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 IgG4 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:

- J9119  Injection, cemiplimab-rwlc, 1 mg (Effective 10/1/19)
- C9044  Injection, cemiplimab-rwlc, 1 mg (Deleted 9/30/19)

**RELATED POLICIES**
Prior Authorization of Drugs

**PUBLISHED**
Provider Update, June 2019

**REFERENCES**
This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member’s subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.