OncoHealth

Libtayo (Cemiplimab)

Effective Date: 9/1/2022
Revision Date(s): n/a
Review Date: 6/21/2022
Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.
- Member has no history of prior PD-1/PD-L1 use.

Indication Specific Criteria

Basal Cell Skin Cancer

- Used as a single agent; AND
- Member has locally advanced or metastatic disease; AND
- Member has been previously treated with a hedgehog pathway inhibitor; OR
    - Treatment with a hedgehog pathway inhibitor is not appropriate

Non-Small Cell Lung Cancer

- Used as a single agent; AND
- Member has recurrent, advanced, or metastatic disease; AND
- Used as first-line therapy; AND
- Member's tumor has ≥50% PD-L1 expression; AND
- Member's tumor is negative for actionable molecular biomarkers[1]

Squamous Cell Skin Cancer

- Used as a single agent; AND
- Member has locally advanced or metastatic disease; AND
- Member is not a candidate for curative surgery and/or radiation therapy

[1] If there is insufficient tissue to allow testing for all of EGFR, KRAS, 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.

Billing

Drug Name	HCPCS Code	Description
Libtayo	J9119	Inj., cemiplimab, 1 mg

References

1. Libtayo. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 6/21/22
2. Libtayo [package insert]. Regeneron Pharmaceuticals, Inc., Tarrytown, NY. Available at: https://www.regeneron.com/downloads/libtayo_fpi.pdf
3. Basal Cell Skin Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed 6/21/22
4. Non-Small Cell Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed 6/21/22
5. Squamous Cell Skin Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf. Accessed 6/21/22

Disclaimer

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 (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. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

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 OncoHealth, Inc.