BlueCross BlueShield Federal Employee Program

IMFINZI (durvalumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

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).

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).

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, and muscle invasive bladder cancer (MIBC). 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; March 2025.
2. NCCN Drugs & Biologics Compendium® Durvalumab 2025. National Comprehensive Cancer Network, Inc. Accessed on March 31, 2025.