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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 12, 2017
Subject:	Imfinzi	**Page:**	1 of 4

Last Review Date: June 16, 2022

Imfinzi

Description

Imfinzi (durvalumab)

Background
Imfinzi (durvalumab) 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 indications: Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody indicated: (1)

1. For the treatment of adult patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy
2. In combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)

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
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 non-small cell lung cancer (NSCLC), or extensive-stage small cell lung cancer (ES-SCLC) 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. 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
2. Extensive-stage small cell lung cancer (ES-SCLC)

AND the following for **ALL** 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. Extensive-stage small cell lung cancer (ES-SCLC)

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

Duration 12 months

NO renewal for Non-small cell lung cancer (NSCLC)

Rationale

Summary

Imfinzi (durvalumab) is indicated for the treatment of non-small cell lung cancer (NSCLC) and extensive-stage small cell lung cancer (ES-SCLC). 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. Safety and effectiveness in pediatric patients have not been established (1).

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

References

1. Imfinzi [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
2. NCCN Drugs & Biologics Compendium® Durvalumab 2022. National Comprehensive Cancer Network, Inc. May 2021. Accessed on April 18, 2022.

Policy History

Date	Action
May 2017	Addition to PA
September 2017	Annual Review
March 2018	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
June 2018	Annual editorial review
June 2019	Annual review
December 2019	Addition of off-label indication extensive-stage SCLC from NCCN per FEP
March 2020	Annual review and reference update
March 2021	Removal of indication per PI: urothelial carcinoma
June 2021	Annual review and reference update
September 2021	Annual review and reference update
June 2022	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.