

## **IMJUDO (tremelimumab-actl)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **Background**

Imjudo (tremelimumab-actl) is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody. CTLA-4 is a negative regulator of T-cell activity. Imjudo is a monoclonal antibody that binds to CTLA-4 and blocks the interaction with its ligands CD80 and CD86, releasing CTLA-4-mediated inhibition of T-cell activation. This blocking of CTLA-4 activity results in decreased tumor growth and increased proliferation of T cells in tumors (1).

#### **Regulatory Status**

FDA-approved indications: Imjudo is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody indicated: (1)

- In combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC)
- In combination with durvalumab 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) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations

Patients should be monitored for multiple immune-related conditions including immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated nephritis, immune-mediated dermatology reactions, immune-mediated pancreatitis, and other immune-mediated adverse reactions. Additionally, patients should be monitored for the development of infusion-related reactions (1).

Imjudo can cause fetal harm when administered to a pregnant woman. Pregnant women and females of reproductive potential should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Imjudo and for 3 months after the last dose of Imjudo (1).

The safety and effectiveness of Imjudo in pediatric patients less than 18 years of age have not been established (1).



**BlueCross  
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### **Summary**

Imjudo is indicated for the treatment of unresectable hepatocellular carcinoma (uHCC) and metastatic non-small cell lung cancer (NSCLC). Patients should be monitored for multiple immune-related conditions. Imjudo may cause fetal harm when administered to a pregnant woman. The safety and effectiveness of Imjudo in pediatric patients less than 18 years of age have not been established (1).

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

### **References**

1. Imjudo [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2023.
2. NCCN Drugs & Biologics Compendium® Tremelimumab-actl 2025. National Comprehensive Cancer Network, Inc. Accessed on January 9, 2025.