JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP052
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Keytruda

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I. POLICY

A. Keytruda (pembrolizumab) 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. Keytruda may be approved for patients who meet the following:
   1. Cutaneous Melanoma
      a. Documentation has been submitted showing Keytruda will be used in one of the following clinical situations:
         I. Monotherapy for unresectable, or metastatic melanoma
         II. Monotherapy or in combination with ipilimumab as subsequent therapy for disease progression of metastatic or unresectable tumors
         III. Monotherapy adjuvant treatment following complete lymph node resection or complete resection of metastatic disease
   2. Non-small Cell Lung Cancer (NSCLC)
      a. Documentation has been submitted showing the following:
         I. The tumor is negative for EGFR, ALK, and RET gene mutations (unless testing is not feasible due to insufficient tissue or if used in single agent subsequent therapy)
         II. Keytruda will be used in one of the following treatments:
            i. Combination with pemetrexed plus carboplatin or cisplatin for nonsquamous cell histology, as first-line or subsequent treatment* for recurrent, advanced, or metastatic disease
            ii. Combination with carboplatin plus paclitaxel or albumin-bound paclitaxel for squamous cell histology, as first-line or subsequent treatment* for recurrent, advanced, or metastatic disease
               1. (*subsequent therapy is only for ROS1 rearrangement positive tumors and patients with prior crizotinib, entrectinib, or ceritinib therapy)
            iii. Combination with pemetrexed as maintenance therapy for nonsquamous cell histology, if there is tumor response or stable disease following a first-line regimen with pembrolizumab and pemetrexed plus cisplatin or carboplatin

iv. Monotherapy as first-line treatment for recurrent, advanced, or metastatic disease if PD-L1 ≥50% as supported by laboratory testing

v. Monotherapy as subsequent treatment for recurrent, advanced, or metastatic disease, if PD-L1 ≥ 1% as supported by laboratory testing

vi. Monotherapy as maintenance therapy following following first-line monotherapy or pembrolizumab and carboplatin plus paclitaxel or albumin-bound paclitaxel regimen, the tumor has responded or disease stabilized

3. Head and Neck Squamous Cell Cancer
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with very advanced head and neck squamous cell carcinoma (HNSCC)
      II. Keytruda will be used in one of the following treatments:
         ii. Monotherapy for first-line treatment in members whose tumors express PDL1 (CPS ≥ 1) or are microsatellite instability-high (MSI-H).
         iii. Monotherapy for subsequent therapy (regardless of PD-L1 status).
         iv. Combination with fluorouracil and either carboplatin or cisplatin (regardless of PD-L1 status).
4. Salivary Gland Tumors
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with tumor mutational burden high (TMB-H) (≥ 10 mutations/megabase [mut/Mb]) recurrent disease, as supported by laboratory testing
      II. Keytruda will be used as monotherapy
5. Classical Hodgkin Lymphoma
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with relapsed, refractory or progressive classical Hodgkin lymphoma
      II. Keytruda will be used as monotherapy
6. Urothelial Carcinoma – Bladder Cancer
   a. Documentation has been submitted showing that Keytruda will be used as monotherapy in one of the following clinical situations:
      I. First-line therapy in one of the following:
         i. Cisplatin ineligible patients whose tumors express PD-L1 (CPS ≥10) with confirmed by laboratory testing
         ii. Patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression for any of the following:
            A. Stage II or Stage IIIA disease, if tumor is present following reassessment of tumor status 2-3 months after primary treatment with concurrent chemoradiotherapy
            B. Stage IIIB disease as downstaging systemic therapy or following partial response or progression after primary treatment with concurrent chemoradiotherapy
            C. Locally advanced or metastatic disease
            D. Metastatic or local recurrence post-cystectomy
            E. Muscle invasive local recurrence or persistent disease in a preserved bladder
      II. Subsequent therapy for any of the following:
         i. Stage II or Stage IIIA disease, if tumor is present following reassessment of tumor status 2-3 months after primary treatment.

ii. Stage IIIB disease following partial response or progression after primary treatment with concurrent chemoradiotherapy
iii. Locally advanced or metastatic disease.
iv. Metastatic or local recurrence post-cystectomy.
v. Muscle invasive local recurrence or persistent disease in a preserved bladder.

III. Subsequent therapy for treatment of high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) in patients meeting the following:
i. Disease is Bacillus Calmette-Guerin (BCG)-unresponsive
ii. Patient is ineligible for, or has elected not to undergo cystectomy

7. Urothelial Carcinoma – Primary Carcinoma of the Urethra
a. Documentation has been submitted showing that Keytruda will be used as monotherapy in one of the following clinical situations:
I. First-line therapy for recurrent, locally advanced, or metastatic disease in one of the following:
i. Cisplatin ineligible patients whose tumors express PD-L1 (CPS ≥10) confirmed by laboratory testing
ii. Patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression
II. Subsequent therapy for recurrent or metastatic disease

8. Urothelial Carcinoma – Upper Genitourinary Tract Tumors or Urothelial Carcinoma of the Prostate
a. Documentation has been submitted showing that Keytruda will be used as monotherapy in one of the following clinical situations:
I. First-line therapy for metastatic disease in one of the following:
i. Cisplatin ineligible members whose tumors express PD-L1 (CPS ≥10) confirmed by laboratory testing
ii. Patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression
II. Subsequent therapy for metastatic disease

9. Solid Tumors
a. Documentation has been submitted showing the following:
I. Patient has been diagnosed with unresectable or metastatic solid tumor disease that has progressed following prior treatment, and there are no satisfactory alternative treatment options
II. Keytruda will be used as monotherapy for one of the following tumors-types confirmed by laboratory testing:
i. microsatellite instability-high or mismatch repair deficient solid tumors
ii. tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) solid tumors

10. Anaplastic Thyroid Carcinoma
a. Documentation has been submitted showing Keytruda will be used as monotherapy for metastatic anaplastic thyroid carcinoma for laboratory-confirmed tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) tumors.

11. Follicular, Hürthle Cell, or Papillary Thyroid Carcinoma
a. Documentation has been submitted showing the following:
I. Keytruda will be used for treatment of unresectable or metastatic follicular, hürthle cell, or papillary thyroid carcinoma for tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) tumors, confirmed by laboratory testing

II. Disease is not amenable to radioactive iodine therapy

12. Medullary Thyroid Carcinoma
    a. Documentation has been submitted showing Keytruda will be used for treatment of unresectable, recurrent, or metastatic medullary thyroid carcinoma for tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) tumors, confirmed by laboratory testing
13. Colorectal Cancer
    a. Documentation has been submitted showing Keytruda will be as monotherapy for inoperable, advanced, or metastatic colorectal cancer, including appendiceal carcinoma, for microsatellite instability-high or mismatch repair deficient tumors, confirmed by laboratory testing
14. Small Bowel Adenocarcinoma
    a. Documentation has been submitted showing Keytruda will be used as monotherapy for advanced or metastatic small bowel adenocarcinoma, including advanced ampullary cancer, for microsatellite instability-high or mismatch repair deficient tumors, confirmed by laboratory testing
15. Malignant Pleural Mesothelioma
    a. Documentation has been submitted showing Keytruda will be used as monotherapy for subsequent treatment of malignant pleural mesothelioma
16. Merkel Cell Carcinoma
    a. Documentation has been submitted showing Keytruda will be used for treatment of Merkel cell carcinoma in patients with recurrent or metastatic disease
17. Gastric Cancer
    a. Documentation has been submitted showing the following:
        I. Patient has one of the following:
            i. Gastric cancer that is not eligible for surgical intervention
            ii. Unresectable locally advanced, recurrent, or metastatic gastric cancer
        II. Keytruda will be used in one of the following clinical situations:
            i. Monotherapy as second-line or subsequent therapy for a tumor with microsatellite instability-high or deficient mismatch repair or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) confirmed by laboratory testing
            ii. Monotherapy as third-line or subsequent therapy for a PD-L1 positive tumor (CPS ≥ 1) confirmed by laboratory testing
            iii. Combination with trastuzumab, platinum and fluoropyrimidine-based chemotherapy in HER2 overexpression positive adenocarcinoma confirmed by laboratory testing
18. Esophageal Cancer and Esophagogastric Junction Cancer
    a. Documentation has been submitted showing the following:
        I. Patient has one of the following:
            i. Esophageal cancer (including esophagogastric junction (EGJ) cancer) that is not eligible for surgical intervention
            ii. Unresectable locally advanced, recurrent, or metastatic esophageal cancer
        II. Keytruda will be used in one of the following clinical situations:
            i. Monotherapy as second-line or subsequent therapy for a tumor with microsatellite instability-high or deficient mismatch repair or tumor mutational burden (TMB) high (≥10 mutations/megabase (mut/Mb)) confirmed by laboratory testing

ii. Second-line or subsequent therapy for laboratory-confirmed PD-L1 tumor expression by CPS ≥10 for squamous cell carcinoma
iii. Monotherapy as third-line or subsequent therapy for a PD-L1 positive tumor (CPS ≥ 1) confirmed by laboratory testing
iv. Combination with platinum and fluoropyrimidine-based chemotherapy for HER2 overexpression negative patients
v. Combination with trastuzumab, platinum and fluoropyrimidine-based chemotherapy for HER2 overexpression positive Patients

19. Cervical Cancer
    a. Documentation has been submitted showing the following:
        I. Keytruda will be used as subsequent therapy for cervical cancer in one of the following clinical situations:
            i. Combination with chemotherapy in patients with persistent, recurrent or metastatic disease whose tumors express PD-L1 (CPS #1) as confirmed by laboratory testing
            ii. Monotherapy for persistent, recurrent or metastatic disease that is microsatellite instability-high or mismatch repair deficient as confirmed by laboratory testing
            iii. Monotherapy for persistent, recurrent or metastatic disease in patients with tumors that express PD-L1 (CPS ≥1), confirmed by laboratory testing, that have experienced disease progression on or after chemotherapy
            iv. Monotherapy for unresectable or metastatic disease in patients with tumors that are tissue tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]), confirmed by laboratory testing, and have progressed following prior treatment and there are no satisfactory alternative treatment options
20. Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer
    a. Documentation has been submitted showing the following:
        I. Keytruda will be used as monotherapy for one of the following conditions:
            i. Epithelial ovarian cancer
            ii. Fallopian tube cancer
            iii. Primary peritoneal cancer
            iv. Carcinosarcoma (malignant mixed Mullerian tumors)
            v. Clear cell carcinoma
            vi. Mucinous carcinoma
            vii. Grade 1 endometrioid carcinoma
            viii. Low-grade serous carcinoma/ovarian borderline epithelial tumors (low malignant potential with invasive implants)
        II. Patient has recurrent or persistent microsatellite instability-high or mismatch repair deficient tumors or tumor mutational burden-high (TMB-H) (tumors ≥ 10 mutations/megabase [mut/Mb]) confirmed by laboratory testing, and no satisfactory alternative treatment options
21. Uveal Melanoma
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for treatment of uveal melanoma for distant metastatic disease
22. Testicular Cancer

a. Documentation has been submitted showing that Keytruda will be used as monotherapy for third-line therapy of testicular cancer in patients with microsatellite instability-high or mismatch repair deficient or tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) tumors, confirmed by laboratory testing

23. Endometrial Carcinoma
    a. Documentation has been submitted showing that Keytruda will be used in one of the following clinical situations:
        I. Treatment of recurrent, metastatic, or high-risk microsatellite instability-high or mismatch repair deficient tumors (confirmed by laboratory testing) that has progressed following prior systemic therapy
        II. Combination with lenvatinib for advanced or recurrent endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient AND the following:
            i. Patient has had disease progression following prior systemic therapy
            ii. Patient is not a candidate for curative surgery or radiation.
        III. Monotherapy for unresectable or metastatic tumor mutational burden-high (TMB-H) (≥10 mutations/ megabase [mut/Mb]) tumors (confirmed by laboratory testing) AND the following:
            i. Patient has experienced disease progression following prior treatment and there is no satisfactory alternative treatment.
24. Anal Carcinoma
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for second-line or subsequent therapy treatment of metastatic anal carcinoma
25. CNS Brain Metastases
    a. Documentation has been submitted showing the following:
        I. Keytruda will be used as monotherapy for treatment of CNS brain metastases
        II. Patient has been diagnosed with melanoma or PD-L1 positive non-small cell lung cancer, confirmed by laboratory testing
26. Primary Mediastinal Large B-Cell Lymphoma
    a. Documentation has been submitted showing the following:
        I. Keytruda will be used as monotherapy for treatment of primary mediastinal large Bcell lymphoma
        II. Patient has been diagnosed with relapsed or refractory disease
27. Pancreatic Adenocarcinoma
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with pancreatic adenocarcinoma with microsatellite instability-high or mismatch repair deficient tumors, confirmed by laboratory testing
        II. Keytruda will be used as monotherapy in one of the following clinical situations:
            i. Subsequent therapy for locally advanced or metastatic disease and disease progression
            ii. Local recurrence in the pancreatic operative bed after resection or recurrent metastatic disease
            iii. First-line therapy for metastatic disease in patients with poor performance status
28. Hepatobiliary Cancers
    a. Documentation has been submitted showing the following:
        I. Patient has been diagnosed with unresectable or metastatic hepatobiliary cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer
        II. Disease has been confirmed through laboratory results to be microsatellite instability-high or mismatch repair deficient
        III. Keytruda will be used as monotherapy for initial treatment or progression of disease
29. Hepatocellular Carcinoma

a. Documentation has been submitted showing that Keytruda will be used for treatment of hepatocellular carcinoma that has been previously treated with sorafenib

30. Vulvar Cancer
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for second-line or subsequent treatment of advanced, recurrent or metastatic squamous cell vulvar cancer in patients with one of the following:
        I. Microsatellite instability-high or mismatch repair deficient tumor confirmed by laboratory testing
        II. Tumor expressing PD-L1 (CPS ≥1) confirmed by laboratory testing, and disease progression on or after chemotherapy
        III. Tumor mutational burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]) tumors confirmed by laboratory testing that have progressed following prior treatment and there are no satisfactory alternative treatment options
31. Renal Cell Carcinoma
    a. Documentation has been submitted showing that Keytruda will be used for treatment of renal cell carcinoma in one of the following clinical situations:
        I. Combination with axitinib or lenvatinib as first-line treatment for advanced, relapsed or stage IV disease
        II. Combination with axitinib or lenvatinib as subsequent therapy for relapsed or stage IV disease with clear cell histology
        III. Monotherapy for relapsed or stage IV disease with non-clear cell histology
32. Thymic Carcinoma
    a. Documentation has been submitted showing Keytruda will be used as monotherapy for thymic carcinoma in one of the following:
        I. Treatment of unresectable, locally advanced, or metastatic disease
        II. Postoperative therapy for residual tumor in patient who cannot tolerate first-line combination regimens
33. Mycosis Fungoides/Sezary Syndrome
    a. Documentation has been submitted showing Keytruda will be used for treatment of Mycosis Fungoides or Sezary syndrome
34. HH.Extranodal NK/T-cell lymphoma, nasal type
    a. Documentation has been submitted showing Keytruda will be used for treatment of extranodal NK/T-cell lymphoma, nasal type, in patients with relapsed or refractory disease
35. Gestational Trophoblastic Neoplasia
    a. Documentation has been submitted showing the following:
        I. Keytruda will be used as monotherapy for treatment of gestational trophoblastic neoplasia for multi-agent chemotherapy-resistant disease
        II. Patient has one of the following:
            i. Recurrent or progressive intermediate trophoblastic tumor (placental site trophoblastic tumor or epithelioid trophoblastic tumor) following treatment with a platinum/etoposide-containing regimen
            ii. High-risk disease
36. Neuroendocrine and Adrenal Tumors
    a. Documentation has been submitted showing Keytruda will be used as one of the following
        I. Treatment of poorly differentiated/large or small cell carcinoma in patients that have progressed following prior treatment and who have no satisfactory alternative treatment options, and Keytruda will be used for one of the following:
            i. Microsatellite instability-high or mismatch repair deficient tumors, confirmed by laboratory testing.

ii. Tumor mutational burden-high tumors (≥10 mutations/megabase [mut/Mb]), confirmed by laboratory testing

II. Treatment of locally advanced or metastatic well differentiated grade 3 neuroendocrine tumors that are tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) (confirmed by laboratory testing), and disease has progressed following prior treatment and there is no satisfactory alternative treatment options

III. Treatment of unresectable or metastatic adrenocortical carcinoma.

37. Cutaneous Squamous Cell Carcinoma
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for treatment of cutaneous squamous cell carcinoma that is not curable by surgery or radiation
38. Soft Tissue Sarcoma
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for treatment of one of the following types of soft tissue sarcoma:
        I. alveolar soft part sarcoma (ASPS)
        II. myxofibrosarcoma
        III. undifferentiated pleomorphic sarcoma (UPS)
        IV. cutaneous angiosarcoma
        V. undifferentiated sarcoma
39. Occult Primary Cancer
    a. Documentation has been submitted showing the following:
        1. Keytruda will be used as monotherapy for treatment of occult primary cancer
        2. Patient has microsatellite instability-high or mismatch repair deficient tumors or tumor mutational burden-high (TMB-H) (≥ 10 mutations/megabase (mut/Mb) tumors), confirmed by laboratory testing
40. Breast Cancer
    a. Documentation has been submitted showing Keytruda will be used for one of the following:
        I. Combination with chemotherapy for treatment of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) with the following:
            i. The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
                A. Human epidermal growth factor receptor 2 (HER-2)
                B. Estrogen
                C. Progesterone
                D. Tumor must express PD-L1 (CPS ≥10)
        II. Neoadjuvant treatment in combination with chemotherapy, or monotherapy for adjuvant treatment after surgery for high-risk early-stage triple-negative breast cancer (TNBC) with the following:
            i. The diagnosis of triple-negative breast cancer is confirmed by the cancer cells testing negative for ALL of the following receptors:
                A. Human epidermal growth factor receptor 2 (HER-2)
                B. Estrogen
                C. Progesterone
        III. Monotherapy for recurrent unresectable or metastatic breast cancer with the following:
            i. Disease has progressed following prior treatment, and the patient has no satisfactory alternative treatment options

ii. Tumors are microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR),or tissue tumor mutation burden-high (TMB-H) (≥10 mutations/megabase [mut/Mb]), as confirmed by laboratory testing

41. Prostate Cancer
    a. Documentation has been submitted showing the following:
        I. Keytruda will be used as monotherapy for subsequent therapy for treatment of castration-resistant distant metastatic prostate cancer
        II. Patient has microsatellite instability-high, mismatch repair deficient, or tumor mutational burden (TMB) ≥10 mutations/megabase tumors confirmed by laboratory testing
42. Bone Cancer – Chondrosarcoma, Chordoma, Ewing Sarcoma, Osteosarcoma
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for unresectable or metastatic tumors AND the following:
        I. Disease has progressed following prior treatment and the patient has no satisfactory alternative treatment options
        II. Tumors are microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or tissue tumor mutation burden-high (TMB-H) (≥10 mutations/megabase (mut/Mb), as confirmed by laboratory testing
43. Penile Cancer
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for subsequent treatment of unresectable or metastatic, laboratory-confirmed microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors that have progressed following prior treatment, and there are no satisfactory alternative treatment options
44. Uterine Sarcoma
    a. Documentation has been submitted showing that Keytruda will be used as monotherapy for subsequent treatment of unresectable or metastatic, laboratory-confirmed tumor mutational burden-high (TMB-H) [≥10 mutations/megabase (mut/Mb)] tumors that have progressed following prior treatment, and there are no satisfactory alternative treatment options
45. Small Cell Lung Cancer
    a. Documentation has been submitted showing Keytruda will be used as monotherapy for subsequent therapy of relapsed or progressive disease

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 disease progression or unacceptable toxicity following treatment
    1. Diagnosis-specific limitations:
        a. Adjuvant treatment of melanoma or high-risk early-stage TNBC:
            I. Continuation in 6-months intervals may be allowed for up to 12 months total
        b. NSCLC, HNSCC, cHL, PMBCL, MSI-H or dMMR Cancers, Gastric Cancer, Esophageal Cancer, Cervical Cancer, HCC, MCC, RCC, Endometrial carcinoma, cSCC, locally recurrent unresectable or metastatic TNBC, TMB-H Cancer:
            I. Continuation in 6-months intervals may be allowed for up to 24 months total of continuous use

c. Urothelial Carcinoma:
   I. Continuation in 6-months intervals may be allowed for up to 24 months total of continuous use
   II. Additional requirement for high-risk BCG-unresponsive non-muscle invasive bladder cancer: Documentation is required showing the disease is not persistent or recurrent

IV. EXCLUSIONS

1. A. Keytruda will **not** be covered for the following:
   1. Pediatric patients with MSI-H central nervous system cancers
   2. Pediatric patients with TMB-H central nervous system cancers
   3. Patients who have experienced disease progression while on programmed death receptor-1 (PD-1) or PD-L1 inhibitor therapy (other than when used as second-line or subsequent therapy for metastatic or unresectable melanoma in combination with ipilimumab following progression on single agent anti-PD-1 immunotherapy).
   4. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

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

VI. CODES

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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, pembrolizumab, 1 mg	J9271

VII. REFERENCES

1. Keytruda [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; October 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 14, 2022.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
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