| MEDICAL PAYMENT and PRIOR-AUTHORIZATION POLICY | |
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| **Policy Name:** | **Yervoy® (Ipilimumab)** |
| Policy Number: | MP-008-MD-PA |
| Approved By: | Medical Management |
| Provider Notice Date: | May 23, 2016 |
| Original Effective Date: | July 1, 2015 |
| Annual Approval Date: | |
| Revision Date: | March 17, 2016 |
| Products: | Pennsylvania Medicaid and Medicare Advantage |
| Application: | All participating and non-participating hospitals |
| Page Number(s): | 1 of 4 |

## Disclaimer

***Gateway Health℠'s (Gateway) medical payment and prior-authorization 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 Plan® (Gateway) 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 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 (DHS) who have been assigned organizational responsibility for the review, approval and

denial of all PH-MCO Prior Authorization policies and procedures.

**PROCEDURES**

Gateway 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.

**AUTHORIZATION and CODING REQUIREMENTS:**

Authorization from Gateway is not required for Observation Services performed on an outpatient basis, as part of an Emergency Room visit, or as a result of false labor. These claims should be billed with a 762 revenue code.

If a provider contacts Gateway's UM department for authorization of an admission that is less than 24 hours, UM will advise the provider that an authorization is not required for observation services. These claims should be billed with a 760 revenue code.

Observation services provided prior to an authorized admission will be covered by the inpatient admission authorization and payment, based on rules of medical necessity. The admission date will be the date the patient presented to the facility.

The number of units reported with HCPCS code G0378 or HCPCS Code G0379 must equal or exceed 8 hours.

The claim for observation services must include one of the following services in addition to the reported observation services. The additional services listed below must have a line item date of service on the same day or the day before the date reported for observation:

- A Type A or B emergency department visit (CPT codes 99284 or 99285 or HCPCS code G0384); or
- A clinic visit (HCPCS code G0463); or
  Critical care (CPT code 99291); or
- Direct referral for observation care reported with HCPCS code G0379 must be reported on the same date of service as the date reported for observation services.
- For payment, a HCPCS Type A ED visit code 99284, 99285, or G0384 Type B ED visit code, critical care (99291), or a G0463 HCPCS clinic visit code is required to be billed on the day before or the day that the patient is placed in observation. If the patient is a direct referral to observation the G0379 may be reported in lieu of an ED or clinic code. In addition, the E/M code associated with these other services must be billed on the same claim form as the observation service and the E/M must be billed with a modifier -25 if it has the same date of service as the observation code G0378.

**REIMBURSEMENT:**

Participating facilities will be reimbursed per their Gateway contract. If a participating facility is contractually reimbursed a case rate, the case rate will be paid per the contract once the minimum of 8 hours is met along with the other observation rules. If a participating facility is contractually reimbursed an hourly rate, the hourly rate will begin once the minimum of 8 hours is met along with the other observation rules, payment beginning with the first hour eligible for reimbursement. If a participating facility is contractually reimbursed in blocks of hours or incrementally, the blocks of hours or increments will begin once the minimum of 8 hours is met along with the other observation rules, payment beginning with the first hour eligible for reimbursement.

Non-participating facilities will not be reimbursed for observation services.

Observation Services as part of a short procedure unit service (revenue code 761) are not compensable as a separate service and are included in the payment for the short procedure unit service. SPU services require prior authorization from Gateway's UM department.

If a member receives services from a lower level of care and is moved into observation and observation rules are met the lower level of care is considered inclusive of observation. For example if a member presents in the emergency department and is moved to observation, observation will be reimbursed and the emergency services will be inclusive of the observation reimbursement and not be separately reimbursed.

If a member is admitted as an inpatient following observation, outpatient surgery or an emergency room event, the Facility is required to notify Gateway Health Plan and obtain an authorization. Failure to obtain an authorization could result in the inpatient claim and all other billed services being denied. All emergency room, outpatient surgery and observation charges related to the inpatient stay are to be included on the inpatient billing form and reimbursement will be at the authorized inpatient rate with no separate payment for the emergency room, outpatient surgery and/or observation charges.

***Policy Source(s):***

*Yervoy® (lpilimumab) [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 Eng/ J Med. 2010;363:711-23*