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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. In combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi continued as a single agent as adjuvant treatment after surgery, for treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.
2. As a single agent, 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.
3. 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.

4. As a single agent, for the treatment of adult patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
5. 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).
6. In combination with gemcitabine and cisplatin, as treatment of adult patients with locally advanced or metastatic biliary tract cancer (BTC).
7. In combination with tremelimumab-actl, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC).
8. In combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) as determined by an FDA-approved test.
9. In combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC).
10. In combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment, followed by single agent Imfinzi, for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).

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. Resectable (tumors ≥ 4 cm and/or node positive) NSCLC
        i. Used in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by Imfinzi as a single agent as adjuvant treatment after surgery
        ii. **NO** known EGFR mutations or ALK rearrangements
    b. Unresectable, stage III NSCLC
        i. Used as a single agent
        ii. Disease has **NOT** progressed following concurrent platinum-based chemotherapy and radiation therapy
    c. Metastatic NSCLC
        i. **NO** sensitizing EGFR or ALK genomic tumor aberrations
        ii. Used in combination with tremelimumab-actl and platinum-based chemotherapy

2. Limited-stage small cell lung cancer (LS-SCLC)
    a. Used as a single agent
    b. Disease has **NOT** progressed following concurrent platinum-based chemotherapy and radiation therapy

3. Extensive-stage small cell lung cancer (ES-SCLC)
    a. Used in combination with etoposide and either carboplatin or cisplatin as first-line treatment followed by Imfinzi as a single agent

4. Locally advanced or metastatic biliary tract cancer (BTC)
    a. Used in combination with gemcitabine and cisplatin followed by Imfinzi as a single agent

5. Unresectable hepatocellular carcinoma (uHCC)
    a. Used in combination with tremelimumab-actl followed by Imfinzi as a single agent

6. Primary advanced or recurrent endometrial cancer
    a. Mismatch repair deficient (dMMR) as determined by an FDA-approved test
    b. Used in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent

7. Muscle invasive bladder cancer (MIBC)
    a. Used in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent Imfinzi as adjuvant treatment following radical cystectomy

8. Resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)
    a. Used in combination with fluorouracil, leucovorin, oxaliplatin, and docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment, followed by Imfinzi as a single agent

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. Non-small cell lung cancer (NSCLC) following resection
    a. Used as a single agent

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

3. Limited-stage small cell lung cancer (LS-SCLC)
    a. Used as a single agent

4. Extensive-stage small cell lung cancer (ES-SCLC)
    a. Used as a single agent

5. Locally advanced or metastatic biliary tract cancer (BTC)
    a. Used as a single agent

6. Unresectable hepatocellular carcinoma (uHCC)
    a. Used as a single agent

7. Primary advanced or recurrent endometrial cancer
    a. Used as a single agent

8. Gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)
    a. Used as a single agent

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)
NO renewal for muscle invasive bladder cancer (MIBC)
ONE renewal for non-small cell lung cancer (NSCLC) following resection

ONE renewal for limited-stage small cell lung cancer (LS-SCLC)
ONE renewal for gastric or gastroesophageal junction adenocarcinoma (GC/GEJC) following resection

Rationale

Summary
Imfinzi (durvalumab) is indicated for the treatment of non-small cell lung cancer (NSCLC), limited-stage small cell lung cancer (LS-SCLC), extensive-stage small cell lung cancer (ES-SCLC), biliary tract cancer (BTC), hepatocellular carcinoma (HCC), endometrial cancer, muscle invasive bladder cancer (MIBC), and gastric or gastroesophageal junction adenocarcinoma (GC/GEJC). 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; November 2025.
2. NCCN Drugs & Biologics Compendium® Durvalumab 2026. National Comprehensive Cancer Network, Inc. Accessed on January 14, 2026.

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
July 2024	Per PI update, added indication of dMMR endometrial cancer
September 2024	Annual review and reference update
October 2024	Per PI update, added indication of resectable NSCLC, ES-SCLC used in combination with etoposide and either carboplatin or cisplatin as first-line treatment, renewal for ES-SCLC, BTC, uHCC used as a single agent
December 2024	Annual review and reference update
January 2025	Per PI update, added indication of LS-SCLC
March 2025	Annual review and reference update
April 2025	Per PI update, added indication of muscle invasive bladder cancer (MIBC). Also added that dMMR endometrial cancer must be confirmed by an FDA-approved test
June 2025	Annual review and reference update
January 2026	Per PI update, added indication of gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.