POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Libtayo is indicated 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.

Compendial Uses
Inoperable or incompletely resected regional squamous cell skin cancer

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy.

III. CRITERIA FOR INITIAL APPROVAL

Cutaneous squamous cell carcinoma
Authorization of 6 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

A. The disease is one of the following:
1. Metastatic
2. Locally advanced
3. Regional and inoperable or incompletely resected

B. The member is not a candidate for curative surgery or curative radiation

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen

V. REFERENCES