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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 12, 2017
Subject:	Imfinzi	**Page:**	1 of 5

Last Review Date: March 8, 2024

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 tremelimumab-actl and platinum-based chemotherapy, for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations
3. 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)
4. In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC)

5. In combination with tremelimumab-actl, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC)

Patients should be monitored for multiple immune-related conditions including immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis and renal dysfunction, solid organ transplant rejection, and immune-mediated pancreatitis. 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** if the conditions indicated below are met.

Imfinzi may be considered **investigational** 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 **ONE** of the following
    a. Unresectable, stage III NSCLC
        i. Disease has **NOT** progressed following concurrent platinum-based chemotherapy and radiation therapy
    b. Metastatic NSCLC
        i. **NO** sensitizing EGFR or ALK genomic tumor aberrations

ii. Used in combination with tremelimumab-actl and platinum-based chemotherapy

2. Extensive-stage small cell lung cancer (ES-SCLC)

3. Locally advanced or metastatic biliary tract cancer (BTC)
   a. Used in combination with gemcitabine and cisplatin

4. Unresectable hepatocellular carcinoma (uHCC)
   a. Used in combination with tremelimumab-actl

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

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic non-small cell lung cancer (NSCLC)
   a. Used in combination with platinum-based chemotherapy

2. Extensive-stage small cell lung cancer (ES-SCLC)

3. Locally advanced or metastatic biliary tract cancer (BTC)
   a. Used in combination with gemcitabine and cisplatin

4. Unresectable hepatocellular carcinoma (uHCC)

AND the following for **ALL** indications:
   a. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Duration 12 months

NO renewal for Unresectable, stage III non-small cell lung cancer (NSCLC)

Rationale

Summary

Imfinzi (durvalumab) is indicated for the treatment of non-small cell lung cancer (NSCLC), extensive-stage small cell lung cancer (ES-SCLC), biliary tract cancer (BTC), and hepatocellular carcinoma (HCC). 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; June 2023.
2. NCCN Drugs & Biologics Compendium® Durvalumab 2024. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2024.

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
September 2022	Annual review and reference update. Addition of indication per PI: locally advanced or metastatic BTC
November 2022	Per PI update, addition of indication: unresectable hepatocellular carcinoma
December 2022	Per PI update, addition of indication: metastatic NSCLC with no sensitizing EGFR or ALK genomic tumor aberrations
January 2023	Removed renewal requirement “used in combination with tremelimumab-actl” from NSCLC and uHCC since tremelimumab-actl is only used short-term
March 2023	Annual review and reference update
September 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.