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Imjudo

Description

Imjudo (tremelimumab-actl)

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).

Related policies
Yervoy

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Imjudo may be considered **medically** if the conditions indicated below are met.

Imjudo 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. Unresectable hepatocellular carcinoma (uHCC)
    a. Used in combination with durvalumab
2. Metastatic non-small cell lung cancer (NSCLC)
    a. **NO** sensitizing EGFR or ALK genomic tumor aberrations
    b. Used in combination with durvalumab and platinum-based chemotherapy

AND ALL of the following:

a. Prescriber agrees to monitor for immune-mediated reactions

b. Prescriber agrees to monitor liver enzymes, adrenocorticotropic hormone (ACTH), and thyroid function at baseline and before each dose
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Imjudo and for 3 months after the last dose

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

None

Rationale

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.

Policy History

Date	Action
November 2022	Addition to PA
December 2022	Per PI update, addition of indication: metastatic NSCLC with no sensitizing EGFR or ALK genomic tumor aberrations. Removed quantity limits
March 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.