Mass General Brigham
Health Plan

Oncology Immunotherapies
Effective 05/06/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693 **Non-Specialty Medications** All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions			

Overview

No PA	Drugs that require PA
Alternatives vary by specific malignancy and may include systemic chemotherapy (e.g., platinum [cisplatin, carboplatin]-containing regimens for non-small cell lung cancer).	Bavencio (avelumab) [MB] Imfinzi (durvalumab) [MB] Imjudo® (tremelimumab-actl) [MB] Jemperli (dostarlimub-gxly) [MB] Keytruda (pembrolizumab) [MB] Libtayo (cemiplimab-rwlc) [MB] Opdivo (nivolumab) [MB] Opdualag (nivolumab and relatlimab-rmbw) [MB] Tecentriq (atezolizumab) [MB] Yervoy (ipilimumab) [MB] Zynyz® (retifanlimab-dlwr) [MB]

MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Bavencio® (avelumab)

ONE of the following:

1. Diagnosis of **renal cell carcinoma (RCC)** – first-line treatment
    a. Prescriber is an oncologist

b. Appropriate dosing
c. Tumor is clear cell histology
d. Requested agent will be used in combination with Inlyta® (axitinib)

2. Diagnosis of **locally advanced or metastatic urothelial carcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing *(weight required)*
    c. **ONE** of the following:
        i. Physician attestation of inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing regimens
        ii. Disease has not progressed following treatment with four to six cycles of first-line platinum-containing chemotherapy
3. Diagnosis of **metastatic Merkel cell carcinoma (MCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing *(weight required)*

Keytruda® (pembrolizumab)

ONE of the following:

1. Diagnosis of **metastatic Merkel cell carcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing *(weight required)*
2. Diagnosis of **cervical cancer**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Tumor expresses PD-L1 (CPS ≥1)
    d. **ONE** of the following:
        i. Requested agent will be used in combination with chemotherapy, with or without bevacizumab
        ii. **BOTH** of the following:
            1. Disease progression following **ONE** systemic chemotherapy regimen
            2. Requested agent will be used as monotherapy
3. Diagnosis of **advanced endometrial carcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Paid claims or physician attestation of inadequate response or adverse reaction to **ONE** prior line of systemic therapy, or contraindication to **ALL** systemic therapies *(see appendix for prior systemic therapy)*
    d. Member is not a candidate for surgery or radiation
    e. **ONE** of the following:
        i. For advanced endometrial carcinoma that is not MSI-H or dMMR, requested agent will be used in combination with Lenvima® (l2envatinib)
        ii. For advanced endometrial carcinoma that is MSI-H or dMMR, requested agent will be used as monotherapy
4. Diagnosis of **advanced renal cell carcinoma (RCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Tumor is clear cell histology and **ONE** of the following:
            1. Requested agent will be used in combination with Inlyta® (axitinib)

2. Requested agent will be used in combination with Lenvima® (3lenvatinib)
3. Requested agent will be used as adjuvant treatment following nephrectomy

ii. **BOTH** of the following:
1. Tumor is non-clear cell histology
2. Paid claims or physician attestation of inadequate response, adverse reaction to **ONE** or contraindication to **BOTH** of the following:
a. Cabometyx® (cabozantinib)
b. Sutent® (sunitinib)

5. Diagnosis of **stage IIB, IIC or III melanoma**
a. Prescriber is an oncologist
b. Appropriate dosing
c. Requested agent will be used as adjuvant treatment following complete resection
6. Diagnosis of **primary mediastinal B-cell lymphoma (PMBCL)**
a. Prescriber is an oncologist
b. Appropriate dosing
c. Physician attestation of inadequate response or adverse reaction to **TWO** systemic chemotherapy regimens or contraindication to the use of **ALL** systemic chemotherapy
7. Diagnosis of **recurrent or metastatic head and neck squamous cell carcinoma (HNSCC)**
a. Prescriber is an oncologist
b. Appropriate dosing
c. **ONE** of the following:
i. Cancer is non-nasopharyngeal and **ONE** of the following:
1. Requested agent is used in combination with a platinum agent (cisplatin or carboplatin) and fluorouracil
2. Tumor is PD-L1 positive (CPS ≥1)
ii. Inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing regimens
8. Diagnosis of **microsatellite instability-high/mismatch repair deficient (MSI-H/dMMR) solid tumors <u>or</u> metastatic colorectal cancer (mCRC)**
a. Prescriber is an oncologist
b. Appropriate dosing *(weight required)*
9. Diagnosis of **urothelial carcinoma** – Locally advanced or metastatic disease
a. Prescriber is an oncologist
b. Appropriate dosing
c. **ONE** of the following:
i. **BOTH** of the following
1. Requested agent will be used as monotherapy
2. Inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing chemotherapy regimens
ii. **BOTH** of the following
1. Requested agent will be used in combination with Padcev®
2. Contraindication to **ALL** cisplatin-containing chemotherapy
10. Diagnosis of **stage III non-small cell lung cancer (NSCLC)**
a. Prescriber is an oncologist
b. Appropriate dosing
c. Tumor expresses PD-L1 (TPS ≥1%)
a. Requested agent will be used with carboplatin and either pemetrexed or paclitaxel *(e.g., may be bypassed is member already completed chemotherapy)*

11. Diagnosis of **tumor mutational burden-high (TMB-H) cancer**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Tumor has ≥10 mutations/megabase (mut/Mb)
12. Diagnosis of **unresectable or metastatic NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Requested agent will be used in combination with pemetrexed and either carboplatin or cisplatin for non-squamous NSCLC in the first-line setting *(e.g., may be bypassed is member already completed chemotherapy)*
        ii. Requested agent will be used in combination with carboplatin and either paclitaxel or albumin-bound paclitaxel for squamous NSCLC in the first-line setting *(e.g., may be bypassed is member already completed chemotherapy)*
        iii. PD-L1 expression and **ONE** of the following:
            1. **BOTH** of the following:
                a. Physician attestation of inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing regimens
                b. Requested agent will be used as monotherapy
            2. **BOTH** of the following:
                a. Member does NOT have EGFR or ALK genomic tumor aberrations
                b. Requested agent will be used as monotherapy in the first-line setting
13. Diagnosis of **resectable Non-Small Cell Lung Cancer (NSCLC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in the neoadjuvant setting in combination with ONE of the following:
        i. carboplatin and paclitaxel
        ii. cisplatin and pemetrexed
        iii. cisplatin and gemcitabine
        iv. cisplatin and paclitaxel
    d. Requested agent will be continued as monotherapy as adjuvant treatment after surgery
14. Diagnosis of **stage IB (T2a ≥4 cm), II, or IIIA NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used as adjuvant treatment following resection and platinum-based chemotherapy
15. Diagnosis of **high-risk early stage triple-negative breast cancer (TNBC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with chemotherapy *(e.g., carboplatin, paclitaxel, cyclophosphamide, doxorubicin, epirubicin)* and then continued as single agent following surgery
16. Diagnosis of **unresectable locally advanced or metastatic TNBC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member is PD-L1 positive (CPS ≥10)
    d. Requested agent will be used in combination with ONE of the following:

i. paclitaxel protein-bound
ii. paclitaxel
iii. gemcitabine and carboplatin

17. Diagnosis of **non-muscle invasive bladder cancer (NMIBC)**
    a. Prescriber is an oncologist or urologist
    b. Appropriate dosing
    c. Physician attestation of inadequate response, adverse reaction, or contraindication to BCG
    d. Disease is high-risk with carcinoma in situ
18. Diagnosis of **metastatic squamous cell carcinoma of the esophagus (ESCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Tumor expresses PD-L1 (CPS ≥10)
    d. Physician attestation of inadequate response or adverse reaction to **ONE** line of systemic therapy, or contraindication to **ALL** other lines of systemic therapy
19. Diagnosis of **advanced, recurrent or metastatic esophageal or esophagogastric junction (EGJ) cancer**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. If previously untreated, requested agent will be used in combination with a fluoropyrimidine- and platinum-containing regimen
        ii. **BOTH** of the following:
            1. Requested agent will be used as monotherapy
            2. Member had at least ONE prior line of systemic therapy for squamous cell tumor with PD-L1 (CPS ≥10)
20. Diagnosis of **unresectable or metastatic HER2-<u>positive</u> gastric adenocarcinoma, or gastroesophageal junction adenocarcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with trastuzumab, fluoropyrimidine-, and platinum-containing chemotherapy
21. Diagnosis of **unresectable or metastatic HER2- <u>negative</u> gastric or gastroesophageal junction (GEJ) adenocarcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with BOTH of the following:
        i. fluoropyrimidine- containing regimen
        ii. platinum-containing regimen
22. Diagnosis of **unresectable or metastatic melanoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
23. Diagnosis of **Hodgkin lymphoma** in **adult** members
    a. Prescriber is a hematologist/oncologist
    b. Appropriate dosing
    c. Member is ≥ 18 years of age
    d. **ONE** of the following:
        i. Member progressed after autologous HSCT with or without brentuximab
        ii. Member ineligible for transplant or inadequate response to two or more lines of prior chemotherapy *(see appendix on systemic therapies for Hodgkin lymphoma)*

iii. Member received allogeneic transplant

24. Diagnosis of **Hodgkin lymphoma** in **pediatric** members
    a. Prescriber is a hematologist/oncologist
    b. Appropriate dosing *(appropriate mg/kg dosing may be accepted without documentation of weight for pediatric members)*
    c. Member is < 18 years of age
    d. Inadequate response or adverse reaction to **TWO** or more lines of prior chemotherapy *(see appendix on systemic therapies for Hodgkin lymphoma)*
25. Diagnosis of **hepatocellular carcinoma (HCC)**
    a. Prescriber is a hematologist/oncologist
    b. Appropriate dosing
    c. Physician attestation of inadequate response, adverse reaction, or contraindication to sorafenib
    d. Member has Child-Pugh class A
26. Diagnosis of **metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member is ≥18 years of age
    d. Member is not a candidate for surgery and/or radiation therapy *(e.g., metastatic CSCC)*
27. Diagnosis of **locally advanced or metastatic biliary tract cancer (BTC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with **BOTH** of the following:
        i. cisplatin
        ii. gemcitabine

Libtayo® (cemiplimab-rwlc)

ONE of the following:

1. Diagnosis of **metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member is ≥18 years of age
    d. Member is not a candidate for surgery and/or radiation therapy *(e.g., metastatic CSCC)*
2. Diagnosis of **Basal Cell Carcinoma (BCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** hedgehog pathway inhibitors
3. Diagnosis of **NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Member has locally advanced cancer and is not a candidate for surgical resection or definitive chemoradiation
        ii. Member has metastatic disease
    d. Member does NOT have EGFR, ALK or ROS 1 tumor aberrations
    e. **ONE** of the following:
        i. Physician attestation that requested agent will be used in combination with platinum-based chemotherapy

ii. **BOTH** of the following
    1. Requested agent will be used as monotherapy in the first line setting
    2. Tumor has PD-L1 expression ≥ 50%

Opdivo® (nivolumab)
ONE of the following:

1. Diagnosis of **Stage IIB, IIC or III melanoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used as adjuvant treatment following complete resection
2. Diagnosis of **unresectable or metastatic melanoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
3. Diagnosis of **Hodgkin lymphoma** in **adult** members
    a. Prescriber is a hematologist/oncologist
    b. Appropriate dosing
    c. Member is ≥ 18 years of age
    d. **ONE** of the following:
        i. Member progressed after autologous HSCT with or without brentuximab
        ii. Member ineligible for transplant or inadequate response to two or more lines of prior chemotherapy *(see appendix on systemic therapies for Hodgkin lymphoma)*
        iii. Member received allogeneic transplant
4. Diagnosis of **Hodgkin lymphoma** in **pediatric** members
    a. Prescriber is a hematologist/oncologist
    b. Appropriate dosing *(appropriate mg/kg dosing may be accepted without documentation of weight for pediatric members)*
    c. Member is < 18 years of age
    d. Inadequate response or adverse reaction to **TWO** or more lines of prior chemotherapy *(see appendix on systemic therapies for Hodgkin lymphoma)*
5. Diagnosis of **hepatocellular carcinoma (HCC)**
    a. Prescriber is a hematologist/oncologist
    b. Appropriate dosing
    c. Physician attestation of inadequate response, adverse reaction, or contraindication to sorafenib
    d. Member has Child-Pugh class A or B
6. Diagnosis of **Malignant pleural mesothelioma (MPM)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with Yervoy® (ipilimumab)
7. Diagnosis of **unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Member has received prior fluoropyrimidine- and platinum-based chemotherapy
        ii. Requested agent will be used in combination with a fluoropyrimidine- and platinum-based chemotherapy regimen in the first-line setting
        iii. Requested agent will be used in combination with ipilimumab in the first-line setting

8. Diagnosis of **microsatellite instability-high/mismatch repair deficient metastatic colorectal cancer (MSI-H/dMMR mCRC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Inadequate response or adverse reaction to **ONE**, or contraindication to **ALL** of the following: fluoropyrimidine, oxaliplatin, and irinotecan-containing regimens
9. Diagnosis of **recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing regimens
10. Diagnosis of **completely resected esophageal or gastroesophageal junction cancer**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member has residual pathologic disease
    d. Member has received neoadjuvant chemoradiotherapy (CRT)
11. Diagnosis of **Advanced or metastatic gastric cancer, gastroesophageal junction (GEJ) cancer or esophageal adenocarcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Cancer is HER2 negative
    d. Requested agent is to be used in combination with a fluoropyrimidine- and platinum-containing regimen
12. Diagnosis of **advanced renal cell carcinoma (RCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. **BOTH** of the following:
            1. Member has clear cell histology
            2. Requested agent will be used in combination with Yervoy® (ipilimumab)
        ii. **BOTH** of the following:
            1. Member has clear cell histology
            2. Requested agent will be used in combination with Cabometyx® (cabozantinib)
        iii. **ALL** of the following:
            1. Member has clear cell histology,
            2. Member has received prior anti-angiogenic therapy (e.g., *axitinib, axitinib plus pembrolizumab, axitinib plus avelumab, sunitinib, pazopanib, lenvatinib plus pembrolizumab and cabozantinib)*
            3. Requested agent will be used as monotherapy
        iv. **BOTH** of the following:
            1. Member has non-clear cell histology
            2. Paid claims or physician attestation of inadequate response, adverse reaction to **ONE** or contraindication to **BOTH** of the following:
                a. Cabometyx® (cabozantinib)
                b. sunitinib
13. Diagnosis of **resectable NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing (nivolumab 360 mg every three weeks, max three cycles)

c. Requested agent will be used in the neoadjuvant setting
d. Requested agent will be used in combination with **ONE** of the following:
    i. carboplatin and paclitaxel
    ii. cisplatin and pemetrexed
    iii. cisplatin and gemcitabine

14. Diagnosis of **unresectable or metastatic NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing regimens
        ii. Requested agent is used in combination with ipilimumab and **ONE** of the following:
            1. Pemetrexed and carboplatin
            2. Pemetrexed and cisplatin
            3. Paclitaxel and carboplatin
        iii. Tumor has PD-L1 expression ≥1% and the requested agent is used in combination with ipilimumab
15. Diagnosis of **urothelial carcinoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing *(appropriate mg/kg dosing may be accepted without documentation of weight)*
    c. **ONE** of the following:
        i. Disease progression during or following **ONE** platinum-containing regimen
        ii. Requested agent will be used as adjuvant treatment following radical resection of the bladder or parts of the urinary tract

Opdualag® (nivolumab/ relatlimab-rmbw)

1. Diagnosis of unresectable or metastatic melanoma
2. Prescriber is an oncologist
3. Paid claim or physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. Opdivo (nivolumab) in combination with Yervoy (ipilimumab)
    b. Opdivo (nivolumab)
    c. Keytruda (pembrolizumab)
4. **ONE** of the following:
    a. Member is negative for the BRAF V600E or V600K mutation
    b. Member is positive for BRAF V600E or V600K mutation, and has had an inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
        i. Tafinlar (dabrafenib) and Mekinist (trametinib)
        ii. Zelboraf (vemurafenib) and Cotellic (cobimetinib)
        iii. Braftovi (encorafenib) and Mektovi (binimetinib)
5. Appropriate dosing

Imfinzi® (durvalumab)

ONE of the following:

1. Diagnosis of **extensive stage small cell lung cancer (ES-SCLC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing

c. Member has extensive stage disease *(e.g., cancer has spread beyond the lungs)*
d. Requested agent will be used in combination with etoposide AND either carboplatin or cisplatin *(e.g., may be bypassed is member already completed chemotherapy)*

2. Diagnosis of **Stage III NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing *(weight required)*
    c. Physician attestation that the disease has not progressed following combination therapy with platinum-based chemotherapy and radiation therapy
3. Diagnosis of **locally advanced or metastatic biliary tract cancer (BTC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Physician attestation that requested agent will be used in combination with gemcitabine and cisplatin
4. Diagnosis of **metastatic NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Physician attestation that requested agent will be used in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy
    d. Member does NOT have EGFR or ALK genomic tumor aberrations
5. Diagnosis of **unresectable hepatocellular carcinoma (uHCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Physician attestation that requested agent will be used in combination with Imjudo (tremelimumab-actl)

Imjudo® (tremelimumab-actl)
ONE of the following:

1. Diagnosis of **metastatic non-small cell lung cancer (NSCLC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Physician attestation that requested agent will be used in combination with Imfinzi (durvalumab) and platinum-based chemotherapy
    d. Member does NOT have EGFR or ALK genomic tumor aberrations
    e. Requested quantity is ≤ 5 doses
2. Diagnosis of **unresectable hepatocellular carcinoma (uHCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Physician attestation that requested agent will be used in combination with Imfinzi (durvalumab)
    d. Requested quantity is one dose

Jemperli® (dostarlimab- gxly)
ONE of the following:

1. Diagnosis of **mismatch repair deficient (dMMR) Recurrent or Advanced Solid Tumors**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member is ≥18 years of age

d. Cancer is dMMR (*Documentation must be provided on the PA request or in attached medical records)*
e. Physician attestation of inadequate response or adverse reaction to **ONE** prior treatment for dMMR, or contraindication to **ALL** other treatments for dMMR

2. Diagnosis of **recurrent or advanced endometrial cancer**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member is ≥18 years of age
    d. **ONE** of the following:
        i. Documentation that cancer is mismatch repair deficient (dMMR) and **ONE** of the following:
            1. **BOTH** of the following:
                a. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** platinum-based chemotherapy regimens
                b. Requested agent will be used as monotherapy
            2. Requested agent agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses followed by monotherapy of Jemperli every six weeks
        ii. **BOTH** of the following:
            1. Documentation that cancer is microsatellite instability-high (MSI-H)
            2. Requested agent will be used in combination with carboplatin and paclitaxel every three weeks for six doses followed by monotherapy of Jemperli every six weeks

Tecentriq® (atezolizumab)
ONE of the following:

1. Diagnosis of **Stage II to IIIA NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Tumor has PD-L1 expression ≥ 1%
    d. Requested agent will be used as adjuvant treatment following complete resection and platinum-based chemotherapy
2. Diagnosis of **unresectable or metastatic NSCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Inadequate response or adverse reaction to **ONE** platinum-containing regimen, or contraindication to **ALL** platinum-containing regimens
        ii. Requested agent will be used in combination with **ALL** of the following in the first-line setting for non-squamous NSCLC (may be bypassed if already completed chemotherapy): Avastin® (bevacizumab), paclitaxel, and carboplatin
        iii. Tumor has PD-L1 expression ≥50%
        iv. Requested agent will be used in combination with albumin-bound paclitaxel and carboplatin in the first-line setting for nonsquamous NSCLC
3. Diagnosis of **HCC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with bevacizumab

d. Member has Child-Pugh Class A

4. Diagnosis of **ES-SCLC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member has extensive stage disease *(e.g., documentation that cancer has spread beyond lungs)*
    d. Requested agent will be used in combination with carboplatin and etoposide (may be bypassed if already completed chemotherapy)
5. Diagnosis of **unresectable or metastatic melanoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Positive BRAF V600E or V600K mutation
    d. The requested agent will be used in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)
    e. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
        i. Tafinlar® (dabrafenib) + Mekinist® (trametinib)
        ii. Cotellic® (cobimetinib) + Zelboraf® (vemurafenib)
        iii. Braftovi® (encorafenib) + Mektovi® (binimetinib)
6. Diagnosis of **unresectable or metastatic alveolar soft part sarcoma (ASPS)**
    a. Prescriber is an oncologist
    b. Appropriate dosing

Yervoy® (ipilimumab)
ONE of the following:

1. Diagnosis of **HCC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with Opdivo® (nivolumab)
    d. Inadequate response, adverse reaction, or contraindication to Nexavar® (sorafenib)
2. Diagnosis of **malignant pleural mesothelioma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with Opdivo® (nivolumab)
3. Diagnosis of **unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with nivolumab in the first-line setting
4. Diagnosis of **unresectable or metastatic melanoma**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. **ONE** of the following:
        i. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
            1. Keytruda® (pembrolizumab)
            2. Opdivo® (nivolumab)
        ii. For treatment of unresectable or metastatic melanoma, requested agent will be used in combination with Opdivo® (nivolumab) or Keytruda® (pembrolizumab)
5. Diagnosis of **metastatic NSCLC**
    a. Prescriber is an oncologist

b. Appropriate dosing
c. **ONE** of the following:
    i. PD-L1 expression ≥1% and requested agent will be used in combination with Opdivo® (nivolumab)
    ii. Requested agent will be used in combination with Opdivo® (nivolumab) and two cycles of platinum doublet chemotherapy

6. Diagnosis of **MSI-H/dMMR mCRC**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Requested agent will be used in combination with Opdivo® (nivolumab)
    d. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
        i. fluoropyrimidine- based therapy
        ii. irinotecan- based therapy
        iii. oxaliplatin- based therapy
7. Diagnosis of **Renal cell carcinoma (RCC)**
    a. Prescriber is an oncologist
    b. Appropriate dosing
    c. Member has clear cell histology
    d. Requested agent will be used in combination with Opdivo® (nivolumab)

Zynyz® (retifanlimabdlwr)
ALL of the following:
1. Diagnosis of metastatic or recurrent locally advanced Merkel cell carcinoma (MCC)
2. Prescriber is an oncologist
3. Appropriate dosing *(weight required)*

Continuation of Therapy
Reauthorization by prescriber will infer a positive response to therapy.

Limitations
1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months (requests for longer than FDA-approved duration of use, please refer to dosing table in appendix for maximum treatment durations)
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.

Appendix
Systemic Therapy for Treatment of Classical Hodgkin Lymphoma

The following regimens may be utilized as systemic therapy for the treatment of Classical Hodgkin lymphoma:

- First-line primary systemic therapy
  - ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine)
  - Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, and prednisone)
  - Brentuximab + AVD (doxorubicin, vinblastine, dacarbazine)
- Second-line options (relapsed/refractory disease)
  - Brentuximab vedotin
  - Brentuximab vedotin + bendamustine
  - Brentuximab vedotin + nivolumab
  - DHAP (dexamethasone, cisplatin, high-dose cytarabine)
  - ESHAP (etoposide, methylprednisolone, high-dose cytarabine and cisplatin)
  - Gemcitabine/bendamustine/vinorelbine
  - GVD (gemcitabine, vinorelbine, liposomal doxorubicin)
  - GVD+ pembrolizumab
  - ICE (ifosfamide, carboplatin, etoposide)
  - ICE+ brentuximab vedotin
  - ICE + nivolumab
  - IGEV (ifosfamide, gemcitabine, vinorelbine)
  - pembrolizumab (for members not candidates for transplant)
- Subsequent options (relapsed/refractory disease)
  - Bendamustine
  - Bendamustine + carboplatin + etoposide
  - C-MOPP (cyclophosphamide, vincristine, procarbazine, prednisone)
  - Everolimus
  - GCD (gemcitabine, carboplatin, dexamethasone)
  - GEMOX (gemcitabine, oxaliplatin)
  - Lenalidomide
  - MINE (etoposide, ifosfamide, mesna, mitoxantrone)
  - Mini-BEAM (carmustine, cytarabine, etoposide, melphalan)
  - Nivolumab (per indications)
  - Pembrolizumab (per indications)
  - Vinblastine

Preferred First- and Second-line Treatment Regimens for Gastric and Esophageal Junction Cancers

Preferred Regimens for Gastric Cancer:

First-Line Therapy	Second-Line and Subsequent Therapy
• HER2 overexpression positive adenocarcinoma: • Fluoropyrimidine (fluorouracil or capecitabine) and cisplatin and trastuzumab (category 1) • Fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin and trastuzumab • HER2 overexpression negative:	• Ramucirumab and paclitaxel (category 1) • Docetaxel (category 1) • Paclitaxel (category 1) • Irinotecan (category 1) • Trifluridine and tipiracil for third line or subsequent therapy (category 1) • Fluorouracil and irinotecan • Fam-trastuzumab deruxtecan-nxki for HER2 overexpression positive adenocarcinoma

• Fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin and nivolumab (PD-L1 CPS≥5)(category 1) • Fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin • Fluoropyrimidine (fluorouracil or capecitabine) and cisplatin	

Preferred Regimens for Esophageal and Esophagogastric Junction Cancer:

First-Line Therapy (Oxaliplatin is generally preferred over cisplatin due to lower toxicity)	Second-Line and Subsequent Therapy (Dependent on prior therapy and PS)
• HER2 overexpression positive adenocarcinoma: • Fluoropyrimidine (fluorouracil or capecitabine) and cisplatin and trastuzumab (category 1) • Fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin and trastuzumab • HER2 overexpression negative: • Fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin and nivolumab (PDL1 CPS ≥5) for adenocarcinoma only (category 1) • Fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin and nivolumab (PDL1 CPS 1-4) for adenocarcinoma only (category 2B) • Fluoropyrimidine (fluorouracil or capecitabine) and cisplatin and pembrolizumab (PDL1 CPS≥10) for adenocarcinoma or squamous cell carcinoma • Fluoropyrimidine (fluorouracil or capecitabine), oxaliplatin and pembrolizumab (PDL1 CPS 1-9) for adenocarcinoma only (category 2B) • Fluoropyrimidine (fluorouracil or capecitabine), cisplatin and pembrolizumab (PDL1 CPS≥10) (category 1) for adenocarcinoma or squamous cell carcinoma • Fluoropyrimidine (fluorouracil or capecitabine), cisplatin and pembrolizumab (PDL1 CPS 1-9) (category 1) for adenocarcinoma only (category 2B)	• Nivolumab for esophageal squamous cell carcinoma (category 1) • Ramucirumab and paclitaxel for adenocarcinoma (category 1 for esophagogastric junction adenocarcinoma; category 2A for esophageal adenocarcinoma) • Docetaxel (category 1) • Paclitaxel (category 1) • Irinotecan (category 1) • Trifluridine and tipiracil for third-line or subsequent therapy for EGJ adenocarcinoma (category 1) • Fluorouracil and irinotecan • Pembrolizumab (for second-line therapy for esophageal squamous cell carcinoma, with PD-L1 expressions levels by CPS ≥10 (category 1); for third-line or subsequent therapy for esophageal and EGJ adenocarcinoma with PD-L1 expression levels by CPS of ≥1) • Fam-trastuzumab deruxtecan-nxki for HER2 overexpression positive adenocarcinoma

• Fluoropyrimidine (fluorouracil or capecitabine) and oxaliplatin for adenocarcinoma or squamous cell carcinoma • Fluoropyrimidine (fluorouracil or capecitabine) and cisplatin for adenocarcinoma	

Systemic Therapy for Treatment of Endometrial Carcinoma

Primary or adjuvant treatment when used for uterine-confined high-risk disease

- Carboplatin/paclitaxel

Recurrent or metastatic disease

	Preferred Regimen	Other Recommended Regimens
Systemic Therapies	• Carboplatin/paclitaxel (cat 1 for carcinosarcoma) Carboplatin/paclitaxel/trastuzumab (for stage III/IV or recurrent HER2-positive uterine serous carcinoma)	• Carboplatin/docetaxel • Cisplatin/doxorubicin • Cisplatin/doxorubicin/paclitaxel Carboplatin/paclitaxel/bevacizumab • Cisplatin • Carboplatin • Doxorubicin • Liposomal doxorubicin • Paclitaxel • Albumin-bound paclitaxel • Topotecan • Bevacizumab • Temsirolimus • Docetaxel • Ifosfamide (for carcinosarcoma) • Ifosfamide/paclitaxel (for carcinosarcoma) • Cisplatin/ifosfamide(for carcinosarcoma)
Biomarker-directed systemic therapy for second line treatment	• Lenvatinib/pembrolizumab (cat 1) for non-MSI-high [MSI-H]/non-MMR deficient [dMMR] tumors • Pembrolizumab for TMB-H or MSI-H/dMMR tumors	• Nivolumab for dMMR/MSI-H tumors • Dostarlimab-gxly for dMMR/MSI-H tumors • Larotrectinib or entrectinib for NTRK gene fusion-positive tumors • Avelumab for dMMR/MSI-H tumors • cabozantinib
Hormone Therapy		
Preferred	Other Recommended	Useful in Certain Circumstances

• Medroxyprogesterone/ tamoxifen (alternating) • Megestrol/ tamoxifen (alternating) Progestational agents • Aromatase inhibitors • Tamoxifen • Fulvestrant	Everolimus/letrozole (for endometrioid histology)	N/A

Availability and Dosing

Drug	Dosing	Availability
Bavencio (avelumab)	<u>MCC* (adults and pediatric members), UC*:</u> 800 mg every two weeks <u>RCC*:</u> 800 mg every three weeks in combination with axitinib 5 mg twice daily	Single-use vials for infusion: 200 mg/10 mL
Imfinzi (durvalumab)	<u>ES-SCLC*:</u> ≥ 30 kg: 1,500 mg in combination with chemotherapy every three weeks for four cycles, followed by 1,500 every four weeks as a single agent <30 kg: 20 mg/kg in combination with chemotherapy every three weeks for four cycles, followed by 10 mg/kg every two weeks as a single agent <u>Stage III NSCLC‡ :</u> ≥ 30 kg: 10 mg/kg every two weeks or 1,500 mg every four weeks (maximum of 12 months for NSCLC) <30 kg: 10 mg/kg every two weeks <u>Biliary tract cancer:</u> Members ≥ 30 kg: 1,500 mg in combination with chemo every 3 weeks up to 8 cycles followed by 1,500 mg every 4 weeks as single agent Members < 30 kg: 20 mg/kg in combination with chemo every 3 weeks up to 8 cycles followed by 20 mg/kg mg every 4 weeks as single agent	Single-use vials for infusion: 120 mg/2.4 mL 500 mg/10 mL

	<u>Metastatic NSCLC- in combination with Imjudo and platinum-based chemotherapy</u> Members ≥ 30 kg: Imfinzi 1,500 mg week 0, week 3, week 6, week 9, week 12, week 16, week 20 and week 24 Members < 30kg Imfinzi 20 mg/kg week 0, week 3, week 6, week 9, week 12, week 16, week 20 and week 24 Refer to package insert for concomitant Imjudo and chemotherapy schedule <u>Unresectable HCC:</u> Members ≥ 30 kg: Single dose of Imjudo 300 mg followed by durvalumab 1,500 mg Day 1 of Cycle 1; then durvalumab 1,500 mg every 4 weeks Members < 30 kg Single dose of Imjudo 4 mg/kg followed by durvalumab 20 mg/kg at Day 1 of Cycle 1; continue durvalumab 20 mg/kg every 4 weeks	
Imjudo® (tremelimumab-actl)	<u>Metastatic NSCLC- in combination with durvalumab and platinum-based chemotherapy</u> Members ≥ 30 kg: Imjudo 75 mg week 0, week 3, week 6, week 9, week 16 Members < 30kg Imjudo 1 mg/kg week 0, week 3, week 6, week 9, week 16 Refer to package insert for concomitant durvalumab and chemotherapy schedule <u>Unresectable HCC:</u> Members ≥ 30 kg: Single dose of Imjudo 300 mg followed by durvalumab 1,500 mg Day 1 of Cycle 1; then durvalumab 1,500 mg every 4 weeks Members < 30 kg Single dose of Imjudo 4 mg/kg followed by durvalumab 20 mg/kg at Day 1 of Cycle 1; continue durvalumab 20 mg/kg every 4 weeks	Single-use vials for infusion: 25 mg/1.25 mL 300 mg/15 mL
Jemperli (dostarlimab-gxly)	<u>dMMR recurrent or advanced solid tumors:</u> Dose 1 through dose 4: 500 mg every three weeks; maintenance, three weeks after dose 4: 1,000 mg every six weeks until disease progression, unacceptable toxicity	Single-use vials for infusion: 500 mg/10 mL

	dMMR recurrent or advanced endometrial cancer following prior treatment with platinum-containing regimen: Dose 1 through dose 4: 500 mg every three weeks; maintenance, three weeks after dose 4: 1,000 mg every six weeks until disease progression, unacceptable toxicity dMMR/MSI-H primary advanced or recurrent endometrial cancer in combination with carboplatin and paclitaxel 500 mg every three weeks for six doses followed by 1,000 mg monotherapy every six weeks until disease progression, unacceptable toxicity or up to three years	
Keytruda (pembrolizumab)	BTC, Cervical cancer†, cHL (adults) †, CSCC†, ESCC†, gastric cancer†, esophageal cancer, HCC†, HNSCC†, MCC†, m elanoma (metastatic *, adjuvant- up to 12 months), MSI- H or dMMR cancer†, MSI -H or dMMR CRC†, NMIBC†, NSCLC † , NSCLC (stage IB-IIIA for adjuvant)‡ , PMBCL (adults)† , TMB-H cancer†, TNBC † , UC † : 200 mg every three weeks or 400 mg every six weeks (Until disease progression, unacceptable toxicity, or **up to 24 months**) Endometrial carcinoma† : 200 mg every 3 weeks or 400 mg every 6 weeks with lenvatinib 20 mg orally once daily for tumors that are not MSI-H or dMMR MSI-H or dMMR endometrial carcinoma 200 mg every 3 weeks or 400 mg every 6 weeks Pediatrics (cHL † , PMBCL†, MSI-H or dMMR cancer † , MCC †, TMB H cancer† - , melanoma [adjuvant]): 2 mg/kg every three weeks (up to a maximum of 200 mg) (Until disease progression, unacceptable toxicity, or **up to 24 months**) RCC † : 200 mg every three weeks or 400 mg every six weeks in combination with axitinib 5 mg twice daily (Until disease progression, unacceptable toxicity, or **up to 24 months**) Adjuvant treatment for RCC: 200 mg every three weeks or 400 mg every six weeks (until disease progression, unacceptable toxicity, or **up to 12 months**)	Single-use vials for infusion: 100 mg/4 mL

Libtayo (cemiplimab-rwlc)	Locally advanced or metastatic CSCC: 350 mg once every three weeks*	Single use vials for infusion: 350 mg/7 mL
Opdivo (nivolumab)	As Monotherapy cHL*, ESCC*, esophageal (adjuvant‡ - up to one year), GEJ (adjuvant‡- up to one year), melanoma (adjuvant‡ -up to one year), metastatic*), SCCHN*, UC (up to one year)*: 240 mg every two weeks or 480 mg every four weeks Combination Therapy: Esophageal squamous cell carcinoma 240 mg every two weeks or 480 mg every four weeks in combination with fluoropyrimidine- and platinum-containing chemotherapy (until disease progression or unacceptable toxicity up to 2 years of Opdivo) 3mg/kg every two weeks or 360 mg every three weeks in combination with ipilimumab 1 mg/kg every six weeks (until disease progression or unacceptable toxicity –up to 2 years) Gastric, GEJ and EAC: 240 mg every two weeks with fluoropyrimidine- and platinum-containing chemotherapy every two weeks OR 360 mg every three weeks with fluoropyrimidine-and platinum-containing chemotherapy HCC*: 240 mg every two weeks or 480 mg every four weeks or 1 mg/kg followed by ipilimumab 3 mg/kg on the same day every three weeks for four doses, then 240 mg every two weeks or 480 mg every four weeks Melanoma (unresectable or metastatic)*: 1 mg/kg every three weeks with ipilimumab 3 mg/kg (maximum of 4 doses of ipilimumab) then nivolumab monotherapy 240 mg every two weeks or 480 mg every four weeks until disease progression or unacceptable toxicity MPM†: 360 mg every three weeks in combination with ipilimumab 1 mg/kg every six weeks (Until disease progression, unacceptable toxicity, or **up to 24 months**) MSI-H/dMMR CRC*: • Adult and pediatric members ≥40 kg: 240 mg every two weeks or 480 mg every four weeks • Pediatric members <40 kg: 3 mg/kg every two	Single-use vials for infusion: 40 mg/4 mL 100 mg/10 mL 120 mg/12 mL 240 mg/24 mL

	weeks • Adult and pediatric members ≥40 kg: 3 mg/kg followed by ipilimumab 1 mg/kg on the same day every three weeks for four doses, then 240 mg every two weeks or 480 mg every four weeks <u>NSCLC*:</u> 3 mg/kg every two weeks with ipilimumab 1 mg/kg every 6 weeks or 360 mg every three weeks with ipilimumab 1 mg/kg every six weeks and two cycles of platinum-doublet chemotherapy or 240 mg every two weeks or 480 mg every four weeks (Until disease progression, unacceptable toxicity, or **up to 24 months**) <u>Resectable NSCLC (neoadjuvant):</u> 360 mg every three weeks (max three cycles) RCC*: • 3 mg/kg followed by ipilimumab 1 mg/kg on the same day every three weeks for four doses, then nivolumab 240 mg every two weeks or 480 mg every four weeks or 240 mg every two weeks or 480 mg every four weeks* • In combination with cabozantinib: 240 mg every two weeks or 480 mg every four weeks (Until disease progression, unacceptable toxicity, or up to 24 months) • In combination with ipilimumab (4 doses), then administer nivolumab as single agent until disease progression or unacceptable toxicity	
Opdualag (nivolumab/ relatlimab-rmbw)	<u>Unresectable or Metastatic Melanoma:</u> Injection: initial; maintenance; maximum, 480 mg nivolumab and 160 mg relatlimab-rmbw intravenously every four weeks Until disease progression or toxicity	Single-dose vial for infusion: 240-80 mg/20 mL

Tecentriq (atezolizumab)	ES-SCLC*: 1,200 mg every three weeks prior to chemotherapy; following completion of chemotherapy, 840 mg every two weeks, 1,200 every three weeks, or 1,680 mg every four weeks HCC*: 1,200 mg, followed by 15 mg/kg bevacizumab on the same day every three weeks; if bevacizumab is discontinued, 840 mg every two weeks, 1,200 every three weeks, or 1,680 mg every four weeks Melanoma: Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer atezolizumab 840 mg every 2 weeks with cobimetinib 60 mg orally once daily (21 days on/7 days off) and vemurafenib 720 mg orally twice daily Metastatic NSCLC* and UC*: 840 mg every two weeks, 1,200 mg every three weeks, or 1,680 mg every four weeks as a single agent; if administered with chemotherapy, 1,200 every three weeks (until disease progression or unacceptable toxicity) Adjuvant treatment of NSCLC: 840 mg every two weeks, 1,200 mg every three weeks, or 1,680 mg every four weeks as a single agent (up to one year, unless disease recurrence or unacceptable toxicity) TNBC*: 840 on days 1 and 15 of each 28-day cycle; administered with paclitaxel protein bound	Single-dose vial for infusion: 840 mg/14 mL 1,200 mg/20 mL

Yervoy (ipilimumab)	HCC*: ipilimumab 3 mg/kg following nivolumab 1 mg/kg on the same day every three weeks for four doses, then nivolumab as a single agent Melanoma (unresectable or metastatic): 3 mg/kg every three weeks for a total of four doses Melanoma (adjuvant treatment): 10 mg/kg every three weeks for four doses, followed by 10 mg/kg every 12 weeks for up to three years MPM†: 1 mg/kg every six weeks with nivolumab 360 mg every three weeks MSI-H or dMMR metastatic CRC*: ipilimumab 1 mg/kg following nivolumab 3 mg/kg on the same day every three weeks for four doses, then nivolumab as a single agent NSCLC† • : Ipilimumab 1 mg/kg every six weeks with Nivolumab 3 mg/kg every two weeks • Ipilimumab 1 mg/kg every six weeks with nivolumab 340 mg every three weeks and two cycles of platinum-doublet chemotherapy RCC (advanced)*: ipilimumab 1 mg/kg following nivolumab 3 mg/kg on the same day, every three weeks for four doses, then nivolumab as a single agent	Single-dose vial for injection: 50 mg/10 mL 200 mg/40 mL
Zynyz® (retifanlimab-dlwr)	MCC (metastatic or recurrent locally advanced): 500 mg intravenously every four weeks until disease progression, unacceptable toxicity or up to 24 months.	Single-dose vial for injection: 500 mg/20 mL

cHL=classical Hodgkin lymphoma, CRC= colorectal cancer, CSCC=cutaneous squamous cell carcinoma**,** dMMR=mismatch repair deficient, ES-SCLC=extensive stage-small cell lung cancer, ESCC=squamous cell carcinoma of the esophagus, GEJ=gastroesophageal junction, HCC=hepatocellular carcinoma, HNSCC=head and neck squamous cell carcinoma, MCC=Merkel cell carcinoma, MPM=malignant pleural mesothelioma, MSI-H=microsatellite instability-high, NMIBC=non-muscle invasive bladder cancer, NSCLC=non-small cell lung cancer, PMBCL=primary mediastinal B-cell lymphoma, RCC=renal cell carcinoma, SCCHN=squamous cell carcinoma of the head and neck, SCLC=small cell lung cancer, TMB-H=tumor mutational burden-high, TNBC=triple-negative breast cancer, UC=urothelial carcinoma
*Until disease progression or unacceptable toxicity.
†Until disease progression, unacceptable toxicity, or up to 24 months in members without disease progression.
‡Until disease progression, unacceptable toxicity, or a maximum of 12 months.

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Review History

Reviewed and created for P&T. Matched MH UPPL criteria to be in compliance with Masshealth unified formulary requirements. Switched from CVS SGM to custom criteria. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. New agent, Imjudo, was added to guideline. The following other updates were made based on expanded indications: Bavencio - Diagnosis update to "Diagnosis of locally advanced or metastatic urothelial carcinoma", Imfinzi -Expanded labeling for BTC, NSCLC, uHCC, Keytruda -

criteria update for Unresectable or metastatic NSCLC and Gastric or GEJ adenocarcinoma, Libtayo- criteria update for NSCLC, Opdivo - Expanded indication for Stage IIB, IIC or III melanoma, Tecentriq - Expanded indication for ASPS. Removed the following due to FDA voluntary withdrawal: Tecentriq for locally advanced or metastatic urothelial carcinoma from and Keytruda for 3rd-line setting for gastric cancer (locally advanced or metastatic gastric or gastroesophageal (GEJ) adenocarcinoma whose tumors expressed PD-L1 and had disease progression on or after ≥ 2 prior lines of therapy). References updated. Effective 6/5/23.
07/12/23 – Reviewed and updated for P&T. Add expanded indication for use for Keytruda (pembrolizumab) as a single agent for adjuvant treatment following resection and platinum-based chemotherapy for adults with stage IB (T2a ≥4 cm), II, or IIIA NSCLC. Formatting updates made throughout policy. Jemperli and Opdualag will only be available under MB. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23.
09/13/23 – Reviewed and updated for P&T. Expanded indication added to guideline: Padcev in combination with Keytruda® (pembrolizumab) for the treatment of adult patients with locally advanced (la) or metastatic urothelial cancer (mUC) who are not eligible for cisplatin-containing chemotherapy. Minor edits to criteria regarding trial and failure versus contraindication to therapies throughout policy. Effective 10/02/23.
11/15/23 – Reviewed and updated for P&T. Zynyz (relatlimab-dlwr) is added with PA and MB designation. Effective 12/04/23.
04/10/24 – Reviewed and updated for P&T. Criteria updates for Keytruda for the following expanded indications: resectable Non-Small Cell Lung Cancer (NSCLC), unresectable or metastatic HER2- negative gastric or gastroesophageal junction (GEJ) adenocarcinoma, and locally advanced or metastatic biliary tract cancer (BTC). Criteria update for Jemperli for use in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H). Effective 5/6/24