Medical Coverage Policy | Libtayo (cemiplimab-rwlc)

EFFECTIVE DATE: 08|01|2019
POLICY LAST UPDATED: 04|16|2019

OVERVIEW

Libtayo™ (cemiplimab-rwlc) is for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

MEDICAL CRITERIA

Libtayo™ (cemiplimab-rwlc) will be approved when ONE of the following are met:

1. There is documentation that the patient is currently being treated with the requested agent

OR

2. ALL of the following:
    a. One of the following:
        i. The patient has a diagnosis of metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC AND ONE of the following:
            1. The patient is NOT a candidate for curative surgery or curative radiation

            OR

            2. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

        OR

        ii. The patient has another FDA labeled indication for the requested agent [i.e., this indication must be supported by ALL requirements in the FDA label (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy)]

        OR

        iii. The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the use is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic use (approval by the Clinical Review Pharmacist required).

    AND

    b. The patient does NOT have any FDA labeled contraindications to therapy with the requested agent

    AND

    c. The patient does NOT have an active autoimmune disease

    AND

d. The requested dose is within FDA labeling or dose is supported by compendia. (NCCN Compendium™[level of evidence 1, 2A], AHFS, DrugDex [FDA approved Class I or Class IIa]), or the prescriber has submitted additional documentation (the dose is supported by clinical research in 2 or more peer reviewed medical journals) supporting the requested therapeutic dose (approval by the Clinical Review Pharmacist required)

Length of Approval: 12 months or for duration of treatment as supported in FDA labeling or NCCN compendia whichever is shorter.

PRIOR AUTHORIZATION
Prior authorization is required for BlueCHiP for Medicare.

POLICY STATEMENT
BlueCHiP for Medicare
Libtayo™ (cemiplimab-rwlc) is medically necessary when the criteria above have been met.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug medically necessary benefits/coverage.

BACKGROUND
Libtayo is a human programmed death receptor-1 (PD-1) blocking antibody. Libtayo is a recombinant human IfG4 monoclonal antibody that binds to PD-1 and blocks its interaction with PD-L1 and PD-L2 which inhibits T-cell proliferation and cytokine production.

Cemiplimab-rwlc is associated with severe and fatal immune-mediated adverse reactions that can occur in any organ system or tissue, including immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, and immune-mediated nephritis and renal dysfunction. Libtayo is also associated with infusion-related reactions and embryo-fetal toxicity.

CODING
BlueCHiP for Medicare
The following HCPCS code is covered when the medical criteria have been met:
C9044 Injection, cemiplimab-rwlc, 1 mg

RELATED POLICIES
Prior Authorization of Drugs

PUBLISHED
Provider Update, June 2019

REFERENCES
1. Libtayo Prescribing information. Regeneron. September 2018.

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