JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP119
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	Subject **Yervoy**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Yervoy

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I. POLICY

A. Yervoy (ipilimumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Yervoy may be approved for patients who meet the following:
   1. Cutaneous Melanoma
      a. Documentation has been submitted showing Yerviy will be used in one of the following clinical situations:
         I. Monotherapy or in combination with nivolumab (for 4 doses followed by nivolumab as a single agent) for metastatic or unresectable disease
         II. Monotherapy or in combination with nivolumab as adjuvant treatment if no evidence of disease following metastasis-directed therapy (i.e., complete resection)
         III. At a low dose in combination with pembrolizumab for disease progression following single-agent anti-PD-1 therapy as subsequent therapy for metastatic or unresectable disease
         IV. Monotherapy for limited resectable local recurrence after prior anti-PD-1 therapy
         V. Authorization of 6 months may be granted for treatment of cutaneous melanoma in any of the following settings:
   2. Uveal Melanoma
      a. Documentation has been submitted showing the following:
         I. Patient has been diagnosed with unresectable or metastatic uveal melanoma
         II. Yervoy will be used as monotherapy or in combination with nivolumab
   3. CNS Brain Metastases
      a. Documentation has been submitted showing the following:
         I. Patient has been diagnosed with melanoma and CNS brain metastases
         II. Yervoy will be used as monotherapy or in combination with nivolumab
   4. Non-Small Cell Lung Cancer (NSCLC)
      a. Documentation has been submitted showing the following:
         I. Patient has been diagnosed with recurrent, advanced or metastatic non-small cell lung cancer

II. Molecular testing showing there are no EGFR exon 19 deletions or exon 21 L858R mutations and ALK rearrangements
III. Yervoy will be used in combination with nivolumab

5. Renal Cell Carcinoma
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with relapsed, advanced, or stage IV renal cell carcinoma with clear cell histology
      II. Yervoy will be used in combination with nivolumab (for 4 doses, followed by single agent nivolumab)
6. Colorectal Cancer
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma
      II. Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors confirmed by laboratory testing
      III. Yervoy will be used in combination with nivolumab (for 4 doses, followed by single agent nivolumab)
7. Pleural or Peritoneal Mesothelioma
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with pleural or peritoneal mesothelioma, including pericardial mesothelioma and tunica vaginalis testis mesothelioma
      II. Yervoy will be used in combination with nivolumab
8. Hepatocellular Carcinoma
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with hepatocellular carcinoma
      II. Yervoy will be used in combination with nivolumab (for 4 doses, followed by single agent nivolumab)
9. Small Bowel Adenocarcinoma
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with hepatocellular carcinoma
      II. Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors confirmed by laboratory testing
      III. Yervoy will be used in combination with nivolumab (for 4 doses, followed by single agent nivolumab)
10. Ampullary Adenocarcinoma
    a. Documentation has been submitted showing the following:
       I. Patient has been diagnosed with progressive, unresectable, or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) ampullary adenocarcinoma
       II. Yervoy will be used in combination with nivolumab
11. Esophageal and Esophagogastric Junction Cancers
    a. Documentation has been submitted showing one of the following:
       I. Patient has been diagnosed with esophageal or esophagogastric junction cancer and meets both of the following:
          i. Patient meets either of the following clinical situations:
             A. Cancer is not eligible for surgical intervention
             B. Unresectable locally advanced, recurrent, or metastatic disease
          ii. Yervoy will be used in combination with nivolumab

II. Patient has been diagnosed with esophageal or esophagogastric junction cancer and meets all of the following:
    i. Patient's tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
    ii. Patient member is medically fit for surgery
    iii. Yervoy will be used in combination with nivolumab for neoadjuvant or perioperative treatment

12. Gastric Cancer
    a. Documentation has been submitted showing one of the following:
        I. Patient has been diagnosed with gastric adenocarcinoma with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors and meets both of the following:
            i. Patient meets either of the following clinical situations:
                A. Cancer is not eligible for surgical intervention
                B. Unresectable locally advanced, recurrent, or metastatic disease
            ii. Yervoy will be used in combination with nivolumab
        II. Patient has been diagnosed with gastric adenocarcinoma cancer and meets all of the following:
            i. Patient's tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
            ii. Patient member is medically fit for surgery
            iii. Yervoy will be used in combination with nivolumab for neoadjuvant or perioperative treatment
13. Kaposi Sarcoma
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with relapsed/refractory classic Kaposi Sarcoma
        II. Yervoy will be used in combination with nivolumab for subsequent treatment
14. Bone Cancer
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with unresectable or metastatic bone cancer
        II. Disease has tumor mutation burden-high (TMB-H) [#10 mutations/megabase (mut/Mb)] tumors
        III. Disease has progressed following prior treatment and has no satisfactory alternative treatment options
        IV. Yervoy will be used in combination with nivolumab
15. Biliary Tract Cancer (Cholangiocarcinoma and Gallbladder Cancer)
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with Biliary Tract Cancer
        II. Patient has for unresectable or resected gross residual (R2) disease, or metastatic disease that is tumor mutation burden-high (TMB-H) .
        III. Yervoy will be used in combination with nivolumab for subsequent treatment
16. Soft Tissue Sarcoma
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with extremity/body wall sarcomas, head/neck sarcomas,retroperitoneal/intra-abdominal sarcomas, rhabdomyosarcoma, or angiosarcoma.
        II. Yervoy will be used in combination with nivolumab
17. Merkel Cell Carcinoma
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with unresectable, recurrent, or stage IV Merkel cell carcinoma.
        II. Yervoy will be used in combination with nivolumab

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 6-month intervals with documentation showing the patient has not experienced unacceptable toxicity or disease progression while on the current regimen:
    1. Diagnosis-specific limitations:
        a. Adjuvant Treatment of Melanoma: Continuation in 6-months intervals may be allowed for up to 3 years total
        b. Cutaneous Melanoma, Renal Cell Carcinoma, Colorectal Cancer, Hepatocellular Cancer: Continuation in 6-months intervals may be allowed for up to 4 doses maximum (if patient has not already received 4 doses)
        c. Non-Small Cell Lung Cancer, Gastric/ Esophageal/Esophagogastric Junction Cancers, or Pleural Mesothelioma: Continuation in 6-months intervals may be allowed for up to 24 months total

IV. EXCLUSIONS

A. Yervoy will not be covered for the following:
    1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, ipilimumab, 1 mg	J9228

VII. REFERENCES

1. Yervoy [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; February 2023.
2. The NCCN Drugs & Biologics Compendium 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 9, 2024.
3. Watanabe N, Nagata T, Satou Y, et al. NS-065/NCNP-01: An Antisense Oligonucleotide for Potential Treatment of Exon 53 Skipping in Duchenne Muscular Dystrophy. Mol Ther Nucleic Acids. 2018;13:442–449.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation

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