Imfinzi

Description

Imfinzi (durvalumab)

Background
Imfinzi (durvalumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial cancer as well as unresectable, stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. Imfinzi is a human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that blocks the interaction of programmed cell death ligand 1 (PD-L1) with the PD-1 and CD80 (B7.1) molecules. PD-L1 blockade with durvalumab led to increased T-cell activation in vitro and decreased tumor size in co-engrafted human tumor and immune cell xenograft mouse models (1).

Regulatory Status
FDA approved indication: Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated for the treatment of patients with: (1)

1. Locally advanced or metastatic urothelial carcinoma who:  
   a. Have either had disease progression during or following platinum-containing chemotherapy  
   b. Have experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

2. Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum based chemotherapy and radiation therapy
Patients should be monitored for multiple immune-related conditions including: immune-mediated pneumonitis, immune-mediated hepatitis, immune-mediated colitis, immune-mediated endocrinopathies, and immune-mediated nephritis. Additionally, patients should be monitored for the development of other conditions including infusion related reactions and severe or life threatening infections (1).

Safety and effectiveness in pediatric patients have not been established (1).

Related policies
Bavencio, Keytruda, Opdivo, Tecentriq

Policy

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

Imfinzi may be considered medically necessary for patients 18 years of age or older for the treatment of locally advanced or metastatic urothelial carcinoma or non-small cell lung cancer (NSCLC) and if the conditions indicated below are met.

Imfinzi may be considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Locally advanced or metastatic urothelial carcinoma with ONE of the following:
   a. Disease progression during or following platinum-containing chemotherapy
   b. Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
2. Non-small cell lung cancer (NSCLC) with **ALL** of the following
   a. Must be unresectable, stage III NSCLC
   b. Disease has **NOT** progressed following concurrent platinum-based chemotherapy and radiation therapy

   **AND** the following for **BOTH** indications:
   a. Prescriber agrees to monitor for immune-mediated toxicities

### Prior – Approval **Renewal** Requirements

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

1. Locally advanced or metastatic urothelial carcinoma

   **AND** the following:
   a. **NO** disease progression or unacceptable toxicities

### Policy Guidelines

**Pre - PA Allowance**

None

**Prior - Approval Limits**

**Duration** 12 months

**Prior – Approval **Renewal** Limits**

Locally advanced or metastatic urothelial carcinoma – **only**

**Duration** 12 months
Summary

Imfinzi (durvalumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who either have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Imfinzi is also indicated for the treatment in patients with unresectable, stage III non-small cell lung cancer (NSCLC) who have not progressed following concurrent treatment with platinum-based chemotherapy and radiation. Patients should be monitored for multiple immune-related conditions including: immune-mediated pneumonitis, immune-mediated hepatitis, immune-mediated colitis, immune-mediated endocrinopathies, and immune-mediated nephritis (1).

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

References


Policy History

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<tr>
<td>May 2017</td>
<td>Addition to PA</td>
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<tr>
<td>September 2017</td>
<td>Annual Review</td>
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<tr>
<td>March 2018</td>
<td>Addition of the diagnosis of unresectable, stage III NSCLC who have not had disease progression following platinum based chemotherapy to initiation criteria and change in initial duration from 6 months to 12 months</td>
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<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
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<tr>
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Keywords

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