

<b>Reference number(s)</b>
2757-A

## SPECIALTY GUIDELINE MANAGEMENT

### LIBTAYO (cemiplimab-rwlc)

#### 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 Indications

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.

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

##### **Cutaneous squamous cell carcinoma**

Authorization of 12 months may be granted for treatment of cutaneous squamous cell carcinoma when all of the following criteria are met:

- A. The disease is metastatic or locally advanced
- B. The patient is not a candidate for curative surgery or curative radiation

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

1. Libtayo [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2018.