Cemiplimab-rwlc (Libtayo®)

NDC CODE(S) 61755-0008-XX LIBTAYO 350MG/7ML Solution (REGENERON PHARMACEUTICALS)

DESCRIPTION

Cemiplimab-rwlc is a recombinant human immunoglobulin G4 (IgG4) monoclonal antibody that binds to PD-1 and blocks its interaction with PD-L1 and PD-L2. This releases the PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response through inhibition of active T-cell immune surveillance of tumors. Binding to and blocking PD-1 activity inhibits T-cell proliferation and cytokine production, resulting in decreased tumor growth.

POLICY

- Cemiplimab-rwlc for the treatment of one of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Cutaneous Squamous Cell Carcinoma (CSCC)
  - Basal Cell Carcinoma (BCC)
  - Non-Small Cell Lung Cancer (NSCLC)
- Cemiplimab-rwlc for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

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 (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, dostarlimab, etc.), unless otherwise specified; **AND**
- Used as a single-agent therapy; **AND**
- Patient has not received previous therapy with a cytotoxic T-lymphocyte antigen 4 (CTLA-4) targeting agent (e.g., ipilimumab, etc.) within the 4 weeks prior to therapy; **AND**

Cutaneous Squamous Cell Carcinoma (CSCC)

- Patient has nodal or distant metastatic disease, locally advanced disease, inoperable or incompletely not fully resectable regional disease, or regional recurrence; **AND**
- Patient is not a candidate for curative surgery or curative radiation therapy

Basal Cell Carcinoma (BCC)

- Patient has locally advanced OR nodal, regional, or distant metastatic disease**; AND**
  - Patient has previously been treated with a hedgehog pathway inhibitor (e.g., vismodegib, sonidegib, etc.) or is not a candidate for treatment; **OR**
- Patient has diffuse BCC formation (e.g., Gorlin syndrome, other genetic forms of multiple BCC); **AND**
  - Patient is not a candidate for treatment with a hedgehog pathway inhibitor

Non-Small Cell Lung Cancer (NSCLC)

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Patient has tumors with high PD-L1 expression (Tumor Proportion Score [TPS] ≥ 50%) (as determined by an FDA-approved or CLIA compliant test*) that are EGFR, ALK, ROS1 negative, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement negative*; **AND**
  - Used as first-line therapy; **OR**
  - Used as continuation maintenance therapy in patients who achieved a tumor response or stable disease after first-line therapy with cemiplimab

** Note: If there is insufficient tissue to allow testing for all of EGFR, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

❖*If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

RENEWAL CRITERIA

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in Initial Approval Criteria **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe infusion reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, skin reactions, etc.), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Non-Small Cell Lung Cancer (continuation maintenance therapy):

- Refer to Initial Approval for criteria

DOSAGE/ADMINISTRATION

INDICATION	DOSE
All indications	Administer 350 mg as an intravenous infusion every 3 weeks, until disease progression or unacceptable toxicity.

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed.

DOSING LIMITS

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

- 350 billable units every 21 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

1. Libtayo [package insert]. Tarrytown, NY; Regeneron Pharmaceuticals; February 2021. Accessed May 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) cemiplimab. National Comprehensive Cancer Network, 2021. 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 May 2021.
3. Falchook GS, Leidner R, Stankevich E, et al. Responses of metastatic basal cell and cutaneous squamous cell carcinomas to anti-PD1 monoclonal antibody REGN2810. J Immunother Cancer. 2016 Nov 15;4:70. doi: 10.1186/s40425-016-0176-3. eCollection 2016.
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5. Migden MR, Khushalani NI, Chang ALS, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2020 Feb;21(2):294-305. doi: 10.1016/S1470-2045(19)30728-4. Epub 2020 Jan 14.
6. Lewis KD, Fury MG, Stankevich, et al. Phase II study of cemiplimab, a human monoclonal anti-PD-1, in patients with advanced basal cell carcinoma (BCC) who experienced progression of disease on, or were intolerant of prior hedgehog pathway inhibitor (HHI) therapy. Annals of Oncology. 2018 Oct 01; Volume 29, Supplement 8,VII440.
7. Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial. Lancet. 2021 Feb 13;397(10274):592-604.
8. Lexicomp Online. (2021, February). AHFS DI. *Cemiplimab-rwlc.* Retrieved June11, 2021 from Lexicomp Online with AHFS.
9. MICROMEDEX Healthcare Series. Drugdex Evaluations. (2021, May). *Cemiplimab-rwlc*. Retrieved June 11, 2021 from MICROMEDEX Healthcare Series.

BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual **Approved Revision: Do Not Implement until 9/30/21**

EFFECTIVE DATE 9/30/2021

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