Libtayo (cemiplimab-rwlc)

Background
Libtayo (cemiplimab-rwlc) is a recombinant human immunoglobulin G4 (IgG4) monoclonal antibody that binds to programmed death receptor-1 (PD-1) and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth (1).

Regulatory Status
FDA-approved indication: Libtayo is a programmed death receptor-1 (PD-1) blocking antibody 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 (1).

Libtayo can cause severe and fatal immune-mediated adverse reactions. These can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, and immune-mediated nephritis and renal dysfunction. Patients should be monitored for signs and symptoms of immune-mediated adverse reactions. Evaluate chemical chemistries, including liver and thyroid function, at baseline and periodically during treatment. Libtayo should be withheld or permanently discontinued and corticosteroids should be administered based on the severity of the reaction (1).
Severe infusion-related reactions may occur during Libtayo treatment. Patients should be monitored for signs and symptoms of infusion-related reactions and the rate of infusion should be interrupted, slowed, or permanently discontinued based on severity of reaction (1).

Libtayo can cause fetal harm when administered to a pregnant woman. The mechanism of action of Libtayo has been shown to lead to increased risk of immune-mediated rejection of a developing fetus resulting in fetal death. Females of reproductive potential should use effective contraception during treatment with Libtayo and for at least 4 months after the last dose (1).

The safety and effectiveness of Libtayo in pediatric patients have not been established (1).

Related policies
Keytruda, Opdivo

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Libtayo may be considered medically necessary in patients 18 years of age and older with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) and if the conditions indicated below are met.

Libtayo is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age
18 years of age and older

Diagnosis
Patient must have ONE of the following:

Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

AND ALL of the following:
1. Patient is not a candidate for curative surgery or curative radiation
2. Prescriber agrees to monitor for immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, and nephritis
3. Prescriber agrees to advise females of reproductive potential to use effective contraception during treatment and for at least 4 months after the last dose.

**Prior – Approval Renewal Requirements**

**Age** 18 years of age and older

**Diagnosis**

Patient must have the following:

- Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

**AND ALL** of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for immune-mediated adverse reactions, including pneumonitis, colitis, hepatitis, and nephritis
3. Prescriber agrees to advise females of reproductive potential to use effective contraception during treatment and for at least 4 months after the last dose

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Quantity** 4 vials every 84 days

**Duration** 12 months

**Prior – Approval Renewal Limits**

Same as above

**Rationale**

**Summary**

Libtayo (cemiplimab-rwlc) is a recombinant human immunoglobulin G4 (IgG4) monoclonal antibody that binds to programmed death receptor-1 (PD-1) and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway mediated inhibition of the immune response, including
the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth. The safety and effectiveness of Libtayo in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Libtayo while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2018</td>
<td>Addition to PA</td>
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<tr>
<td>November 2018</td>
<td>Annual review. Addition of requirement for females of reproductive potential to use contraception during therapy and for at least 4 months after the last dose per SME</td>
</tr>
<tr>
<td>June 2019</td>
<td>Annual review and reference update</td>
</tr>
</tbody>
</table>

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.