Opdivo® (nivolumab)
(Intravenous)

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I. Length of Authorization Δ 1,35,43,47,49,50,52-54,65,68,72,73,79,81,82,89,129,130,137,139-141

- Initial: Prior authorization validity will be provided initially for 6 months (180 days), unless otherwise specified.
  - Use in the treatment of Classical Hodgkin Lymphoma (cHL):
    - ❖ Adult cHL in combination with brentuximab vedotin: Prior authorization validity may be provided up to a maximum of 24 weeks of therapy (8 doses).
    - ❖ Pediatric cHL in combination with brentuximab vedotin-based therapy: Prior authorization validity may be provided up to a maximum of 12 weeks of therapy (4 doses).
    - ❖ Adult and Pediatric cHL in combination with ICE (ifosfamide, carboplatin, etoposide): Prior authorization validity may be provided up to a maximum of 12 weeks of therapy (6 doses).
    - ❖ Adult and Pediatric cHL in combination with AVD (doxorubicin, vinblastine, dacarbazine): Prior authorization validity may be provided up to a maximum of 24 weeks of therapy (12 doses).
  - Use in the treatment of Cutaneous Melanoma:
    - ❖ Cutaneous Melanoma neoadjuvant therapy in combination with ipilimumab: Prior authorization validity may be provided for a maximum of 2 doses.
    - ❖ Cutaneous Melanoma neoadjuvant therapy as a single agent: Prior authorization validity may be provided for a maximum of 4 doses.
    - ❖ Cutaneous Melanoma adjuvant treatment in combination with ipilimumab: Prior authorization validity may be provided for a maximum of 4 doses.
  - Merkel Cell Carcinoma neoadjuvant therapy: Prior authorization validity may be provided for up to a maximum of 2 doses.
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.

- Esophageal and Esophagogastric/Gastroesophageal Junction Cancer neoadjuvant or perioperative therapy (adenocarcinoma): Prior authorization validity may be provided for a maximum of 12 weeks of pre-operative therapy (6 doses), followed by a maximum of 36 weeks (9 doses) of postoperative therapy after surgery.
- Gastric Cancer neoadjuvant or perioperative therapy: Prior authorization validity may be provided for a maximum of 12 weeks of pre-operative therapy (6 doses), followed by a maximum of 36 weeks (9 doses) of postoperative therapy after surgery.
- Non-Small Cell Lung Cancer neoadjuvant treatment followed by optional adjuvant treatment: Prior authorization validity may be provided for a maximum of 4 neoadjuvant doses and 13 adjuvant doses.
- Prior authorization validity may NOT be renewed for the following indications:
  - Adult cHL in combination with brentuximab vedotin
  - Pediatric cHL in combination with brentuximab vedotin-based therapy
  - Adult and Pediatric cHL in combination with ICE (ifosfamide, carboplatin, etoposide)
  - Adult and Pediatric cHL in combination with AVD (doxorubicin, vinblastine, dacarbazine)
  - Merkel Cell Carcinoma (neoadjuvant therapy)
  - Cutaneous Melanoma (neoadjuvant therapy)
  - Cutaneous Melanoma (adjuvant therapy in combination with ipilimumab)
  - Gallbladder Cancer (neoadjuvant therapy)
- Prior authorization validity may be renewed up to a maximum of 1 year of therapy* for the following:
  - Anal Carcinoma (in combination with paclitaxel and carboplatin followed by single-agent maintenance therapy)
  - Cutaneous Melanoma (adjuvant therapy single agent)
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer (adjuvant therapy following neoadjuvant chemoradiotherapy)
  - Squamous Cell Skin Cancer (weight-based 3 mg/kg dosing)
  - Urothelial Carcinoma (adjuvant therapy)
- Prior authorization validity may be renewed up to a maximum of 2 years of therapy* for the following:
  - Biliary Tract Cancer (subsequent therapy)
  - Bone Cancer (in combination with ipilimumab)
  - Cervical Cancer
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer [first-line therapy, subsequent therapy (excluding single agent use for squamous cell carcinoma), or induction therapy for relieving dysphagia]
  - Gastric Cancer (first-line therapy or subsequent therapy)

- ❖ Kaposi Sarcoma (in combination with ipilimumab)
- ❖ Renal Cell Carcinoma (in combination with cabozantinib)
- ❖ Pleural Mesothelioma (first-line/induction therapy in combination with ipilimumab)**
- ❖ Peritoneal Mesothelioma (first-line therapy in combination with ipilimumab)**
- ❖ Non-Small Cell Lung Cancer (in combination with ipilimumab with or without platinum-doublet chemotherapy)
- ❖ Ovarian, Fallopian Tube, and Primary Peritoneal Cancer – Clear Cell Carcinoma of the Ovary
- ❖ Squamous Cell Skin Cancer (flat 240 mg dosing)
- ❖ Vaginal Cancer
- ❖ Vulvar Cancer
- ❖ Urothelial Carcinoma (first line therapy in combination with gemcitabine and cisplatin, followed by single-agent maintenance therapy)

*** Including pericardial mesothelioma and tunica vaginalis testis mesothelioma*

Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.		
Dosing Frequency	**Maximum length of therapy**	**Maximum number of doses**
2 weeks	1 year	26 doses
	2 years	52 doses
3 weeks	2 years	35 doses
4 weeks	1 year	13 doses
	2 years	26 doses

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

Indication	Billable Units (BU)	Per unit time (days)
Adrenal Gland, Biliary, cHL, Cutaneous Melanoma, Gastric, Gestational Trophoblastic Neoplasia (GTN), SCCHN, HCC, Kaposi Sarcoma; Ovarian, Fallopian Tube, & Primary Peritoneal Cancer; RCC, Soft Tissue Sarcoma, Thyroid Carcinoma, Extranodal NK/T-Cell Lymphoma	1440 billable units	84 days
Anal, Ampullary Adenocarcinoma, Appendiceal, Bone, CLL/SLL, CNS cancers, CRC, Esophageal and Esophagogastric/ Gastroesophageal Junction Cancer, Merkel Cell, PM, PeM, Pericardial Mesothelioma, Tunica Vaginalis Testis Mesothelioma, Squamous Cell Skin, PMBCL, NSCLC, SCLC, Small Bowel Adenocarcinoma, Vulvar Cancer, Vaginal Cancer, & Cervical Cancer	2040 billable units	84 days
Uveal Melanoma	6960 billable units	84 days
Uterine Neoplasms	*Initial* 340 billable units	14 days x 8 doses

	Maintenance 480 billable units	28 days
Urothelial Carcinoma (Bladder Cancer)	*Initial* 360 billable units	21 days x 6 doses
	Maintenance 480 billable units	28 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided for the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified [Δ]; **AND**
- Therapy will not be used concomitantly with subcutaneous nivolumab; **AND**

Ampullary Adenocarcinoma ‡ [2]

- Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA) compliant test❖; **AND**
  - Used in combination with ipilimumab if good performance status (ECOG PS 0-1 with good biliary drainage and adequate nutritional intake), intermediate performance status (ECOG PS 2), or poor performance status (ECOG PS 3); **AND**
    - Used as first-line therapy for metastatic intestinal type disease; **OR**
    - Used as subsequent therapy for disease progression; **OR**
  - Used as a single agent; **AND**
    - Used as first-line therapy for metastatic intestinal type disease if poor performance status (ECOG PS 3); **OR**
    - Used as subsequent therapy for disease progression if intermediate performance status (ECOG PS 2) or poor performance status (ECOG PS 3)

Anal Carcinoma ‡ [2,6,35]

- Member has squamous cell carcinoma; **AND**
  - Used as a single agent as subsequent therapy for metastatic disease; **OR**
  - Used in combination with paclitaxel and carboplatin, then continued as a single agent; **AND**
    - Used for treatment of inguinal node recurrence; **OR**
    - Used as first-line treatment for metastatic disease

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡ [2,72]

- Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used in combination with ipilimumab; **AND**
  - Used as subsequent treatment for progression on or after systemic treatment for unresectable, gross residual (R2), or metastatic disease; **AND**
    - Disease is refractory to standard therapies or there are no standard treatment options available; **OR**
  - Used as neoadjuvant therapy for resectable locoregionally advanced disease *(**<u>NOTE:</u> Only applies to Gallbladder Cancer)*; **AND**
    - Member has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
    - Member has incidental finding on pathologic review (cystic duct node positive or T1b or greater and/or T1a with positive margins); **OR**
    - Member has mass on imaging; **OR**
    - Member has jaundice

Urothelial Carcinoma (Bladder Cancer) † ‡ [1,2,30,51,62,92]

- Used as a single agent; **AND**
  - Used for locally advanced or metastatic urothelial carcinoma that progressed during or following platinum-containing chemotherapy* †; **OR**
  - Used as adjuvant therapy; **AND**
    - Member has urothelial carcinoma of the bladder †, male bulbar urethra, prostate with stromal invasion, or upper genitourinary (GU) tract (ureter or renal pelvis) †; **AND**
    - Member is at high risk for disease recurrence**; **OR**
- Used in combination with cisplatin and gemcitabine followed by nivolumab maintenance therapy; **AND**
  - Used as first-line systemic therapy in cisplatin eligible members*; **AND**
  - Member has one of the following diagnoses:
    - Locally advanced, unresectable, or metastatic urothelial carcinoma
    - Muscle invasive bladder cancer with local recurrence or persistent disease in a preserved bladder
    - Metastatic or local bladder cancer recurrence post-cystectomy
    - Primary carcinoma of the urethra; **AND**
      - Clinical stage T3-4, cN1-2 disease or cN1-2 palpable inguinal lymph nodes; **OR**
      - Recurrent or metastatic disease
    - Metastatic upper genitourinary (GU) tract tumors
    - Metastatic urothelial carcinoma of the prostate

**** Note:*** [10,51,60,70]

– *If member was progression free for >12 months after platinum therapy, consider re-treatment with platinum-based therapy if the member is still platinum eligible (see below for cisplatin- or platinum-ineligible comorbidities).*

- *Cisplatin-ineligible comorbidities may include the following: CrCl < 60 mL/min, ECOG PS ≥ 2 or KPS ≤ 70%, hearing loss of ≥ 25 decibels (dB) at two contiguous frequencies, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class ≥ 3. Carboplatin may be substituted for cisplatin in the metastatic setting for cisplatin-ineligible members such as those with a GFR less than 60 mL/min.*
- *Platinum-ineligible comorbidities may include the following: CrCl < 30 mL/min, ECOG PS ≥ 3, grade ≥ 2 peripheral neuropathy, or NYHA Heart Failure class > 3, etc.*

***** Note:*** [1,62]

– *High risk for disease recurrence is defined as:*

- *ypT2-ypT4a or ypN+ for members who received neoadjuvant platinum-based therapy (excluding urothelial carcinoma of the prostate with stromal invasion);* ***OR***
- *pT3-pT4a or pN+ for members who did not receive neoadjuvant platinum-based therapy*

Bone Cancers ‡ [2,72]

- Member has one of the following: Chondrosarcoma, Ewing Sarcoma*, Conventional Chordoma (including chondroid), High-Grade undifferentiated pleomorphic sarcoma (UPS), or Osteosarcoma; **AND**
  - Used in combination with ipilimumab; **AND**
  - Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Member has unresectable or metastatic disease that progressed following prior treatment; **AND**
  - Member has no satisfactory alternative treatment options; **OR**
- Member has Dedifferentiated chondrosarcoma; **AND**
  - Used as a single agent; **OR**
  - Used in combination with sunitinib; **OR**
  - Used in combination with ipilimumab; **AND**
    - Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Member has unresectable or metastatic disease that progressed following prior treatment; **AND**
    - Member has no satisfactory alternative treatment options

**Other primary round cell tumors of the bone (eg, CIC::DUX4, BCOR::CCNB3) can be treated like Ewing Sarcoma*

Adult Central Nervous System (CNS) Cancers ‡ [2,5,34,41,42]

- Used as a single-agent or in combination with ipilimumab for the treatment of brain metastases in members with BRAF non-specific melanoma; **OR**
- Used as a single-agent for the treatment of brain metastases in members with PD-L1 positive (Tumor Proportion Score [TPS] ≥1%) non-small cell lung cancer (NSCLC)

Pediatric Central Nervous System (CNS) Cancers ‡ [2,71]

- Member is ≤ 21 years of age; **AND**
- Member has hypermutant diffuse high-grade glioma; **AND**
  - Used for recurrent or progressive disease as a single agent *(excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant)*; **OR**
  - Used as adjuvant therapy *(excluding diffuse midline glioma, H3 K27-altered or pontine location)*; **AND**
    - Member is < 3 years of age and used as a single agent; **OR**
    - Member is ≥ 3 years of age and used following standard brain radiation therapy (RT) with or without concurrent temozolomide

Cervical Cancer ‡ [2,49,63]

- Used as subsequent therapy; **AND**
  - Member has recurrent or metastatic adenocarcinoma, adenosquamous carcinoma or squamous cell carcinoma; **AND**
    - Used in combination with ipilimumab; **OR**
    - Used as a single agent; **AND**
      - Tumor expresses PD-L1 (e.g., CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖; **OR**
  - Member has persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC); **AND**
    - Used in combination with ipilimumab

Colorectal Cancer (CRC) † ‡ [1,2,31,32]

- Member is at least 12 years of age; **AND**
- Member has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) disease OR polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used in combination with ipilimumab or as a single agent; **AND**
    - Used as primary/initial treatment for unresectable or medically inoperable, recurrent, advanced, or metastatic disease; **OR**

        - Used as subsequent therapy for unresectable or medically inoperable, advanced, or metastatic disease; **OR**
        - Used as neoadjuvant therapy for advanced or metastatic disease; **OR**
    - Used in combination with ipilimumab; **AND**
        - Member has previously received checkpoint inhibitor monotherapy; **AND**
        - Used for advanced or metastatic disease

Appendiceal Neoplasms and Cancers ‡ [2,133]

- Member has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) disease OR polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) >50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent or in combination with ipilimumab if no previous treatment with a checkpoint inhibitor (*Note: Nivolumab + ipilimumab may be considered as subsequent therapy if checkpoint inhibitor monotherapy was previously received*); **AND**
- Used for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease

Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers † ‡ Φ [1,2,44,52,56,69]

- Used as first-line therapy in members with no prior checkpoint inhibitor therapy or no tumor progression while on therapy with a checkpoint inhibitor; **AND**
    - Member has squamous cell carcinoma; **AND**
        - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
            - Used in combination with ipilimumab or in combination with fluoropyrimidine- and platinum-containing chemotherapy; **AND**
                - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖ (independent of PD-L1 status); **OR**
                - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
    - Member has adenocarcinoma; **AND**
        - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
            - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; **AND**
                - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖ (independent of PD-L1 status); **OR**

        - ➢ Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
    - Used in combination with ipilimumab; **AND**
        - ➢ Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Used as subsequent therapy in members with no prior checkpoint inhibitor therapy or no tumor progression while on therapy with a checkpoint inhibitor; **AND**
    - Member has squamous cell carcinoma; **AND**
        - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
            - Used as a single agent; **OR**
            - Used in combination with ipilimumab; **AND**
                - ➢ Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
    - Member has adenocarcinoma; **AND**
        - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
        - Used in combination with ipilimumab; **AND**
        - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Used as adjuvant/postoperative treatment of completely resected disease; **AND**
    - Member has squamous cell carcinoma or adenocarcinoma; **AND**
    - Used as a single agent in members with residual disease following neoadjuvant/preoperative chemoradiotherapy (CRT); **OR**
- Used as neoadjuvant or perioperative therapy; **AND**
    - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Member has adenocarcinoma; **AND**
        - Used in combination with ipilimumab; **AND**
            - Used as primary treatment for members who are medically fit for surgery with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **OR**
        - Used as a single agent; **AND**
            - Used as postoperative management following R0 resection in members who have received preoperative therapy with nivolumab and ipilimumab; **OR**

- Used as induction systemic therapy for relieving dysphagia; **AND**
  - Member is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **AND**
  - Member has squamous cell carcinoma; **AND**
    - Used in combination with ipilimumab or in combination with fluoropyrimidine- and platinum-containing chemotherapy; **AND**
      - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖ (independent of PD-L1 status); **OR**
      - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test❖

Gastric Cancer † ‡ Φ [1,2,53,56]

- Used as first-line therapy in members with no prior checkpoint inhibitor therapy or no tumor progression while on therapy with a checkpoint inhibitor; **AND**
  - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
    - Used in combination with fluoropyrimidine- and platinum-containing chemotherapy; **AND**
      - Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
      - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖ (independent of PD-L1 status); **OR**
    - Used in combination with ipilimumab; **AND**
      - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Used as subsequent therapy in members with no prior checkpoint inhibitor therapy or no tumor progression while on therapy with a checkpoint inhibitor; **AND**
  - Member is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease; **AND**
  - Used in combination with ipilimumab; **AND**
  - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
- Used as neoadjuvant or perioperative therapy; **AND**
  - Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used in combination with ipilimumab; **AND**

- Used as primary treatment prior to surgery for potentially resectable locoregional disease (cT2 or higher, any N) in members who are medically fit for surgery; **OR**
- Used as a single agent; **AND**
  - Used as postoperative management following R0 resection in members who have received preoperative therapy with nivolumab and ipilimumab

Gestational Trophoblastic Neoplasia ‡ [2,36]

- Used as single-agent or in combination with ipilimumab; **AND**
- Member has multiagent chemotherapy-resistant disease; **AND**
  - Member has intermediate placental site trophoblastic tumor (PSTT) or epithelioid trophoblastic tumor (ETT); **AND**
    - Member has recurrent or progressive disease; **OR**
  - Member has high risk disease (i.e., ≥7 Prognostic score or stage IV disease)

Squamous Cell Carcinoma of the Head and Neck (SCCHN) † ‡ [1,2,29,78]

- Member has Cancer of the Nasopharynx; **AND**
- Patient has a contraindication, intolerance, or failure to **Loqtorzi® (toripalimad-tpzi)** prior to the consideration of Opdivo®; **AND**
  - Used in combination with cisplatin and gemcitabine for oligometastatic or metastatic disease; **OR**
- Member has Very Advanced Head and Neck Cancer*; **AND**
  - Member has nasopharyngeal cancer; **AND**
- Patient has a contraindication, intolerance, or failure to **Loqtorzi® (toripalimad-tpzi)** prior to the consideration of Opdivo®; **AND**
    - Used in combination with cisplatin and gemcitabine for members with performance status (PS) 0-1; **AND**
    - Used for one of the following:
      - Unresectable disease with prior radiation therapy (RT); **OR**
      - Recurrent/persistent disease with distant metastases; **OR**
  - Member has NON-nasopharyngeal cancer; **AND**
    - Used as a single agent; **AND**
      - Member has unresectable, recurrent, persistent, or metastatic disease; **AND**
      - Disease has progressed on or after platinum-containing chemotherapy; **OR**
    - Used in combination with cetuximab; **AND**
      - Member has unresectable, recurrent, persistent, or metastatic disease

** Very Advanced Head and Neck Cancer includes: newly diagnosed (M0) locally advanced T4b, N0-3 disease, newly diagnosed unresectable regional nodal disease, or those unfit for surgery, metastatic disease at initial presentation (M1), or recurrent or persistent disease with or without distant metastases.*

Hepatocellular Carcinoma (HCC) † ‡ Φ [1,2,21,86,87]

- Used as first-line therapy; **AND**
  - Used in combination with ipilimumab; **AND**
  - Member has unresectable or metastatic disease; **OR**
- Used as subsequent therapy; **AND**
  - Used in combination with ipilimumab; **AND**
    - Member was previously treated with sorafenib **†**; **OR**
    - Member had disease progression on or after systemic therapy and has not previously been treated with anti-CTLA4-based combinations; **OR**
  - Used as a single agent for disease progression on or after systemic therapy

Adult Classical Hodgkin Lymphoma (cHL) † ‡ Φ [1,2,27,28,73,117-118]

- Used as a single agent; **AND**
  - Member has relapsed or progressive disease after autologous hematopoietic stem cell transplantation (HSCT) and brentuximab vedotin **†**; **OR**
  - Used for disease that is refractory to at least 3 prior lines of therapy that includes autologous HSCT **†**; **OR**
  - Used as palliative subsequent therapy**^**; **AND**
    - Member has relapsed or refractory disease; **AND**
    - Member is not a candidate for high-dose therapy and autologous stem cell rescue (HDT/ASCR); **OR**
  - Used post-allogeneic hematopoietic cell transplant; **OR**
  - Used as primary treatment in members who are not candidates for anthracycline therapy; **AND**
    - Member has a contraindication to brentuximab vedotin; **AND**
    - Used in combination with or without involved-site radiation therapy (IRST); **OR**
- Used in combination with ICE**^** (ifosfamide, carboplatin, etoposide); **AND**
  - Used as subsequent therapy for relapsed or primary refractory disease; **OR**
- Used in combination with brentuximab vedotin**^**; **AND**
  - Used as subsequent therapy for relapsed or primary refractory disease; **OR**
  - Used as primary treatment for members who are not candidates for anthracycline therapy; **AND**
    - Used in combination with or without ISRT; **OR**

- Used in combination with doxorubicin, vinblastine, and dacarbazine (AVD); **AND**
  - Used as primary treatment for stage III-IV disease; **OR**
  - Used as primary treatment for stage I-II unfavorable disease (i.e., B symptoms, bulky mediastinal disease and/or >10 cm adenopathy, ≥4 nodal sites, and/or ESR ≥50 mm/hr)

^*Use of nivolumab as single agent palliative therapy, or in combination with ICE or brentuximab vedotin is allowable with or without prior checkpoint inhibitor therapy.*

Pediatric Classical Hodgkin Lymphoma (cHL) † ‡ [1,2,27,28, 117-118,131-132]

- Member is ≤ 18 years of age* unless otherwise specified; **AND**
  - Used as primary treatment for III-IV disease; **AND**
    - Used in combination with doxorubicin, vinblastine and dacarbazine (AVD) *(applies to members ≥12 years of age ONLY)*; **OR**
  - Member has relapsed or refractory disease; **AND**
    - Used in combination with ifosfamide, carboplatin, etoposide (ICE)**; **OR**
    - Used as a single agent**; **AND**
      - Member is heavily pretreated with platinum or anthracycline-based chemotherapy or a decrease in cardiac function was observed; **OR**
    - Used in combination with brentuximab vedotin with or without bendamustine; **AND**
      - Member is heavily pretreated with platinum or anthracycline-based chemotherapy or a decrease in cardiac function was observed; **AND**
        - Used as re-induction therapy or as subsequent therapy (if not previously used); **OR**
        - Used as re-induction therapy in highly favorable members who may avoid autologous stem cell rescue (ASCR) (i.e., initial stage other than IIIB or IVB, no prior exposure to RT, duration of CR1 >1 year, absence of extranodal disease or B symptoms at relapse); **AND**
          - Used in combination with involved-site radiation therapy (ISRT)

** Pediatric Classic Hodgkin Lymphoma may be applicable to adolescent and young adult (AYA) members up to the age of 39 years.*

***There is no pediatric data for this regimen*

Kaposi Sarcoma ‡ [2,79]

- Used as a single agent or in combination with ipilimumab; **AND**
- Used as subsequent therapy; **AND**
- Used for relapsed/refractory advanced (T1, extensive T0 cutaneous, or nodal) disease; **AND**
- Disease has progressed on or not responded to first-line therapy; **AND**
- Disease has progressed on alternate first-line therapy

Renal Cell Carcinoma (RCC) † ‡ [1,2,25,26]

- Used in combination with ipilimumab; **AND**
  - Member has clear cell histology; **AND**
    - Used as first-line therapy; **AND**
      - Member has poor or intermediate risk advanced disease **†**; **OR**
      - Member has relapsed or stage IV disease*****; **OR**
    - Used as subsequent therapy (with or without history of prior immuno-oncology therapy) in members with relapsed or stage IV disease; **OR**
- Used as a single agent; **AND**
  - Used as subsequent therapy in members with advanced, relapsed, or stage IV disease and clear cell histology; **OR**
  - Member has relapsed or stage IV disease and non-clear cell histology*****; **OR**
- Used in combination with cabozantinib (Cabometyx only); **AND**
  - Member has clear cell histology; **AND**
    - Used as first-line therapy for advanced, relapsed, or stage IV disease*****; **OR**
    - Used as subsequent therapy in members with relapsed or stage IV disease; **OR**
  - Member has non-clear cell histology; **AND**
    - Member has relapsed or stage IV disease*****; **OR**
    - Member has hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated RCC

When used as first-line therapy for stage IV disease, disease must be M1 or unresectable T4, M0

Cutaneous Melanoma † ‡ Φ [1,2,15-18,82,93]

- Used as first-line therapy for unresectable or metastatic***** disease; **AND**
  - Member is at least 12 years of age; **AND**
  - Used as a single agent or in combination with ipilimumab; **OR**
- Used as subsequent therapy for unresectable or metastatic***** disease; **AND**
  - Member is at least 12 years of age; **AND**
    - Used as re-induction therapy in members who experienced disease control *(i.e., complete or partial response or stable disease)* and no residual toxicity from prior anti-PD-1 immunotherapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **AND**
      - Used as a single agent or in combination with ipilimumab; **OR**
    - Used after disease progression, intolerance, and/or projected risk of progression with BRAF-targeted therapy; **AND**
      - Used as a single agent or in combination with ipilimumab; **OR**
- Used as adjuvant treatment; **AND**

- Used as a single agent; **AND**
  - Member is at least 12 years of age; **AND**
    - Member has stage IIB, stage IIC, or metastatic disease and has undergone complete resection †; **OR**
    - Member has stage III disease; **AND**
      - Member has undergone complete resection †; **OR**
      - Member has resected sentinel node positive disease, during radiographic surveillance OR after complete lymph node dissection (CLND); **OR**
      - Member has clinically positive node(s) following wide excision of the primary tumor and therapeutic lymph node dissection (TLND); **OR**
      - Member has clinical satellite/in-transit metastases and has no evidence of disease (NED) after complete excision to clear margins OR NED after initial treatment with local or regional therapy; **OR**
      - Used following wide excision alone or wide excision with negative sentinel lymph node biopsy *(stage IIIB/C/D disease only)*; **OR**
      - Used for disease that is sentinel lymph node negative or sentinel lymph node biopsy not performed *(stage IIIB/C/D disease only)*; **OR**
    - Member has local satellite/in-transit recurrence and has NED after complete excision OR NED after initial treatment with local or regional therapy; **OR**
    - Member has resectable disease limited to nodal recurrence following excision of the recurrence; **OR**
    - Member has oligometastatic disease and NED following metastasis-directed therapy (i.e., T-VEC/intralesional therapy, stereotactic ablative radiation therapy or complete resection) OR following systemic therapy followed by resection; **OR**
  - Used in combination with ipilimumab; **AND**
    - Member has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., complete resection, stereotactic ablative radiation therapy or T-VEC/intralesional therapy) OR following systemic therapy followed by resection; **OR**
- Used as neoadjuvant therapy; **AND**
  - Used as a single agent or in combination with ipilimumab; **AND**
    - Member has stage III disease; **AND**
      - Used as primary treatment for clinically positive, resectable nodal disease; **OR**
      - Used for limited resectable disease with clinical satellite/in-transit metastases; **OR**
    - Member has limited resectable local satellite/in-transit recurrence; **OR**
    - Member has resectable disease limited to nodal recurrence

**Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive nodes, or clinical satellite/in-transit metastases, as well as unresectable/borderline resectable local satellite/in-transit recurrence,*

unresectable nodal recurrence, oligometastatic disease, and widely disseminated distant metastatic disease and/or brain metastases.

Uveal Melanoma ‡ [2,19,20,80]

- Member has metastatic or unresectable disease; **AND**
- Used as a single agent or in combination with ipilimumab

Merkel Cell Carcinoma ‡ [2,4,33,65,83]

- Used as neoadjuvant treatment; **AND**
  - Used as a single agent; **AND**
    - Member is a surgical candidate with primary clinical N0 locally advanced disease where curative surgery and curative radiation therapy were originally deemed not feasible; **OR**
    - Member has primary clinical N+, M0 regional disease with biopsy positive draining nodal basin; **OR**
- Used for M1 disseminated disease; **AND**
  - Used as a single agent or in combination with ipilimumab; **OR**
- Used for in-transit N+ regional disease; **AND**
  - Used as a single agent or in combination with ipilimumab; **OR**
- Used for recurrent N+ regional disease; **AND**
  - Curative surgery and curative radiation therapy (RT) are not feasible; **AND**
  - Used as a single agent or in combination with ipilimumab; **OR**
- Used for primary N+, M0 regional disease with biopsy positive draining nodal basin; **AND**
  - Curative surgery and curative RT are not feasible; **AND**
  - Used as a single agent or in combination with ipilimumab

Peritoneal Mesothelioma (PeM)* ‡ [2,64,90]

- Used as a single agent or in combination with ipilimumab as subsequent therapy (if chemotherapy was administered first-line); **OR**
- Used in combination with ipilimumab as first-line therapy; **AND**
  - Used as adjuvant treatment for medically operable disease following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC); **AND**
    - Member has surgical or pathologic high-risk features**; **OR**
  - Member has medically inoperable disease and/or complete cytoreduction not achievable, or presence of any high-risk features**; **OR**
  - Member has disease progression following CRS + HIPEC if no prior adjuvant systemic therapy was given

**Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

***High-risk features include: biphasic/sarcomatoid histology, nodal metastasis, Ki-67 >9%, thrombocytosis, PS=2, bicavitary disease, high disease burden/incomplete cytoreduction (Peritoneal Cancer Index [PCI] >17, completeness of cytoreduction (cc) score >1)*

Pleural Mesothelioma (PM)* † ‡ Φ [1,2,37,38,47,64,81]

- Used as a single agent or in combination with ipilimumab as subsequent therapy (if chemotherapy was administered first-line); **OR**
- Used in combination with ipilimumab; **AND**
  - Used as first-line therapy; **OR**
  - Used as induction therapy prior to surgical exploration; **AND**
    - Member has clinical stage I disease and epithelioid histology

**Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,22,23,43,45,46]

- Member has resectable (tumors ≥ 4 cm or node positive) disease; **AND**
  - Member has no known EGFR mutations or ALK gene fusions; **AND**
  - Used as neoadjuvant therapy in combination with platinum-doublet chemotherapy (e.g., cisplatin/carboplatin in combination with paclitaxel, pemetrexed, gemcitabine, or docetaxel) with the option of continuing single-agent nivolumab as adjuvant treatment after surgery; **OR**
- Used for recurrent, advanced, or metastatic disease; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Members who have tumors that are negative for actionable biomarkers****** (may be KRAS G12C mutation positive); **OR**
      - Members who are positive for one of the following biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, ERBB2 (HER2), or NRG1 gene fusion; **AND**
    - Used in combination with one of the following:
      - Used in combination with ipilimumab; **OR**
      - Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); **OR**
  - Used as subsequent therapy; **AND**
    - Used as a single agent; **OR**
    - Used for one of the following:
      - Members who are positive for one of the following biomarkers and have received prior targeted therapy**§**: EGFR S768I, L861Q, and/or G719X; **OR**
      - Members who are positive for one of the following biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or ERBB2 (HER2); **AND**

        - Used in combination with one of the following:
            - Used in combination with ipilimumab; **OR**
            - Used in combination with ipilimumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); **OR**
    - Used as continuation maintenance therapy in combination with ipilimumab; **AND**
        - Member has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy

*** Note: Actionable biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2). Complete biomarker testing including molecular assessment of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, NRG1, and ERBB2 (HER2) via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these members are treated as though they do not have driver oncogenes.*
§ Genomic Aberration/Mutational Driver Targeted Therapies: Refer to guidelines for appropriate use

Pediatric Aggressive Mature B-Cell Lymphomas – Primary Mediastinal Large B-Cell Lymphoma (PMBCL) ‡ [2,74-76]

- Member is ≤ 18 years of age*; **AND**
    - Used in combination with brentuximab vedotin; **AND**
        - Used for relapsed or refractory disease; **OR**
        - Used as consolidation/additional therapy if a partial response was achieved after therapy for relapsed or refractory disease; **OR**
    - Used as a single agent for relapsed or refractory disease

** Pediatric Primary Mediastinal Large B-Cell Lymphoma may be applicable to adolescent and young adult (AYA) members <39 years who are treated in a pediatric oncology setting.*

Small Bowel Adenocarcinoma ‡ [2,31,39]

- Used as a single agent or in combination with ipilimumab; **AND**
- Member has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease OR polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Member has advanced or metastatic disease (*Note: Nivolumab + ipilimumab may be considered as subsequent therapy if checkpoint inhibitor monotherapy was previously received*); **OR**
    - Member has locally unresectable or medically inoperable disease; **AND**
        - Used as primary treatment

Small Cell Lung Cancer (SCLC) ‡ Φ [2,24,61]

- Used as subsequent systemic therapy as a single agent for relapsed or progressive disease

Soft Tissue Sarcoma ‡ [2,72,84]

- Extremity/Body Wall* or Head/Neck*
  - Used as a single agent or in combination with ipilimumab; **AND**
  - Used as subsequent therapy for advanced/metastatic disease with disseminated metastases; **AND**
    - Member has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; **OR**
    - Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
      - Member has no satisfactory alternative treatment options
- Retroperitoneal/Intra-Abdominal**
  - Used as a single agent or in combination with ipilimumab; **AND**
  - Used as one of the following:
    - Alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable localized disease; **OR**
    - Palliative subsequent therapy for stage IV disease with disseminated metastases; **AND**
  - Used for one of the following:
    - Member has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas; **OR**
    - Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
      - Member has no satisfactory alternative treatment options
- Pleomorphic Rhabdomyosarcoma
  - Used as a single agent or in combination with ipilimumab; **AND**
  - Used as subsequent therapy for advanced/metastatic disease
- Borderline/Malignant Phyllodes Tumor of the Breast
  - Used as a single agent or in combination with ipilimumab; **AND**
  - Used as subsequent therapy for unresectable or metastatic disease; **AND**
  - Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖**; AND**
  - Member has no satisfactory alternative treatment options
- Angiosarcoma
  - Used in combination with ipilimumab

- Dedifferentiated Liposarcoma with or without Concurrent Well-Differentiated Liposarcoma
  - Used as a single agent or in combination with ipilimumab
- Epithelioid Hemangioendothelioma
  - Used as a single agent or in combination with ipilimumab; **AND**
  - Used as subsequent therapy for unresectable or metastatic disease; **AND**
  - Member has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖**; AND**
  - Member has no satisfactory alternative treatment options

**For atypical lipomatous tumor/well-differentiated liposarcoma (ALT/WDLPS) of the extremity, abdominal wall, or trunk that was initially diagnosed as ALT/WDLPS and shows evidence of de-differentiation, treat as other soft tissue sarcomas.*

***For well-differentiated liposarcoma (WDLPS-retroperitoneum, paratesticular) with or without evidence of de-differentiation, treat as other soft tissue sarcomas.*

Extranodal NK/T-Cell Lymphomas ‡ [2,40]

- Used as a single agent for relapsed or refractory disease; **AND**
- Used following additional therapy with an alternative asparaginase-based chemotherapy regimen not previously used; **AND**
- Participation in a clinical trial is unavailable

Uterine Neoplasms ‡ [2,48,72]

- Member has Endometrial Carcinoma; **AND**
  - Used as subsequent therapy as one of the following:
    - Single agent for recurrent disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **OR**
    - In combination with ipilimumab for recurrent unresectable or metastatic disease that is tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
      - Disease has progressed following prior treatment and there are no satisfactory alternative treatment options; **AND**
  - Will not be used for either of the following:
    - Therapy for locoregional recurrence in members with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
    - Therapy after surgical exploration for locoregional recurrence in members with disease confined to the vagina or paravaginal soft tissue; **OR**
- Member has Uterine Sarcoma; **AND**
  - Used as subsequent therapy in combination with ipilimumab; **AND**

- Member has unresectable or metastatic disease that is tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Disease has progressed following prior treatment and there are no satisfactory alternative treatment options

Vulvar Cancer ‡ [2,49,136]

- Used as subsequent treatment for advanced, recurrent, or metastatic disease; **AND**
  - Used as single agent for HPV-related tumors; **OR**
  - Used in combination with ipilimumab

Thyroid Carcinoma ‡ [2,94-96]

- Used as a single agent; **AND**
- Used for stage IVC (metastatic) anaplastic carcinoma

Vaginal Cancer ‡ [2,49,97]

- Used as subsequent therapy for recurrent or metastatic disease; **AND**
  - Used in combination with ipilimumab; **OR**
  - Used as a single agent; **AND**
    - Tumor expresses PD-L1 (e.g., CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) ‡ [2]

- Member has histologic transformation (Richter); **AND**
- Used as a single agent or in combination with ibrutinib; **AND**
  - Used as additional therapy for partial response, refractory disease, or progression while on prior treatment ^; **OR**
  - Used as first-line treatment for Richter transformation if previously treated for CLL; **OR**
  - Used as continuation therapy for complete response until progression

^*Prior treatment could have included immune checkpoint inhibitor therapy (e.g., PD-1/PD-L1-directed therapy)*

Adrenal Gland Tumor ‡ [2,128]

- Member has locoregional unresectable or metastatic adrenocortical carcinoma (ACC); **AND**
- Used in combination with ipilimumab

Squamous Cell Skin Cancer ‡ [2,129,130]

- Used as a single agent; **AND**
  - Member has locally advanced disease; **AND**

- Used as primary treatment if curative surgery and curative radiation therapy (RT) are not feasible; **OR**
- Used as additional treatment if positive surgical margins and curative surgery and curative RT are not feasible; **OR**

- Member has regional disease that is unresectable, inoperable, or incompletely resected if curative RT is not feasible; **OR**
- Member has satellitosis/in-transit metastasis that is unresectable or incompletely resected; **OR**
- Member has regional recurrence or distant metastatic disease

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡ [2,141]

- Used in combination with ipilimumab; **AND**
  - Member has clear cell carcinoma of the ovary; **AND**
    - Used for persistent or recurrent platinum-resistant disease; **OR**
  - Member has small cell carcinoma of the ovary (hypercalcemic type); **AND**
    - Used for progressive or recurrent disease

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/CompanionDiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [Δ 1,2,4-6,15-42,43,47,49,50,52-54,68,72,73,79,81,82,89]

Prior authorization validity may be renewed based upon the following criteria:

- Member continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), severe immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis/hepatotoxicity, endocrinopathies, nephritis/renal dysfunction, adverse skin reactions/rash, etc.), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Δ Notes:

- Members responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.
- Members previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for

continued therapy beyond the 24-month limit without interruption or discontinuation.
- Members who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ 1,4-6,19,20,27,24,31-42,48-50,52-54,55,58,59,61,65,67,68,71-87,89,91,93,96,98-119,121-124,127-137,139-141

Indication	Dose
Ampullary Adenocarcinoma	Single agent: • Administer 3 mg/kg intravenously every 2 weeks, 240 mg intravenously every 2 weeks, or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then 3 mg/kg every 2 weeks, or 240 mg every 2 weeks, or 480 mg every 4 weeks until disease progression or unacceptable toxicity
Anal Carcinoma	Single agent: • Administer 240 mg intravenously every 2 weeks, 480 mg intravenously every 4 weeks, 3 mg/kg intravenously every 2 weeks, or 6 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with paclitaxel and carboplatin: • Administer 240 mg intravenously every 2 weeks, 480 mg intravenously every 4 weeks, 3 mg/kg intravenously every 2 weeks, or 6 mg/kg intravenously every 4 weeks for up to a maximum of 1 year. *(Note: combination therapy may be administered for up to 24 weeks, followed by single agent maintenance therapy)*
Biliary Tract Cancers	Subsequent therapy: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years Neoadjuvant therapy (gallbladder cancer only): • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 2 to 6 months
Urothelial Carcinoma (Bladder Cancer)	First-line therapy: • Administer 360 mg intravenously every 3 weeks for up to 6 cycles (given in combination with gemcitabine and cisplatin), followed by a single-agent maintenance dose of 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity for up to 2 years Disease progression or second-line treatment: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every

	4 weeks until disease progression or unacceptable toxicity Adjuvant treatment: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year
Bone Cancer	In combination with ipilimumab: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years Single agent or in combination with sunitinib: • Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
Adult CNS Cancers	Single agent: • Administer 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks, or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 1 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks, or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Pediatric CNS Cancers	Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity
Colorectal Cancer (CRC)	Adult members and for pediatric members ≥ 12 years and ≥ 40 kg: • **Single agent:** Administer 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks, 480 mg intravenously every 4 weeks, or 6 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity • **In combination with ipilimumab:** ○ Administer 240 mg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), followed by single agent regimen until disease progression or unacceptable toxicity; **OR** ○ Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), followed by single agent regimen until disease progression or unacceptable toxicity Pediatric members ≥ 12 years and < 40 kg: • **Single agent:** Administer 3 mg/kg intravenously every 2 weeks or 6 mg/kg every 4 weeks until disease progression or unacceptable toxicity • **In combination with ipilimumab:** Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), followed by single agent regimen until disease progression or unacceptable toxicity
Appendiceal Neoplasms and Cancers	• **Single agent:** Administer 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks, or 480 mg intravenously every 4 weeks, or 6 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity

	• **In combination with ipilimumab:** Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then follow with the single agent regimen until disease progression or unacceptable toxicity
Esophageal and Esophagogastric/ Gastroesophageal Junction Cancer	First-line therapy (MSI-H/dMMR adenocarcinoma and squamous cell carcinoma): • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 16 weeks, followed by 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks for a maximum of 2 years of treatment; **OR** • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks (given in combination with fluoropyrimidine- and platinum-containing chemotherapy) for a maximum of 2 years of treatment First line therapy (PD-L1 squamous cell carcinoma): • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks or 480 mg intravenously every 4 weeks (given in combination with fluoropyrimidine- and platinum-containing chemotherapy) until disease progression or unacceptable toxicity for up to 2 years; **OR** • Administer 3 mg/kg intravenously every 2 weeks or 360 mg intravenously every 3 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years First line therapy (PD-L1 adenocarcinoma): • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks (given in combination with fluoropyrimidine- and platinum-containing chemotherapy) until disease progression or unacceptable toxicity for up to 2 years Subsequent therapy (MSI-H/dMMR adenocarcinoma and squamous cell carcinoma): • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 16 weeks, followed by 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks for a maximum of 2 years of treatment Subsequent therapy (squamous cell carcinoma): • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks as a single agent until disease progression or unacceptable toxicity Neoadjuvant/perioperative therapy (MSI-H/dMMR adenocarcinoma): • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 12 weeks, followed by surgery and then post-operative therapy *(See below)* Post-operative therapy (MSI-H/dMMR adenocarcinoma): • Administer 480 mg intravenously every 4 weeks for 36 weeks (9 doses) Adjuvant therapy following neoadjuvant chemoradiotherapy (adenocarcinoma and squamous carcinoma): • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every

	4 weeks until disease progression or unacceptable toxicity for up to 1 year Induction therapy for relieving dysphagia (MSI-H/dMMR squamous cell carcinoma): • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 16 weeks, followed by 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks for a maximum of 2 years of treatment; **OR** • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks (given in combination with fluoropyrimidine- and platinum-containing chemotherapy) for a maximum of 2 years of treatment Induction therapy for relieving dysphagia (PD-L1 squamous cell carcinoma): • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks (given in combination with fluoropyrimidine- and platinum-containing chemotherapy) for a maximum of 2 years of treatment; **OR** • Administer 3 mg/kg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years
Gastric Cancer	First-line therapy: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 16 weeks, followed by 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks for a maximum of 2 years of treatment; **OR** • Administer 240 mg intravenously every 2 weeks or 360 mg intravenously every 3 weeks (given in combination with fluoropyrimidine- and platinum-containing chemotherapy) until disease progression or unacceptable toxicity for up to 2 years Subsequent therapy: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 16 weeks, followed by 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks for a maximum of 2 years of treatment Neoadjuvant/perioperative therapy: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) for 12 weeks, followed by surgery and then post-operative therapy *(See below)* Post-operative therapy: • Administer 480 mg intravenously every 4 weeks for 36 weeks (9 doses)
Gestational Trophoblastic Neoplasia (GTN)	Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity
SCCHN	Single agent OR in combination with cisplatin and gemcitabine:

	• Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with cetuximab: • Administer 240 mg intravenously every 2 weeks until disease progression or unacceptable toxicity
Hepatocellular Carcinoma (HCC)	Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 1 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Adult cHL	Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with brentuximab vedotin • Administer 3 mg/kg intravenously every 3 weeks for up to 24 weeks (8 doses) In combination with ICE (ifosfamide, carboplatin, and etoposide) • Administer 240 mg intravenously every 2 weeks for up to 12 weeks (6 doses) In combination with AVD (doxorubicin, vinblastine, dacarbazine) • Administer 240 mg intravenously every 2 weeks for up to 24 weeks (12 doses)
Pediatric cHL	Single agent: • Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity (*Note: There is no pediatric data for this regimen*) In combination with brentuximab vedotin-based therapy • Administer 3 mg/kg intravenously every 3 weeks for up to 12 weeks (4 doses) In combination with ICE (ifosfamide, carboplatin, and etoposide) • Administer 240 mg intravenously every 2 weeks for up to 12 weeks (6 doses) (*Note: There is no pediatric data for this regimen*) In combination with AVD (doxorubicin, vinblastine, dacarbazine) • Members ≥ 12 years of age weighing 40 kg or more: Administer 240 mg intravenously every 2 weeks for up to 24 weeks (12 doses) • Members 12 to 17 years of age weighing less than 40 kg: Administer 3 mg/kg (up to 240 mg max) every 2 weeks for up to 24 weeks (12 doses)
Kaposi Sarcoma	Single agent: • Administer 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years

Renal Cell Carcinoma (RCC)	Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then follow with the single agent regimen until disease progression or unacceptable toxicity In combination with cabozantinib (Cabometyx): • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity for up to 2 years
Pleural Mesothelioma (PM) & Peritoneal Mesothelioma (PeM) *(including pericardial mesothelioma and tunica vaginalis testis mesothelioma)*	Single agent: • Administer 3 mg/kg intravenously or 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Subsequent therapy: ○ Administer 3 mg/kg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity; **OR** ○ Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity • All other lines of therapy: ○ Administer 360 mg intravenously every 3 weeks or 3 mg/kg every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years
Cutaneous Melanoma	Adult members and pediatric members ≥ 12 years and ≥ 40 kg: Single agent • Unresectable or metastatic disease: Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity • Adjuvant treatment: Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year • Neoadjuvant treatment: Administer 3 mg/kg intravenously every 14 days for 4 doses In combination with ipilimumab • Unresectable or metastatic disease: Administer 1 mg/kg intravenously or 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then follow with the single agent regimen • Adjuvant treatment: Administer 1 mg/kg intravenously or 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day) • Neoadjuvant treatment: Administer 3 mg/kg intravenously every 3 weeks for up

	to 2 doses (given in combination with ipilimumab on the same day) Pediatric members ≥ 12 years and < 40 kg: Single agent • Unresectable or metastatic disease: Administer 3 mg/kg intravenously every 2 weeks or 6 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity • Adjuvant treatment: Administer 3 mg/kg intravenously every 2 weeks or 6 mg/kg intravenously every 4 weeks until disease recurrence or unacceptable toxicity for up to 1 year In combination with ipilimumab • Unresectable or metastatic disease: Administer 1 mg/kg intravenously or 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then follow with the single agent regimen • Adjuvant treatment: Administer 1 mg/kg intravenously or 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day)
Uveal Melanoma	Single agent: • Administer up to 10 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 1 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then 3 mg/kg intravenously every 2 weeks, or 240 mg every 2 weeks, or 480 mg every 4 weeks until disease progression or unacceptable toxicity
Merkel Cell Carcinoma	Neoadjuvant treatment: • Administer 240 mg intravenously every 2 weeks (days 1 and 15) for a total of 2 doses All other settings: Single agent: • Administer 240 mg intravenously every 2 weeks or 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 1 mg/kg intravenously OR 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then follow with the single agent regimen; **OR** • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity
Non-Small Cell Lung Cancer (NSCLC)	Neoadjuvant treatment followed by optional adjuvant treatment: • Administer 360 mg intravenously with platinum-doublet chemotherapy every 3 weeks for up to 4 cycles with the option of continuing single-agent nivolumab as adjuvant treatment after surgery at 480 mg intravenously every 4 weeks for up to 13 cycles or until disease recurrence or unacceptable toxicity Single agent: • Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every

	4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 360 mg intravenously every 3 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years; **OR** • Administer 3 mg/kg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity for up to 2 years In combination with ipilimumab and platinum-doublet chemotherapy: • Administer 360 mg intravenously every 3 weeks (given in combination with ipilimumab every 6 weeks and histology-based platinum-doublet chemotherapy every 3 weeks for 2 cycles) until disease progression or unacceptable toxicity for up to 2 years
Pediatric Primary Mediastinal Large B-Cell Lymphoma (PMBCL)	Single agent: • Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity In combination with brentuximab vedotin: • Administer 3 mg/kg intravenously, with brentuximab vedotin on day 1, every 2 weeks until disease progression or unacceptable toxicity
Small Bowel Adenocarcinoma	Single agent: • Administer 3 mg/kg intravenously every 2 weeks, or 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks, or 6 mg/kg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab on the same day), then 3 mg/kg or 240 mg intravenously every 2 weeks until disease progression or unacceptable toxicity
Small Cell Lung Cancer (SCLC)	Administer 3 mg/kg intravenously every 2 weeks or 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Soft Tissue Sarcoma	Single agent: • Administer 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity In combination with ipilimumab: • Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity
Extranodal NK/T-Cell Lymphoma & Thyroid Carcinoma	Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity
Uterine Neoplasms	• Administer 3 mg/kg intravenously every 2 weeks for 8 doses, then 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity; **OR**

<table>
<tr><td></td><td>• Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity</td></tr>
<tr><td>Vulvar Cancer, Vaginal Cancer, & Cervical Cancer</td><td><u>Single agent:</u>
• Administer 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity for up to 2 years
<u>In combination with ipilimumab</u>:
• Administer nivolumab 3 mg/kg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression, unacceptable toxicity or for a maximum of 2 years; OR
• Administer nivolumab 1 mg/kg intravenously every 3 weeks for 4 doses (given in combination with ipilimumab every 3 weeks), then followed by single agent regimen until disease progression, unacceptable toxicity or for a maximum of 2 years</td></tr>
<tr><td>CLL/SLL</td><td><u>Single agent or in combination with ibrutinib:</u>
• Administer 3 mg/kg intravenously every 2 weeks or 240 mg intravenously every 2 weeks or 480 mg intravenously every 4 weeks, until disease progression or unacceptable toxicity</td></tr>
<tr><td>Adrenal Gland Tumors</td><td>Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity</td></tr>
<tr><td>Squamous Cell Skin Cancer</td><td><u>Weight-based dosing:</u>
• Administer 3 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity for up to 1 year
OR
<u>Flat dosing:</u>
• Administer 240 mg intravenously every 2 weeks until disease progression or unacceptable toxicity for up to 2 years</td></tr>
<tr><td>Ovarian, Fallopian Tube, & Primary Peritoneal Cancer</td><td><u>Clear cell carcinoma of the ovary:</u>
• Administer 3 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with ipilimumab on the same day), then 480 mg intravenously every 4 weeks until disease progression or unacceptable toxicity for up to 2 years
<u>Small cell carcinoma of the ovary (hypercalcemic type):</u>
• Administer 240 mg intravenously every 2 weeks (given in combination with ipilimumab every 6 weeks) until disease progression or unacceptable toxicity</td></tr>
<tr><td colspan="2"><u>Dosing should be calculated using actual body weight and not flat dosing (as applicable) based on the following:</u>
<table>
<tr><th>Frequency (days)</th><th>Dosing (mg/kg)</th><th>Weight (kg)</th><th>Dose (mg)</th></tr>
<tr><td rowspan="3">14</td><td rowspan="3">3</td><td><80</td><td>220</td></tr>
<tr><td><73</td><td>200</td></tr>
<tr><td><66</td><td>180</td></tr>
</table></td></tr>
</table>

			<58	160
			<51	140
			<44	120
	21	4.5	<80	340
			<78	320
			<73	300
			<68	280
			<63	260
			<58	240
			<53	220
			<48	200
			<44	180
	28	6	<80	440
			<77	420
			<73	400
			<69	380
			<66	360
			<62	340
			<58	320
			<55	300
			<51	280
			<47	260
			<44	240

Note: This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide. Member-specific variables should be taken into account.

VI. Billing Code/Availability Information

HCPCS Code:

- J9299 – Injection, nivolumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Opdivo 40 mg/4 mL single-dose vial: 00003-3772-xx
- Opdivo 100 mg/10 mL single-dose vial: 00003-3774-xx
- Opdivo 120 mg/12 mL single-dose vial: 00003-3756-xx
- Opdivo 240 mg/24 mL single-dose vial: 00003-3734-xx

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion

Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C00.3	Malignant neoplasm of upper lip, inner aspect
C00.4	Malignant neoplasm of lower lip, inner aspect
C00.5	Malignant neoplasm of lip, unspecified, inner aspect
C00.6	Malignant neoplasm of commissure of lip, unspecified
C00.8	Malignant neoplasm of overlapping sites of lip
C00.9	Malignant neoplasm of lip, unspecified
C01	Malignant neoplasm of base of tongue
C02.0	Malignant neoplasm of dorsal surface of tongue
C02.1	Malignant neoplasm of border of tongue
C02.2	Malignant neoplasm of ventral surface of tongue
C02.3	Malignant neoplasm of anterior two-thirds of tongue, part unspecified
C02.4	Malignant neoplasm of lingual tonsil
C02.8	Malignant neoplasm of overlapping sites of tongue
C02.9	Malignant neoplasm of tongue, unspecified
C03.0	Malignant neoplasm of upper gum
C03.1	Malignant neoplasm of lower gum
C03.9	Malignant neoplasm of gum, unspecified
C04.0	Malignant neoplasm of anterior floor of mouth
C04.1	Malignant neoplasm of lateral floor of mouth
C04.8	Malignant neoplasm of overlapping sites of floor of mouth
C04.9	Malignant neoplasm of floor of mouth, unspecified
C05.0	Malignant neoplasm of hard palate
C05.1	Malignant neoplasm of soft palate
C05.2	Malignant neoplasm of uvula
C05.8	Malignant neoplasm of overlapping sites of palate
C05.9	Malignant neoplasm of palate, unspecified
C06.0	Malignant neoplasm of cheek mucosa
C06.2	Malignant neoplasm of retromolar area

C06.80	Malignant neoplasm of overlapping sites of unspecified parts of mouth
C06.89	Malignant neoplasm of overlapping sites of other parts of mouth
C06.9	Malignant neoplasm of mouth, unspecified
C09.0	Malignant neoplasm of tonsillar fossa
C09.1	Malignant neoplasm of tonsillar pillar (anterior) (posterior)
C09.8	Malignant neoplasm of overlapping sites of tonsil
C09.9	Malignant neoplasm of tonsil, unspecified
C10.0	Malignant neoplasm of vallecula
C10.1	Malignant neoplasm of anterior surface of epiglottis
C10.2	Malignant neoplasm of lateral wall of oropharynx
C10.3	Malignant neoplasm of posterior wall of oropharynx
C10.4	Malignant neoplasm of branchial cleft
C10.8	Malignant neoplasm of overlapping sites of oropharynx
C10.9	Malignant neoplasm of oropharynx, unspecified
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C12	Malignant neoplasm of pyriform sinus
C13.0	Malignant neoplasm of postcricoid region
C13.1	Malignant neoplasm of aryepiglottic fold, hypopharyngeal aspect
C13.2	Malignant neoplasm of posterior wall of hypopharynx
C13.8	Malignant neoplasm of overlapping sites of hypopharynx
C13.9	Malignant neoplasm of hypopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer’s ring
C14.8	Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified

C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.3	Angiosarcoma of liver

C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C32.0	Malignant neoplasm of glottis
C32.1	Malignant neoplasm of supraglottis
C32.2	Malignant neoplasm of subglottis
C32.3	Malignant neoplasm of laryngeal cartilage
C32.8	Malignant neoplasm of overlapping sites of larynx
C32.9	Malignant neoplasm of larynx, unspecified
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb

C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose

C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C44.02	Squamous cell carcinoma of skin of lip
C44.121	Squamous cell carcinoma of skin of unspecified eyelid, including canthus
C44.1221	Squamous cell carcinoma of skin of right upper eyelid, including canthus
C44.1222	Squamous cell carcinoma of skin of right lower eyelid, including canthus
C44.1291	Squamous cell of carcinoma of skin of left upper eyelid, including canthus
C44.1292	Squamous cell carcinoma of skin of left lower eyelid, including canthus
C44.221	Squamous cell carcinoma of skin of unspecified ear and external auricular canal
C44.222	Squamous cell carcinoma of skin of right ear and external auricular canal
C44.229	Squamous cell carcinoma of skin of left ear and external auricular canal
C44.320	Squamous cell carcinoma of skin of unspecified parts of face
C44.321	Squamous cell carcinoma of skin of nose
C44.329	Squamous cell carcinoma of skin of other parts of face
C44.42	Squamous cell carcinoma of skin of scalp and neck
C44.520	Squamous cell carcinoma of anal skin
C44.521	Squamous cell carcinoma of skin of breast
C44.529	Squamous cell carcinoma of skin of other part of trunk
C44.621	Squamous cell carcinoma of skin of unspecified upper limb, including shoulder
C44.622	Squamous cell carcinoma of skin of right upper limb, including shoulder
C44.629	Squamous cell carcinoma of skin of left upper limb, including shoulder
C44.721	Squamous cell carcinoma of skin of unspecified lower limb, including hip
C44.722	Squamous cell carcinoma of skin of right lower limb, including hip

C44.729	Squamous cell carcinoma of skin of left lower limb, including hip
C44.82	Squamous cell carcinoma of overlapping sites of skin
C44.92	Squamous cell carcinoma of skin, unspecified
C45.0	Mesothelioma of pleura
C45.1	Mesothelioma of peritoneum
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, unspecified
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous system
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck

C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb, including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of eyelid, including canthus
C4A.111	Merkel cell carcinoma of right upper eyelid, including canthus
C4A.112	Merkel cell carcinoma of right lower eyelid, including canthus
C4A.121	Merkel cell carcinoma of left upper eyelid, including canthus
C4A.122	Merkel cell carcinoma of left lower eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.21	Merkel cell carcinoma of right ear and external auricular canal
C4A.22	Merkel cell carcinoma of left ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.31	Merkel cell carcinoma of nose
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.51	Merkel cell carcinoma of anal skin
C4A.52	Merkel cell carcinoma of skin of breast
C4A.59	Merkel cell carcinoma of other part of trunk
C4A.60	Merkel cell carcinoma of unspecified upper limb, including shoulder
C4A.61	Merkel cell carcinoma of right upper limb, including shoulder
C4A.62	Merkel cell carcinoma of left upper limb, including shoulder
C4A.70	Merkel cell carcinoma of unspecified lower limb, including hip
C4A.71	Merkel cell carcinoma of right lower limb, including hip
C4A.72	Merkel cell carcinoma of left lower limb, including hip
C4A.8	Merkel cell carcinoma of overlapping sites
C4A.9	Merkel cell carcinoma, unspecified
C51.0	Malignant neoplasm of labium majus

C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.8	Malignant neoplasm of overlapping sites of vulva
C51.9	Malignant neoplasm of vulva, unspecified
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C58	Malignant neoplasm of placenta
C61	Malignant neoplasm of prostate
C64.1	Malignant neoplasm of right kidney, except renal pelvis

C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C66.1	Malignant neoplasm of right ureter
C66.2	Malignant neoplasm of left ureter
C66.9	Malignant neoplasm of unspecified ureter
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder
C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
C68.0	Malignant neoplasm of urethra
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle

C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.9	Malignant neoplasm of central nervous system, unspecified
C73	Malignant neoplasm of thyroid gland
C74.00	Malignant neoplasm of cortex of unspecified adrenal gland
C74.01	Malignant neoplasm of cortex of right adrenal gland
C74.02	Malignant neoplasm of cortex of left adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C76.0	Malignant neoplasm of head, face and neck
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.31	Secondary malignant neoplasm of brain
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.1	Secondary Merkel cell carcinoma
C7B.8	Other secondary neuroendocrine tumors
C81.10	Nodular sclerosis Hodgkin lymphoma, unspecified site

C81.11	Nodular sclerosis Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.12	Nodular sclerosis Hodgkin lymphoma, intrathoracic lymph nodes
C81.13	Nodular sclerosis Hodgkin lymphoma, intra-abdominal lymph nodes
C81.14	Nodular sclerosis Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.15	Nodular sclerosis Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.16	Nodular sclerosis Hodgkin lymphoma, intrapelvic lymph nodes
C81.17	Nodular sclerosis Hodgkin lymphoma, spleen
C81.18	Nodular sclerosis Hodgkin lymphoma, lymph nodes of multiple sites
C81.19	Nodular sclerosis Hodgkin lymphoma, extranodal and solid organ sites
C81.20	Mixed cellularity Hodgkin lymphoma, unspecified site
C81.21	Mixed cellularity Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.22	Mixed cellularity Hodgkin lymphoma, intrathoracic lymph nodes
C81.23	Mixed cellularity Hodgkin lymphoma, intra-abdominal lymph nodes
C81.24	Mixed cellularity Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.25	Mixed cellularity Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.26	Mixed cellularity Hodgkin lymphoma, intrapelvic lymph nodes
C81.27	Mixed cellularity Hodgkin lymphoma, spleen
C81.28	Mixed cellularity Hodgkin lymphoma, lymph nodes of multiple sites
C81.29	Mixed cellularity Hodgkin lymphoma, extranodal and solid organ sites
C81.30	Lymphocyte depleted Hodgkin lymphoma, unspecified site
C81.31	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.32	Lymphocyte depleted Hodgkin lymphoma, intrathoracic lymph nodes
C81.33	Lymphocyte depleted Hodgkin lymphoma, intra-abdominal lymph nodes
C81.34	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of axilla and upper limb
C81.35	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.36	Lymphocyte depleted Hodgkin lymphoma, intrapelvic lymph nodes
C81.37	Lymphocyte depleted Hodgkin lymphoma, spleen
C81.38	Lymphocyte depleted Hodgkin lymphoma, lymph nodes of multiple sites
C81.39	Lymphocyte depleted Hodgkin lymphoma, extranodal and solid organ sites
C81.40	Lymphocyte-rich Hodgkin lymphoma, unspecified site
C81.41	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of head, face, and neck
C81.42	Lymphocyte-rich Hodgkin lymphoma, intrathoracic lymph nodes
C81.43	Lymphocyte-rich Hodgkin lymphoma, intra-abdominal lymph nodes
C81.44	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of axilla and upper limb

C81.45	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of inguinal region and lower limb
C81.46	Lymphocyte-rich Hodgkin lymphoma, intrapelvic lymph nodes
C81.47	Lymphocyte-rich Hodgkin lymphoma, spleen
C81.48	Lymphocyte-rich Hodgkin lymphoma, lymph nodes of multiple sites
C81.49	Lymphocyte-rich Hodgkin lymphoma, extranodal and solid organ sites
C81.70	Other Hodgkin lymphoma unspecified site
C81.71	Other Hodgkin lymphoma lymph nodes of head, face, and neck
C81.72	Other Hodgkin lymphoma intrathoracic lymph nodes
C81.73	Other Hodgkin lymphoma intra-abdominal lymph nodes
C81.74	Other Hodgkin lymphoma lymph nodes of axilla and upper limb
C81.75	Other Hodgkin lymphoma lymph nodes of inguinal region and lower limb
C81.76	Other Hodgkin lymphoma intrapelvic lymph nodes
C81.77	Other Hodgkin lymphoma spleen
C81.78	Other Hodgkin lymphoma lymph nodes of multiple sites
C81.79	Other Hodgkin lymphoma extranodal and solid organ sites
C81.90	Hodgkin lymphoma, unspecified site
C81.91	Hodgkin lymphoma, unspecified lymph nodes of head, face, and neck
C81.92	Hodgkin lymphoma, unspecified intrathoracic lymph nodes
C81.93	Hodgkin lymphoma, unspecified intra-abdominal lymph nodes
C81.94	Hodgkin lymphoma, unspecified lymph nodes of axilla and upper limb
C81.95	Hodgkin lymphoma, unspecified lymph nodes of inguinal region and lower limb
C81.96	Hodgkin lymphoma, unspecified intrapelvic lymph nodes
C81.97	Hodgkin lymphoma, unspecified spleen
C81.98	Hodgkin lymphoma, unspecified lymph nodes of multiple sites
C81.99	Hodgkin lymphoma, unspecified extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites

C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C84.90	Mature T/NK-cell lymphomas, unspecified, unspecified site
C84.91	Mature T/NK-cell lymphomas, unspecified, lymph nodes of head, face, and neck
C84.92	Mature T/NK-cell lymphomas, unspecified, intrathoracic lymph nodes
C84.93	Mature T/NK-cell lymphomas, unspecified, intra-abdominal lymph nodes
C84.94	Mature T/NK-cell lymphomas, unspecified, lymph nodes of axilla and upper limb
C84.95	Mature T/NK-cell lymphomas, unspecified, lymph nodes of inguinal region and lower limb
C84.96	Mature T/NK-cell lymphomas, unspecified, intrapelvic lymph nodes
C84.97	Mature T/NK-cell lymphomas, unspecified, spleen
C84.98	Mature T/NK-cell lymphomas, unspecified, lymph nodes of multiple sites
C84.99	Mature T/NK-cell lymphomas, unspecified, extranodal and solid organ sites
C84.Z0	Other mature T/NK-cell lymphomas, unspecified site
C84.Z1	Other mature T/NK-cell lymphomas, lymph nodes of head, face, and neck
C84.Z2	Other mature T/NK-cell lymphomas, intrathoracic lymph nodes
C84.Z3	Other mature T/NK-cell lymphomas, intra-abdominal lymph nodes
C84.Z4	Other mature T/NK-cell lymphomas, lymph nodes of axilla and upper limb
C84.Z5	Other mature T/NK-cell lymphomas, lymph nodes of inguinal region and lower limb
C84.Z6	Other mature T/NK-cell lymphomas, intrapelvic lymph nodes
C84.Z7	Other mature T/NK-cell lymphomas, spleen
C84.Z8	Other mature T/NK-cell lymphomas, lymph nodes of multiple sites
C84.Z9	Other mature T/NK-cell lymphomas, extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes

C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C86.00	Extranodal NK/T-cell lymphoma, nasal type not having achieved remission
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D09.0	Carcinoma in situ of bladder
D37.02	Neoplasm of uncertain behavior of tongue
D37.04	Neoplasm of uncertain behavior of the minor salivary glands
D37.05	Neoplasm of uncertain behavior of pharynx
D37.09	Neoplasm of uncertain behavior of other specified sites of the oral cavity
D37.1	Neoplasm of uncertain behavior of stomach
D37.3	Neoplasm of uncertain behavior of appendix
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.0	Neoplasm of uncertain behavior of larynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
D39.2	Neoplasm of uncertain behavior of placenta
D48.60	Neoplasm of uncertain behavior of unspecified breast
D48.61	Neoplasm of uncertain behavior of right breast
D48.62	Neoplasm of uncertain behavior of left breast
O01.9	Hydatidiform mole, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

Z85.12	Personal history of malignant neoplasm of trachea
Z85.22	Personal history of malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.51	Personal history of malignant neoplasm of bladder
Z85.59	Personal history of malignant neoplasm of other urinary tract organ
Z85.71	Personal history of Hodgkin lymphoma
Z85.810	Personal history of malignant neoplasm of tongue
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx
Z85.820	Personal history of malignant melanoma of skin
Z85.821	Personal history of Merkel cell carcinoma
Z85.830	Personal history of malignant neoplasm of bone
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue
Z85.858	Personal history of malignant neoplasm of other endocrine glands

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdictio	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC