Gateway Health

Policy and Procedure

Policy Name:	Yervoy® (Ipilimumab)
Policy Number:	MP-008-ALL-ALL
Division:	Health Services
Responsible Department:	Medical Management Medical Policy
Related Department(s):	Utilization Management, Claims & Systems Configuration, Appeals & Grievances
Copied Department(s):	Provider Relations, Clinical Pharmacy
Related Policy Number(s):	CP-206.75-MD-PA, CP-200-MD-PA, CP-202-MD-PA, CP-206-MD-PA, UM-225-MD-PA, RCL-103-ALL-ALL, RCL-106-ALL-ALL, RCL-108-ALL-ALL
Effective Date:	
Revision Date(s):	
Inactive date:	
Prior Policy Number:	
Required Signatures	
Division Vice President	
Director/Manager	Edwin J. Kairis MD

Policy Statement

Gateway Health Plan® provides coverage under the medical surgical and specialty pharmacy benefits of the Company's Medicaid and Medicare products for medically necessary administration of Yervoy® (Ipilimumab). Coverage will be provided utilizing the criteria developed by the Gateway Health Plan® (Gateway) Pharmacy and Therapeutics Subcommittee and approved by the Quality Improvement/Utilization Management Committee.

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 warrants individual consideration, based upon review of applicable medical records.

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

Definitions

Prior Authorization Review Panel – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Attachments

Attachment A: Table of Diagnosis Codes
Attachment B: Scientific Background and Reference Sources
Attachment C: The Eastern Cooperative Oncology Group (ECOG) Performance Status

Procedures

Gateway Health Plan® considers ipilimumab (Yervoy) medically necessary for the treatment of Central Nervous System Cancer and Melanoma. In addition the member must meet the following criteria:

1. Central Nervous System Cancer
   The patient must be diagnosed with Central Nervous System Cancer with limited (one to three) metastatic lesions; AND
   A. Yervoy® is being used as monotherapy for brain metastases if active against the primary tumor (melanoma) for recurrent disease
   B. The dosing is within the following prescribing-supported parameters:
      a. Dose does not exceed more than four total doses over the first 16 weeks
      b. Dose does not exceed one dose every 12 weeks for ongoing treatment

2. The patient must be diagnosed with Central Nervous System Cancer with multiple (greater than three) metastatic lesions; AND
    A. Yervoy® is being used as monotherapy if active against the primary tumor (melanoma) for brain metastases in patient with recurrent stable systemic disease
    B. The doing is within the following prescribing-supported parameters:
        - The dose does not exceed more than four total doses over the first 16 weeks of treatment
        - The dose does not exceed one dose every 12 weeks for ongoing treatment
        - The dose does not exceed 10 mg/kg/dose

3. The patient must be diagnosed with Melanoma; AND
    A. The patient is 18 years of age or older; AND
    B. Yervoy® is being used as adjuvant treatment of Stage III sentinel node positive or clinically positive node(s) melanoma; OR
    C. Yervoy® is being used as adjuvant treatment of nodal recurrent resectable or dissectible melanoma; OR
    D. 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
    E. 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
    F. 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
    G. 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):
    H. The dosing is within the following prescribing-supported parameters:
        - The dose does not exceed four doses over the first 12 weeks for adjuvant therapy
        - The dose does not exceed more than four doses over a maximum of 16 weeks for unresectable or metastatic disease when used as monotherapy
        - The dose does not exceed 10 mg/kg/dose for adjuvant therapy
        - The dose does not exceed 3 mg/kg/dose as monotherapy for unresectable or metastatic disease

4. There are no Medicare coverage determinations addressing coverage for Yervoy, Therefore, this medical policy is applicable to Gateway's Medicare plans.

5. Contraindications-None

6. Procedure Code
   J9228-Injection, Ipilimumab, 1 mg, IV

7. When Yervoy® is not covered
   All other indications not otherwise listed are considered experimental/investigational as the scientific evidence does not support the use of ipilimumab for any other indication.

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

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

9. Place of Service for this medication to be administered is outpatient.

10. Length of Coverage
    - Approval is provided for a twelve month duration when used as adjuvant treatment
    - Approval is provided for a seventeen weeks when used in metastatic or unresectable disease

11. 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
    Accessed 02/02/2016.

Policy Implementation/Update/Information

Date	Policy Information

Attachment A

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
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
D03.60	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

Attachment B

Scientific Background and Reference Sources

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

Attachment C

The Eastern Cooperative Oncology Group (ECOG) Performance Status

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50 percent of waking hours
3	Capable of only limited self-care, confined to bed or chair more than 50 percent of waking hours
4	Completely disabled. Cannot carry on any self-care: totally confined to bed or chair
5	Dead

Oken MM, Creech RH, Tormey DC, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol.*1982;5(6):649-655.