POLICY: Oncology – Libtayo® (cemiplimab-rwlc injection for intravenous use – Regeneron/Sanofi-Genzyme)

APPROVAL DATE: 10/02/2019

OVERVIEW

Libtayo, a programmed death receptor-1 (PD-1) blocking antibody, is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for surgery or curative radiation.[1] Libtayo is a recombinant human immunoglobulin G4 (IgG4) monoclonal antibody that binds to PD-1 and blocks its interaction with PD-L1 and PD-L2, thereby releasing the PD-1 pathway-mediated inhibition of the immune response.

Libtayo is available as a solution in a single-dose vial of 350 mg/7 mL. It should be stored in a refrigerator 2° to 8°C (36° to 46°F). Libtayo vials should be protected from light and cannot be frozen.

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines (version 2.2019 – October 23, 2018) on squamous cell carcinoma (SCC), the primary goals of treatment are the complete removal of the tumor and the maximal preservation of function and cosmesis.[2] Surgical excision offers the most effective and efficient means for curative therapy, but considerations of patient preference, preservation of function and cosmesis may lead to choosing radiation therapy as primary treatment to achieve optimal results. . In a footnote, the guidelines note that Libtayo may be considered as a systemic therapy option for patients with locally advanced or metastatic cutaneous squamous cell carcinoma, who are not candidates for curative surgery or radiation therapy . Prior to Libtayo there were no systemic therapy options FDA-approved for the treatment of CSCC.

POLICY STATEMENT

This policy involves the use of Libtayo. Prior authorization is recommended for medical benefit coverage of Libtayo. Approval is recommended for those who meet the conditions of coverage in Criteria and Dosing.. Due to the specialized skills required for evaluation and diagnosis of patients treated with Libtayo, as well as the monitoring required for adverse events and long-term efficacy, approval requires Libtayo to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for the duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Libtayo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

Cutaneous Squamous Cell Carcinoma (CSCC). Approve for 1 year if the patient meets ALL of the following criteria (A, B and C):

A) The patient has locally advanced or metastatic CSCC; AND
B) The patient is not a candidate for curative surgery or curative radiation; AND
C) The medication is prescribed by, or in consultation with, an oncologist.

Dosing. Approve the following dose:

A) 350 mg administered as an intravenous (IV) infusion over 30 minutes not more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Libtayo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Libtayo® injection for intravenous use [prescribing information]. Tarrytown, NY and Bridgewater, NJ: Regeneron/Sanofi-Genzyme; September 2018.
2. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (Version 2.2019 – October 23, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed September 30, 2019.

HISTORY

Type of Revision	Summary of Changes	Approval Date
New policy	New criteria	10/10/2018
Annual revision	Deleted "Initial/Extended Approval", "Duration of Therapy", and "Waste Management" to update to new format. For Dosing, added "Approve the following dose" and "not more frequently than once" every 3 weeks.	10/02/2019