Cemiplimab-rwlc (Libtayo®)

Prior Authorization Drug Coverage Policy

Effective Date: 3/1/2021
Revision Date: n/a
Review Date: 10/4/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of cemiplimab-rwlc. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (NCCN Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

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, releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth.

FDA Indications[1]

Cemiplimab-rwlc is FDA indicated for the following:

- Treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

Coverage Determinations[1,2]

Cemiplimab-rwlc will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Cutaneous Squamous Cell Carcinoma (CSCC)

- The member has a diagnosis of metastatic or locally advanced CSCC **AND**
- The member is not a candidate for curative surgery or curative radiation **AND**
- Cemiplimab-rwlc will be used as monotherapy

Recommended dosage: 350 mg IV every 3 weeks

Basal Cell Carcinoma (BCC)

- The member has a diagnosis of metastatic or locally advanced BCC **AND**
- The member was previously treated with a hedgehog pathway inhibitor **OR** for whom a hedgehog pathway inhibitor is not appropriate.
- Cemiplimab-rwlc will be used as monotherapy

Recommended dosage: 350 mg IV every 3 weeks

Non-Small Cell Lung Cancer (NSCLC)

- The member has a diagnosis of recurrent, advanced, or metastatic NSCLC **AND**
- Cemiplimab-rwlc will be used as first-line treatment in patients whose tumors high have high PD-L1 expression [Tumor Proportion Score (TPS) ≥ 50%] as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations **AND**
- Cemiplimab-rwlc will be used as monotherapy

Recommended dosage: 350 mg IV every 3 weeks

All indications:

- Cemiplimab-rwlc will be approved through clinical review for up to a 6-month duration

Coverage Limitations

Treatment with cemiplimab-rwlc is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on cemiplimab-rwlc
- The member has received prior therapy with an anti-Programmed Cell Death Receptor 1 (PD-1), anti-Programmed Cell Death Receptor Ligand 1 (PD-L1) or anti-Programmed Cell Death Receptor Ligand 2 (PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), OX-40, CD137)
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
    - Severe and Fatal Immune-Mediated Adverse Reactions:
    - Infusion-Related Reactions
    - Embryo-Fetal Toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information

Billing

- Description: Inj., cemiplimab-rwlc, 1 mg
- HCPCS: J9119

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Libtayo [package insert]. Regeneron Pharmaceuticals, Inc., Tarrytown, NY. Available at: https://www.regeneron.com/sites/default/files/Libtayo_FPI.pdf
2. Cemiplimab. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Migden MR, Rischin D, Schmults CD, et al. PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 Jul 26;379(4):341-351. doi: 10.1056/NEJMoa1805131. Epub 2018 Jun 4.
4. Migden MR, Khushalani NI, Chang AL, et al. Primary analysis of Phase 2 results of cemiplimab, a human monoclonal anti-PD-1, in patients (pts) with locally advanced cutaneous squamous cell carcinoma (laCSCC). J Clin Oncol 37, 2019 (suppl; abstr 6015)