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.
  - Classic Hodgkin Lymphoma (CHL) single agent maintenance therapy: Prior authorization validity may be renewed for up to a maximum of 2 years (730 days).

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:

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

Universal Criteria

- Patient 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 [Δ † ‡ Φ 1-3,11]

- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**

- Used as first-line therapy; **AND**
  - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA) compliant test❖; **AND**
    - Patient has human epidermal growth factor receptor 2 (HER2)-negative adenocarcinoma; **AND**
      - Used in combination with oxaliplatin or cisplatin AND either fluorouracil or capecitabine; **OR**
    - Patient has squamous cell carcinoma; **AND**
      - Used in combination with oxaliplatin or cisplatin AND either fluorouracil or capecitabine; **OR**
      - Used in combination with paclitaxel AND either oxaliplatin or cisplatin; **OR**
- Used as subsequent therapy; **AND**
  - Used as a single agent; **AND**
  - Patient has esophageal squamous cell carcinoma (ESCC) †

Gastric Cancers Δ † ‡ Φ [1,3,11]

- Used in combination with oxaliplatin or cisplatin AND either fluorouracil or capecitabine; **AND**
- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
- Used as first-line therapy; **AND**
- Patient has HER2-negative disease; **AND**
- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test**v**

Hepatocellular Carcinoma ‡ [3,9e]

- Used as single-agent therapy; **AND**
- Used as first-line systemic therapy; **AND**
- Patient does not have Child-Turcotte-Pugh (CTP) Class C liver disease; **AND**
- Used for one of the following:
  - Patient has liver-confined, unresectable disease and is deemed ineligible for transplant; **OR**
  - Patient has extrahepatic/metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy; **AND**

- Use of tislelizumab will be restricted to patients with a contraindication or intolerance to durvalumab

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma ‡ [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)

Small Bowel Adenocarcinoma ‡ [3,7,14,18e]

- Used as single agent treatment; **AND**
- Patient has microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has locally advanced unresectable or metastatic disease; **AND**
- Used as subsequent treatment

Colon Cancer ‡ [3,12,14,18e]

- Used as single agent treatment; **AND**
- Patient has MSI-H/dMMR disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for locally unresectable, medically inoperable, advanced, or metastatic disease; **AND**
- Used as subsequent treatment

Appendiceal Neoplasms and Cancers ‡ [3,14,16,18e]

- Used as single agent treatment; **AND**
- Patient has MSI-H/dMMR disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease; **AND**
- Used as subsequent treatment

Rectal Cancer ‡ [3,13-14,18e]

- Used as single agent treatment; **AND**
- Patient has MSI-H/dMMR disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for locally advanced unresectable or metastatic disease; **AND**
- Used as subsequent treatment

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**
- Used for locally advanced unresectable or metastatic disease; **AND**
- Will not be used for either of the following:
  - Therapy for locoregional recurrence in patients with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
  - Therapy after surgical exploration for locoregional recurrence in patients with disease confined to the vagina or paravaginal soft tissue

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

❖ *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 [1,3]

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

- Patient 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:**

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Patients 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.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients 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.
- Patients diagnosed with Gastric, Esophageal, and Esophagogastric/Gastroesophageal Junction Cancers who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease and who have received previous checkpoint inhibitor therapy are eligible for treatment with tislelizumab as palliative therapy provided there has been no prior tumor progression while on therapy with a checkpoint inhibitor.

V. Dosage/Administration Δ [1,4,7-11,14-16,18]

Indication	Dose
CLL/SLL	• Administer 200 mg intravenously once every 3 weeks, until disease progression or unacceptable toxicity
CHL	• 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
All Other Indications	• 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 • 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 (STANDARD)

1. Tevimbra [package insert]. Pennington, NJ: BeOne Medicines USA, Inc.; December 2025. Accessed January 2026.
2. Shen L, Kato K, Kim SB, et al; RATIONALE-302 Investigators. Tislelizumab Versus Chemotherapy as Second-Line Treatment for Advanced or Metastatic Esophageal Squamous Cell Carcinoma (RATIONALE-302): A Randomized Phase III Study. J Clin Oncol. 2022 Sep 10;40(26):3065-3076. Doi: 10.1200/JCO.21.01926. Epub 2022 Apr 20. Erratum In: J Clin Oncol. 2024 Feb 1;42(4):486.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) tislelizumab-jsgr. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2026.
4. Qin S, Kudo M, Meyer T, et al. Tislelizumab vs Sorafenib as First-Line Treatment for Unresectable Hepatocellular Carcinoma: A Phase 3 Randomized Clinical Trial. JAMA Oncol. 2023 Dec 1;9(12):1651-1659. doi: 10.1001/jamaoncol.2023.4003.
5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Version 2.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Head and Neck Cancers, Version 1.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.
7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Small Bowel Adenocarcinoma, Version 4.2025. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Anal Carcinoma, Version 5.2025. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks

owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.

9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for CISplatin/Gemcitabine + Tislelizumab-jsgr: Cancer of the Nasopharynx Order Template, HDN147. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed September 2025.
10. Al-Sawaf O, Ligtvoet R, Robrecht S, et al. Tislelizumab plus zanubrutinib for Richter transformation: the phase 2 RT1 trial. Nat Med 2024;30:240-248
11. Qiu MZ, Oh DY, Kato K, et al.; Tislelizumab plus chemotherapy versus placebo plus chemotherapy as first line treatment for advanced gastric or gastro-oesophageal junction adenocarcinoma: RATIONALE-305 randomised, double blind, phase 3 trial. BMJ. 2024 May 28;385:e078876.
12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Colon Cancer, Version 5.2025. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.
13. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Rectal Cancer, Version 4.2025. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.
14. Li J, Xu Y, Zang A, et al. Tislelizumab in previously treated, locally advanced unresectable/metastatic microsatellite instability-high/mismatch repair-deficient solid tumors. Chin J Cancer Res. 2024 Jun 30;36(3):257-269. doi: 10.21147/j.issn.1000-9604.2024.03.03. PMID: 38988490; PMCID: PMC11230881.
15. Rizwan A, Giovinazzo H, Yu T, et al. Alternative Dosing Regimens of Tislelizumab Using a Pharmacometrics Model-Based Approach. Clin Transl Sci. 2025 May;18(5):e70223. doi: 10.1111/cts.70223. PMID: 40286320; PMCID: PMC12033006.
16. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Appendiceal Neoplasms and Cancers, Version 1.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.
17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hodgkin Lymphoma, Version 1.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks

owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.

18. Ding K, Liu H, Ma J, et al. Tislelizumab with gemcitabine and oxaliplatin in patients with relapsed or refractory classic Hodgkin lymphoma: a multicenter phase II trial. Haematologica 2023;108:2146-2154.
19. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Uterine Neoplasms, Version 2.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2026.

VIII. References (ENHANCED)

1e. Shen L, Kato K, Kim SB et al.. Tislelizumab Versus Chemotherapy as Second-Line Treatment for Advanced or Metastatic Esophageal Squamous Cell Carcinoma (RATIONALE-302): A Randomized Phase III Study. J Clin Oncol. 2022 Sep 10;40(26):3065-3076. doi: 10.1200/JCO.21.01926

2e. Kato K, Cho BC, Takahashi M, et al. Nivolumab versus chemotherapy in patients with advanced esophageal squamous cell carcinoma refractory or intolerant to previous chemotherapy (ATTRACTION-3): a multicentre, randomised, open-label, phase 3 trial. Lancet Oncol. 2019;20(11):1506-1517. doi:10.1016/S1470-2045(19)30626-6.

3e. Kojima T, Shah MA, Muro K, et al. Randomized Phase III KEYNOTE-181 Study of Pembrolizumab Versus Chemotherapy in Advanced Esophageal Cancer. J Clin Oncol. 2020 Dec 10;38(35):4138-4148. doi: 10.1200/JCO.20.01888.

4e. Janjigian YY, Shitara K, Moehler M, et al. First-line nivolumab plus chemotherapy versus chemotherapy alone for advanced gastric, gastro-oesophageal junction, and oesophageal adenocarcinoma (CheckMate 649): a randomised, open-label, phase 3 trial. Lancet. 2021;398(10294):27-40. doi:10.1016/S0140-6736(21)00797-2.

5e. Rha SY, Oh DY, Yanez P et al. Pembrolizumab plus chemotherapy versus placebo plus chemotherapy for HER2-negative advanced gastric cancer (KEYNOTE-859): a multicentre, randomised, double-blind, phase 3 trial. Lancet Oncol. 2023 Nov;24(11):1181-1195. doi: 10.1016/S1470-2045(23)00515-6

6e. Assersohn L, Brown G, Cunningham D, et al. Phase II study of irinotecan and 5-fluorouracil/leucovorin in patients with primary refractory or relapsed advanced oesophageal and gastric carcinoma. Ann Oncol. 2004 Jan;15(1):64-9. doi: 10.1093/annonc/mdh007.

7e. Xu J, Kato K, Raymond E, et al. Tislelizumab plus chemotherapy versus placebo plus chemotherapy as first-line treatment for advanced or metastatic oesophageal squamous cell carcinoma (RATIONALE-306): a global, randomised, placebo-controlled, phase 3 study. Lancet Oncol. 2023 May;24(5):483-495. doi: 10.1016/S1470-2045(23)00108-0.

8e. Sun JM, Shen L, Shah MA, et al. Pembrolizumab plus chemotherapy versus chemotherapy alone for first-line treatment of advanced oesophageal cancer (KEYNOTE-590): a randomised, placebo-

controlled, phase 3 study. Lancet. 2021 Aug 28;398(10302):759-771. doi: 10.1016/S0140-6736(21)01234-4.

9e. Abou-Alfa GK, Chan SL, Kudo M, et al. Phase 3 randomized, open-label, multicenter study of tremelimumab (T) and durvalumab (D) as first-line therapy in patients (pts) with unresectable hepatocellular carcinoma (uHCC): HIMALAYA. Journal of Clinical Oncology 2022 40:4_suppl, 379-379.

10e. Abou-Alfa GK, Lau G, Kudo M, et al. Tremelimumab plus durvalumab in unresectable hepatocellular carcinoma. NEJM Evid 2022;1:EVIDoa2100070.

11e. Llovet JM, Ricci S, Mazzaferro et al. Sorafenib in advanced hepatocellular carcinoma. N Engl J Med. 2008 Jul 24;359(4):378-90

12e. Kudo M, Finn RS, Qin S, et al. Lenvatinib versus sorafenib in first-line treatment of patients with unresectable hepatocellular carcinoma: a randomised phase 3 non-inferiority trial. Lancet. 2018 Mar 24;391(10126):1163-1173

13e. Finn RS, Qin S, Ikeda M, et al; IMbrave150 Investigators. Atezolizumab plus Bevacizumab in Unresectable Hepatocellular Carcinoma. N Engl J Med. 2020 May 14;382(20):1894-1905

14e. Othman Al-Sawaf, Ligtvoet R, Robrecht S, et al. Tislelizumab plus zanubrutinib for Richter transformation: the phase 2 RT1 trial. Nature Medicine. Published online December 9, 2023. doi:https://doi.org/10.1038/s41591-023-02722-9

15e. Wierda WG, Lewis DJ, Ghia Paolo et al. Efficacy of Pirtobrutinib, a Highly Selective, Non-Covalent (Reversible) BTK Inhibitor in Richter Transformation: Results from the Phase 1/2 BRUIN Study. Blood. 2022;140;suppl 846-849

16e. Yang Y, Pan J, Yang H, et al. Tislelizumab plus chemotherapy as first-line treatment for recurrent or metastatic nasopharyngeal cancer: A multicenter phase 3 trial (RATIONALE-309). Cancer Cell. 2023 Jun 12;41(6):1061-1072.e4. doi: 10.1016/j.ccell.2023.04.014.

17e. Hai-Qiang Mai et al., Final overall survival analysis of JUPITER-02: A phase 3 study of toripalimab versus placebo in combination with gemcitabine and cisplatin as first-line treatment for recurrent or metastatic nasopharyngeal carcinoma (NPC). JCO 41, 6009-6009(2023). DOI:10.1200/JCO.2023.41.16_suppl.6009

18e. Wang FH, Wei XL, Feng J, et al. Efficacy, Safety, and Correlative Biomarkers of Toripalimab in Previously Treated Recurrent or Metastatic Nasopharyngeal Carcinoma: A Phase II Clinical Trial (POLARIS-02). J Clin Oncol. 2021;39(7):704-712. doi:10.1200/JCO.20.02712

19e. Hong S, Zhang Y, Yu G, et al. Gemcitabine plus cisplatin versus fluorouracil plus cisplatin as first-line therapy for recurrent or metastatic nasopharyngeal carcinoma: Final overall survival analysis of GEM20110714 phase III study. J Clin Oncol 2021;39:3273-3282.

20e. Chan AT, Hsu MM, Goh BC, et al. Multicenter, phase II study of cetuximab in combination with carboplatin in patients with recurrent or metastatic nasopharyngeal carcinoma. J Clin Oncol. 2005 May 20;23(15):3568-76

21e. Li J, XU y, Zang A, et al. Tislelizumab in previously treated, locally advanced unresectable/metastatic microsatellite instability-high/mismatch repair-deficient solid tumors. Chin J Cancer Res. 2024 Jun 30;36(3):257–269. doi: 10.21147/j.issn.1000-9604.2024.03.03

22e. Berton D, Banerjee S, Curigliano G, et al. Antitumor activity of dostarlimab in patients with mismatch repair-deficient/microsatellite instability–high tumors: A combined analysis of two cohorts in the GARNET study. Journal of Clinical Oncology. Volume 39, Issue 15_suppl. doi/abs/10.1200/JCO.2021.39.15_suppl.2564.

23e. Overman MJ, McDermott R, Leach JL, et al. Nivolumab in patients with metastatic DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer (CheckMate 142): an open-label, multicentre, phase 2 study. Lancet Oncol. 2017 Sep;18(9):1182-1191. doi: 10.1016/S1470-2045(17)30422-9. Epub 2017 Jul 19.

24e. Marabelle A, Le DT, Ascierto PA, et al. Efficacy of Pembrolizumab in Patients With Noncolorectal High Microsatellite Instability/Mismatch Repair-Deficient Cancer: Results From the Phase II KEYNOTE-158 Study. J Clin Oncol. 2020 Jan 1;38(1):1-10. Doi: 10.1200/JCO.19.02105. Epub 2019 Nov 4.

25e. Morris VK, Salem ME, Nimeiri H, et al. Nivolumab for previously treated unresectable metastatic anal cancer (NCI9673): a multicentre, single-arm, phase 2 study. Lancet Oncol. 2017 Apr;18(4):446-453. doi: 10.1016/S1470-2045(17)30104-3. Epub 2017 Feb 18.

26e. Ott PA, Piha-Paul SA, Munster P, et al. Safety and antitumor activity of the anti-PD-1 antibody pembrolizumab in patients with recurrent carcinoma of the anal canal. Ann Oncol. 2017;28(5):1036–1041. doi:10.1093/annonc/mdx029.

27e. Marabelle A, Cassier PA, Fakih M, et al. Pembrolizumab for previously treated advanced anal squamous cell carcinoma: results from the non-randomised, multicohort, multicentre, phase 2 KEYNOTE-158 study. Lancet Gastroenterol Hepatol. 2022 May;7(5):446-454.

28e. Rao S, Anandappa G, Capdevila J, et al. A phase II study of retifanlimab (INCMGA00012) in patients with squamous carcinoma of the anal canal who have progressed following platinum-based chemotherapy (POD1UM-202). ESMO Open. 2022 Aug;7(4):100529. doi: 10.1016/j.esmoop.2022.100529. Epub 2022 Jul 8. PMID: 35816951; PMCID: PMC9463376.

29e. Doki Y, Ajani JA, Kato K, et al. Nivolumab combination therapy in advanced esophageal squamous-cell carcinoma. N Engl J Med 2022;386:449-462.

30e. Jain N, Senapati J, Thakral B, et al. A phase 2 study of nivolumab combined with ibrutinib in patients with diffuse large B-cell Richter transformation of CLL. Blood Adv. 2022 Oct 28;7(10):1958–1966. doi: 10.1182/bloodadvances.2022008790.

31e. Armand P, Murawski N, Molin D, et al. Pembrolizumab in relapsed or refractory Richter syndrome. Br J Haematol. 2020 Jun 16;190(2):e117–e120. doi: 10.1111/bjh.16762

32e. Lenz HJ, Lonardi S, Zagonel V et al. Nivolumab (NIVO) + low-dose ipilimumab (IPI) as first-line (1L) therapy in microsatellite instability-high/DNA mismatch repair deficient (MSI-H/dMMR) metastatic

colorectal cancer (mCRC): Clinical update. J Clin Oncol. Vol 37, Num 15 supple. https://doi.org/10.1200/JCO.2019.37.15_suppl.35

33e. Andre T, Shiu KK, Kim TW, et al. Pembrolizumab versus chemotherapy for microsatellite instability-high/mismatch repair deficient metastatic colorectal cancer: The phase 3 KEYNOTE-177 Study. J Clin Oncol. Vol 38, Num 18 supple. https://doi.org/10.1200/JCO.2020.38.18_suppl.LBA

34e. Lakhani N, Cosman, Banerji, et al. A first-in-human phase I study of the PD-1 inhibitor, retifanlimab (INCMGA00012), in patients with advanced solid tumors (POD1UM-101). ESMO Open. 2024 Feb 21;9(4):102254. doi: 10.1016/j.esmoop.2024.102254

35e. Le DT, Kim TW, Van Cutsem E, et al. Phase II Open-Label Study of Pembrolizumab in Treatment-Refractory, Microsatellite Instability–High/Mismatch Repair–Deficient Metastatic Colorectal Cancer: KEYNOTE-164. J Clin Oncol. Vol 38, Num 1. https://doi.org/10.1200/JCO.19.0210

36e. Chalabi M, Verschoor YL, Tan PB, et al. Neoadjuvant Immunotherapy in Locally Advanced Mismatch Repair-Deficient Colon Cancer. N Engl J Med. 2024 Jun 6;390(21):1949-1958. doi: 10.1056/NEJMoa2400634.

37e. Zhang J, Cai J, Deng Y, et al. Complete response in patients with locally advanced rectal cancer after neoadjuvant treatment with nivolumab. Onc Imm. Vol 8, 2019. Issue 12. doi.org/10.1080/2162402X.2019.1663108

38e. Cercek A, Lumish M, Sinopoli J, et al. PD-1 Blockade in Mismatch Repair–Deficient, Locally Advanced Rectal Cancer. N Engl J Med 2022;386:2363-2376. DOI: 10.1056/NEJMoa2201445

39e. Rousseau B, Bièche I, Éric Pasmant, et al. PD-1 Blockade in Solid Tumors with Defects in Polymerase Epsilon. *Cancer Discovery*. 2022;12(6):1435-1448. doi:https://doi.org/10.1158/2159-8290.cd-21-0521

40e. Moskowitz AJ, Shah G, Schöder H, et al. Phase II Trial of Pembrolizumab Plus Gemcitabine, Vinorelbine, and Liposomal Doxorubicin as Second-Line Therapy for Relapsed or Refractory Classical Hodgkin Lymphoma. *Journal of Clinical Oncology*. 2021;39(28):3109-3117. doi:https://doi.org/10.1200/jco.21.01056

41e. Bryan LJ, Casulo C, Allen PB, et al. Pembrolizumab Added to Ifosfamide, Carboplatin, and Etoposide Chemotherapy for Relapsed or Refractory Classic Hodgkin Lymphoma. *JAMA Oncology*. Published online March 16, 2023. doi:https://doi.org/10.1001/jamaoncol.2022.7975

42e. Mei MG, Lee HJ, Palmer JM, et al. Response-adapted anti-PD-1–based salvage therapy for Hodgkin lymphoma with nivolumab alone or in combination with ICE. *Blood*. 2022;139(25):3605-3616. doi:https://doi.org/10.1182/blood.2022015423

43e. Herrera AF, Moskowitz AJ, Bartlett NL, et al. Interim results of brentuximab vedotin in combination with nivolumab in patients with relapsed or refractory Hodgkin lymphoma. *Blood*. 2018;131(11):1183-1194. doi:https://doi.org/10.1182/blood-2017-10-811224

44e. O'Malley DM, Bariani GM, Cassier PA, et al. Pembrolizumab in Patients With Microsatellite Instability–High Advanced Endometrial Cancer: Results From the KEYNOTE-158 Study. *Journal of Clinical Oncology*. 2022;40(7):752-761. doi:https://doi.org/10.1200/jco.21.01874

45e. Othman Al-Sawaf, Robrecht S, Giza A, Rajamani A, Eichhorst B. Correlates of response to combined checkpoint and BTK inhibition for treatment of richter transformation: Extended follow-up from the prospective RT1 trial. *Blood*. 2025;146(Supplement 1):90. doi:https://doi.org/10.1182/blood-2025-90

46e. Tedeschi A, Frustaci AM, Condoluci A, et al. Atezolizumab, venetoclax, and obinutuzumab combination in Richter transformation diffuse large B-cell lymphoma (MOLTO): a multicentre, single-arm, phase 2 trial. *The Lancet Oncology*. 2024;25(10):1298-1309. doi:https://doi.org/10.1016/s1470-2045(24)00396-6

47e. Wang Y, LaPlant BR, Sameer Ashok Parikh, et al. Efficacy of pembrolizumab monotherapy and in combination with BCR inhibitors for Richter transformation of chronic lymphocytic leukemia (CLL). *Journal of Clinical Oncology*. 2024;42(16_suppl):7050-7050. doi:https://doi.org/10.1200/jco.2024.42.16_suppl.7050

48e. Yang Z, Zhang X, Zhang J, et al. Rationale and design of a prospective, multicenter, phase II clinical trial of safety and efficacy evaluation of long course neoadjuvant chemoradiotherapy plus tislelizumab followed by total mesorectal excision for locally advanced rectal cancer (NCRT-PD1-LARC trial). BMC cancer. 2022;22(1). doi:https://doi.org/10.1186/s12885-022-09554-9

49e. Pang K, Yang Y, Tian D, et al. Long-course chemoradiation plus concurrent/sequential PD-1 blockade as neoadjuvant treatment for MMR-status-unscreened locally advanced rectal cancer: protocol of a multicentre, phase 2, randomised controlled trial (the POLAR-STAR trial). BMJ Open. 2023;13(9):e069499. doi:https://doi.org/10.1136/bmjopen-2022-069499

50e. Prime Therapeutics Management. Tevimbra Clinical Literature Review Analysis. Last updated January 2026. Accessed January 2026.

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
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
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

ICD-10	ICD-10 Description
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
C21.8	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
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

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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