

Tevimbra® (tislelizumab-jsgr) (Intravenous)

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I. Length of Authorization ^Δ

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter, unless otherwise specified.
 - Anal Carcinoma in combination with carboplatin and paclitaxel, then continued as a single agent: Prior authorization validity may be renewed for up to a maximum of 12 months.
 - Classic Hodgkin Lymphoma (CHL) single agent maintenance therapy: Prior authorization validity may be renewed for up to a maximum of 2 years.

II. Dosing Limits

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

- CLL/SLL: 200 billable units every 21 days
- CHL: 200 billable units every 21 days x 8 doses, then 200 billable units every 56 days for 2 years.
- All other Indications: 1200 billable units every 84 days

III. Initial Approval Criteria ¹

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified ^Δ; **AND**

Esophageal and Esophagogastric/Gastroesophageal Junction Cancers † ‡ Φ ¹⁻³

- Member is medically fit and planned for esophagectomy; **AND**
 - Used as induction systemic therapy for relieving dysphagia; **AND**
 - Member has cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **AND**

- Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA) compliant test❖; **AND**
- Member has squamous cell carcinoma; **AND**
 - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
 - Used in combination with paclitaxel and platinum-based chemotherapy; **OR**
- Member is not a surgical candidate or has unresectable, recurrent, or metastatic disease; **AND**
 - 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**
 - Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
 - Member has human epidermal growth factor receptor 2 (HER2)-negative adenocarcinoma; **AND**
 - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
 - Member has squamous cell carcinoma; **AND**
 - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **OR**
 - Used in combination with paclitaxel and platinum-based chemotherapy; **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**
 - Used as a single agent; **AND**
 - Member has esophageal squamous cell carcinoma (ESCC) †

Gastric Cancers † ‡ Φ^{1,3,11}

- Used in combination with platinum and fluoropyrimidine-based chemotherapy; **AND**
- Member is not a surgical candidate or has unresectable, recurrent, or metastatic disease; **AND**
- 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 HER2-negative disease; **AND**
- Tumor expresses PD-L1 (CPS \geq 1) as determined by an FDA-approved or CLIA-compliant test❖

Hepatocellular Carcinoma ‡³

- Used as single-agent therapy; **AND**
 - Used as first-line systemic therapy; **AND**
 - Member has liver-confined, unresectable disease and is deemed ineligible for transplant; **OR**

- Member has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy; **OR**
- Used as subsequent therapy; **AND**
 - Member has disease progression on or after systemic therapy

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) ‡^{3,5}

- Used in combination with zanubrutinib for histologic (Richter) transformation; **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)

Head and Neck Cancers ‡^{3,6}

- Member has Cancer of the Nasopharynx; **AND**
 - Used as subsequent therapy; **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**
 - Member has a performance status 0-1; **AND**
 - Used as subsequent therapy in combination with cisplatin and gemcitabine; **AND**
 - Used for one of the following:
 - Unresectable locoregional recurrence with prior radiation therapy (RT)
 - Unresectable second primary with prior RT
 - Unresectable persistent disease with prior RT
 - Recurrent/persistent disease with distant metastases

* Very Advanced Head and Neck Cancer includes: Newly diagnosed (M0) locally advanced T4b, N0-3, or 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.

Small Bowel Adenocarcinoma ‡^{3,7,14}

- Used as single agent treatment; **AND**
- Member has microsatellite instability-high (MSI-H)/deficient mismatch repair (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; **OR**
- Member has locally unresectable or medically inoperable disease; **AND**
 - Used as primary treatment

Anal Carcinoma ‡^{3,8}

- 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

Colon Cancer ‡^{3,12,14}

- Used as single agent treatment; **AND**
- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for locally unresectable, medically inoperable, advanced, or metastatic disease

Appendiceal Neoplasms and Cancers ‡^{3,14,16}

- Used as single agent treatment; **AND**
- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease

Rectal Cancer ‡^{3,13-14}

- Used as single agent treatment; **AND**
- Member has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB > 50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for locally unresectable, medically inoperable, advanced or metastatic disease

Adult Classic Hodgkin Lymphoma (CHL) ‡^{3,17,18}

- Used in combination with GEMOX (gemcitabine, oxaliplatin)[^]; **AND**
- Used as subsequent therapy for relapsed or primary refractory disease with or without prior checkpoint inhibitor (e.g., PD-1/PD-L1-directed therapy) exposure

[^]Tislelizumab may be continued as maintenance therapy

Endometrial Carcinoma (Uterine Neoplasms) ‡³

- Used for recurrent MSI-H/dMMR disease; **AND**
- Used as single agent subsequent therapy; **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

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

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

IV. Renewal Criteria ^{Δ 1,3}

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

- Member continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.

^Δ **Notes:**

- Members responding to therapy who relapse \geq 6 months after discontinuation due to duration 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 without interruption or discontinuation.
- Members who complete adjuvant therapy and progress \geq 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 1,4,7-11,14-16,18,20}

| Indication | Dose |
|------------|--|
| CLL/SLL | <ul style="list-style-type: none"> • Administer 200 mg intravenously once every 3 weeks, until disease progression or unacceptable toxicity |
| CHL | <ul style="list-style-type: none"> • Administer 200 mg intravenously once every 3 weeks in combination with GEMOX for up to 8 cycles, followed by single agent maintenance therapy of 200 |

| | |
|-----------------------|---|
| | mg every 8 weeks for up to 2 years |
| Anal Carcinoma | <ul style="list-style-type: none"> Administer 150 mg intravenously once every 2 weeks, until disease progression or unacceptable toxicity; OR Administer 200 mg IV once every 3 weeks, until disease progression or unacceptable toxicity; OR Administer 300 mg once every 4 weeks, until disease progression or unacceptable toxicity; OR Administer 400 mg IV once every 6 weeks, until disease progression or unacceptable toxicity <p><i>Note: when given in combination with carboplatin and paclitaxel, combination therapy may be administered for up to 24 weeks, followed by single agent maintenance therapy for up to a maximum of 12 months of therapy</i></p> |
| All Other Indications | <ul style="list-style-type: none"> Administer 150 mg intravenously once every 2 weeks, until disease progression or unacceptable toxicity; OR Administer 200 mg intravenously once every 3 weeks, until disease progression or unacceptable toxicity; OR Administer 300 mg intravenously once every 4 weeks, until disease progression or unacceptable toxicity; OR Administer 400 mg intravenously once every 6 weeks, until disease progression or unacceptable toxicity |

VI. Billing Code/Availability Information

HCPCS Code:

- J9329 – Injection, tislelizumab-jsgr, 1 mg; 1 billable unit = 1 mg

NDC:

- Tevimbra 100 mg/10 mL single-dose vial: 72579-0121-xx

VII. References

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squamous cell carcinoma of the anal canal (SCAC) not previously treated with systemic chemotherapy [abstract]. Ann Oncol 2024;35:S1217.

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

Non-quantitative treatment limitations (NQLs) 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 NQL 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 |
|--------|--|
| C11.0 | Malignant neoplasm 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 |
| C14.0 | Malignant neoplasm of pharynx, unspecified |
| C14.2 | Malignant neoplasm of Waldeyer's ring |
| 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 |
| | Malignant neoplasm of pyloric antrum |
| C16.4 | Malignant neoplasm of pylorus |

| ICD-10 | ICD-10 Description |
|--------|--|
| 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 |
| C22.8 | Malignant neoplasm of liver, primary, unspecified as to type |
| C22.9 | Malignant neoplasm of liver, not specified as primary or secondary |
| C30.0 | Malignant neoplasm of nasal cavity |
| 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 |

| ICD-10 | ICD-10 Description |
|--------|---|
| 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 |
| 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 |
| C79.89 | Secondary malignant neoplasm of other specified sites |
| 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 |

| ICD-10 | ICD-10 Description |
|--------|---|
| 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, 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| 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 |
| C91.10 | Chronic lymphocytic leukemia of B-cell type not having achieved remission |
| C91.12 | Chronic lymphocytic leukemia of B-cell type in relapse |
| D37.05 | Neoplasm of uncertain behavior of pharynx |
| 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 |
| D38.5 | Neoplasm of uncertain behavior of other respiratory organs |
| D38.6 | Neoplasm of uncertain behavior of respiratory organ, 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 |

| ICD-10 | ICD-10 Description |
|---------|--|
| Z85.068 | Personal history of other malignant neoplasm of small intestine |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus |
| Z85.71 | Personal history of Hodgkin lymphoma |
| Z85.818 | Personal history of malignant neoplasm of other sites of lip, oral cavity, and pharynx |

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 | | |
|---|---|---|
| Jurisdiction | 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) |
| 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 |