   C. The patients has Stage III (unresectable) or IV (metastatic) disease; AND
   D. The dosing is within the following prescribing-supported parameter(s):
      1)Monotherapy: Does not exceed 3 mg/kg every 3 weeks for a total of 4 doses; OR
      2)Yervoy (ipilimumab) in combination with Opdivo (nivolumab): Does not exceed 1 mg/kg (Opdivo), followed by 3 mg/kg (Yervoy) on the same day, every 3 weeks for 4 doses, then 240 mg (Opdivo) every 2 weeks.

2. Coverage may be provided when the diagnosis is cutaneous melanoma with pathologic involvement of regional lymph nodes of > 1 mm who have undergone complete resection, including total lymphadenectomy and the following criteria are met:
   a. The patient is age 18 years or older; AND
   b. Treatment is prescribed by an oncologist/hematologist; AND
   c. Treatment is used as adjuvant treatment for patients with pathologic involvement of regional lymph nodes of > 1 mm who have undergone complete resection, including total lymphadenectomy; AND
   d. The dosing is within the following prescribing-supported parameter(s):
      1)Does not exceed 10 mg/kg every 3 weeks for 4 doses, followed by 10 mg/kg every 12 weeks for up to 3 years or until documented disease recurrence or unacceptable toxicity.

3. When Yervoy is not covered
   For conditions other than those listed above because the scientific evidence has not been established.

   Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis (es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

   When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Gateway Health℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   Yervoy is administered in an outpatient setting.

6. Coverage Determination
   Gateway Health ℠ follows the coverage determinations made by CMS as outlined in either the national coverage determinations (NCD) or the state-specific local carrier determination (LCD).

   For Ohio, there is no state-specific LCD or NCD for Yervoy. For additional information, please see: http://www.cgsmedicare.com/partb/medicalpolicy/index.html

Governing Bodies Approval
US Food and Drug Administration (FDA): Ipilimumab (Yervoy®) was approved by the FDA on March 25, 2011 for the treatment of unresectable or late-stage metastatic melanoma. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125377s0000lbl.pdf

CODING REQUIREMENTS

Procedure Codes

CPT/HCPCS Codes	Description
J9228	Ipilimumab, 1 mg, IV

Diagnosis Codes

ICD-10 Code	Description
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear & external auricular canal
C43.21	Malignant melanoma of right ear & external auricular canal
C43.22	Malignant melanoma of left ear & external auricular canal
C43.3	Malignant melanoma of other & unspecified parts of face
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp & neck
C43.5	Malignant melanoma of trunk
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast

C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C73.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C79.31	Secondary malignant neoplasm of brain
D03.0	Melanoma in situ of lip
D03.1	Melanoma in situ of eyelid, including canthus
D03.10	Melanoma in situ of unspecified eyelid, including canthus
D03.11	Melanoma in situ of right eyelid, including canthus
D03.12	Melanoma in situ of left eyelid, including canthus
D03.2	Melanoma in situ of ear and external auricular canal
D03.20	Melanoma in situ of unspecified ear and external auricular canal
D03.21	Melanoma in situ of right ear and external auricular canal
D03.22	Melanoma in situ of left ear and external auricular canal
D03.3	Melanoma in situ of other and unspecified parts of face
D03.30	Melanoma in situ of unspecified part of face
D03.39	Melanoma in situ of other parts of face
D03.4	Melanoma in situ of scalp and neck
D03.5	Melanoma in situ of trunk
D03.51	Melanoma in situ of anal skin
D06.52	Melanoma in situ of breast (skin) (soft tissue)
D03.59	Melanoma in situ of other part of trunk
D03.6	Melanoma in situ of upper limb, including shoulder
D03.6	Melanoma in situ of upper limb, including shoulder
D03.60	Melanoma in situ of unspecified upper limb, including shoulder
D03.61	Melanoma in situ of right upper limb, including shoulder
D03.62	Melanoma in situ of left upper limb, including shoulder
D03.7	Melanoma in situ of lower limb, including hip
D03.70	Melanoma in situ of unspecified lower limb, including hip
D03.71	Melanoma in situ of right lower limb, including hip
D03.72	Melanoma in situ of left lower limb, including hip
D03.8	Melanoma in situ of other sites
D03.9	Melanoma in situ, unspecified

REMBURSEMENT

Participating facilities will be reimbursed per their Gateway Health℠ contract.

POLICY SOURCE(S)

Yervoy® (Ipilimumab) [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 03/2011

NCCN Guidelines Version 1.2015: Central Nervous System Cancers

NCCN Guidelines Version 2.2016: Melanoma

Hodi FS, O'Day SJ, McDermott DF, *et al*. Improved survival with ipilimumab in patients with metastatic melanoma. *N Engl J Med.* 2010; 363:711-23

Policy History:

Date	Activity
N/A	LCD/NCD effective date
03/15/2017	QI/UM Committee approval
05/01/2017	Provider effective date