CLINICAL MEDICATION POLICY	
Policy Name:	Yervoy® (Ipilimumab)
Policy Number:	MP-008-MD-PA
Responsible Departments:	Medical Management Medical Policy; Clinical Pharmacy
Provider Notice Date:	06/19/2017
Original Effective Date:	07/19/2017
Annual Approval Date:	02/02/2018
Revision Date:	12/13/2016
Products:	Pennsylvania Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

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 Medicaid products for medically necessary intravenous 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.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

DEFINITIONS

Medical Necessity – A service or benefit is medically necessary if it is compensable under the Medical Assistance program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability.
- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability.
- The service or benefit will assist the patient to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the patient and those functional capacities that are appropriate for patients of the same age.

PROCEDURES

1. Gateway Health℠ considers ipilimumab (Yervoy) medically necessary for the treatment of cutaneous melanoma and unresectable or metastatic melanoma when the following criteria are met:

    A. Coverage may be provided when the diagnosis is unresectable or metastatic melanoma and the following criteria are met:
        1) The member is 18 years of age or older; AND
        2) Treatment is prescribed by an oncologist or hematologist; AND
        3) The member has Stage III (unresectable) or Stage IV (metastatic) disease; AND
        4) The dosing is within the following prescribing-supported parameter(s):
            a) Monotherapy: Does not exceed 3 mg/kg every 3 weeks for a total of 4 doses, OR
            b) 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

    B. Coverage may be provided when the diagnosis is cutaneous melanoma and the following criteria are met:
        1) The member is 18 years of age or older; AND
        2) Treatment is prescribed by an oncologist or hematologist; AND
        3) Treatment is used as adjuvant treatment for members with pathologic involvement of regional lymph nodes of > 1 mm who have undergone complete resection, including total lymphadenectomy; AND
        4) The dosing is within the following prescribing-supported parameters: 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

2. When Yervoy is not covered
    Yervoy is not covered for conditions than those listed above because the scientific evidence has not been established.

Coverage may be provided for any non-FDA labeled indication or a medically accepted indication that is supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis for which it is prescribed and 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 over ride criteria when, in their professional judgment, the requested medication is medically necessary.

3. Post-payment Audit Statement
   The medical record should 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.

4. Place of Service
   The place of service for the administration of Yervoy is outpatient.

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. Accessed February 2, 2016 and available at:
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125377s0000lbl.pdf

CODING REQUIREMENTS

Procedure Codes:

HCPCS Code	Description
J9228	Ipilimumab, 1 mg, IV

Diagnosis Codes:

ICD-10 Codes	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
C43.72	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
D03.60	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

REIMBURSEMENT

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
03/07/2016	Initial policy developed
05/23/2016	Provider effective date
12/13/2016	Revisions: Annual Review, updated indications and dosage, and updated references **Criteria Changes:** • **Central Nervous System Cancer disease** indication has been completely removed from criteria that highlights limited lesions and criteria that highlights multiple lesions; • The criteria for Melanoma disease indication has had SIGNIFICANT revisions- OLD *CRITERIA Yervoy® is being used as adjuvant treatment of Stage III sentinel node positive or clinically positive node(s) melanoma; OR Yervoy® is being used as adjuvant treatment of nodal recurrent resectable or dissectible melanoma; OR Yervoy® is being used as monotherapy for metastatic or unresectable disease as the first line therapy if clinical stability is anticipated for > 12 weeks; OR Yervoy® is being used as monotherapy for metastatic or unresectable disease; OR Yervoy® is being used as monotherapy for metastatic or unresectable disease as second line therapy or subsequent therapy for disease progression or following maximum clinical benefit from BRAF targeted therapy for patients with performance status 0 – 2; OR Yervoy® is being used as monotherapy for metastatic or unresectable disease as re-induction therapy in select patients who experienced no significant systemic toxicity during prior ipilimumab therapy AND who relapse after initial clinical response or progress after stable disease > three months; OR Yervoy® is being used in combination with Nivolumab for metastatic or unresectable disease as first-line treatment OR second-line with performance status 0-2 (PS 0-2 for second/subsequent therapy only):* NEW CRITERIA *Coverage may be provided when the diagnosis is unresectable or metastatic melanoma and the following criteria are met:. The patient is 18 years of age or older; AND Treatment is prescribed by an oncologist or hematologist; AND the patient has Stage III (unresectable) or Stage IV (metastatic) disease... 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: The patient is 18 years of age or older; AND Treatment is prescribed by an* oncologist *or hematologist; AND 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* NEW CRITERIA *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: The patient is 18 years of age or older; AND Treatment is prescribed by an oncologist or hematologist; AND 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;* • Dosage information has been updated for **all disease indications**
5/17/2017	QI/UM Committee approval
7/19/2017	Provider effective date