PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Imjudo Prior Authorization Policy
- Imjudo® (tremelimumab-actl intravenous infusion – AstraZeneca)

REVIEW DATE: 10/16/2024

OVERVIEW

Imjudo, a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) monoclonal antibody, is indicated for the following uses:[1]

- **Hepatocellular carcinoma**, in combination with Imfinzi® (durvalumab intravenous infusion), for the treatment of adults with unresectable disease.
- **Non-small cell lung cancer** (NSCLC), in combination with Imfinzi and platinum-based chemotherapy, for the treatment of adults with metastatic disease and no epidermal growth factor receptor (*EGFR*) mutations or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations.

Guidelines

Imjudo is addressed in the National Comprehensive Cancer Network guidelines.

- **Esophageal and Esophagogastric Junction Cancers:** The guidelines (version 4.2024 – July 30, 2024) recommend Imjudo in combination with Imfinzi for the neoadjuvant treatment of microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) adenocarcinoma in patients who are medically fit for surgery.[2,5]
- **Gastric Cancer:** The guidelines (version 4.2024 – August 12, 2024) recommend Imjudo in combination with Imfinzi for the neoadjuvant treatment of microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) locoregional disease in patients who are medically fit for surgery.[2,6]
- **Hepatocellular Carcinoma:** The guidelines (version 3.2024 – September 24, 2024) recommend Imjudo as a preferred first-line treatment in combination with Imfinzi for liver-confined, unresectable disease in patients deemed ineligible for transplant or extrahepatic/metastatic hepatocellular carcinoma in patients who are not eligible for resection, transplant, or locoregional therapy.[2,3]
- **Non-Small Cell Lung Cancer:** The guidelines (version 10.2024 – September 23, 2024) recommend Imjudo, in combination with Imfinzi, plus chemotherapy for the first-line treatment of recurrent, advanced, or metastatic disease with programmed death-ligand 1 (PD-L1) expression ≥ 1% and negative for actionable molecular markers.[2,4] The guidelines also recommend Imjudo in combination with Imfinzi plus chemotherapy for disease with PD-L1 expression < 1%, and for disease that is positive for a variety of molecular markers.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Imjudo. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Imjudo as well as the monitoring required for adverse events and long-term efficacy, approval requires Imjudo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Imjudo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Hepatocellular Carcinoma.** Approve for 30 days if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has liver-confined unresectable disease and according to the prescriber, the patient is deemed ineligible for transplant; OR
     - **ii.** Patient has extrahepatic or metastatic disease and according to the prescriber, the patient is deemed ineligible for resection, transplant, or locoregional therapy; AND
   - **C)** Imjudo is used as first-line systemic therapy; AND
   - **D)** Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion); AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

2. **Non-Small Cell Lung Cancer.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent, advanced, or metastatic disease; AND
   - **C)** Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion); AND
   - **D)** Patient meets ONE of the following (i, ii, iii, or iv):
     - **i.** Patient meets BOTH of the following (a and b):
       - **a)** The tumor is negative for actionable molecular markers; AND
         Note: Examples of actionable molecular markers include epidermal growth factor receptor (*EGFR*) mutations, anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations, *ROS1*, *BRAF*, *NTRK1/2/3*, *MET*, *RET*, and *ERBB2* (*HER2*). Patient may be *KRAS G12C* mutation positive.
       - **b)** Imjudo is used as first-line therapy; OR
     - **ii.** Patient meets BOTH of the following (a and b):
       - **a)** The tumor is positive for ONE of the following [(1), (2), or (3)]:
         - **(1)** Epidermal growth factor receptor (*EGFR*) exon 20 mutation positive; OR
         - **(2)** *ERBB2* (*HER2*) mutation positive; AND
       - **b)** Imjudo is used as first-line therapy; OR
     - **iii.** Patient meets BOTH of the following (a and b):
       - **a)** The tumor is positive for ONE of the following [(1), (2), (3), or (4)]:
         - **(1)** *BRAF V600E* mutation positive; OR
         - **(2)** *NTRK1/2/3* gene fusion positive; OR
         - **(3)** *MET* exon 14 skipping mutation positive; OR
         - **(4)** *RET* rearrangement positive; AND
       - **b)** Imjudo is used as first-line or subsequent therapy; OR
     - **iv.** Patient meets ALL of the following (a, b, and c):
       - **a)** The tumor is positive for ONE of the following [(1), (2), (3), or (4)]:
         - **(1)** *EGFR* exon 19 deletion or exon 21 L858R mutation positive; OR
         - **(2)** *EGFR S768I*, *L861Q*, and/or *G719X* mutation positive; OR
         - **(3)** *ALK* rearrangement positive; OR
         - **(4)** *ROS1* rearrangement; AND
       - **b)** The patient has received targeted drug therapy for the specific mutation; AND
         Note: Examples of targeted drug therapy include Gilotrif (afatinib tablets), Tagrisso (osimertinib tablets), erlotinib, Iressa (gefitinib tablets), Xalkori (crizotinib capsules), Zykadia (ceritinib capsules), Alecensa (alectinib capsules), Alunbrig (brigatinib tablets),

Lorbrena (lorlatinib tablets), Rozlytrek (entrectinib capsules), or Vizimpro (dacomitinib tablets).

c) Imjudo is used as subsequent therapy; AND

E) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

3. Esophageal and Esophagogastric Junction Cancers. Approve for 30 days if the patient meets ALL of the following (A, B, C, D, E, F, and G):

A) Patient is ≥ 18 years of age; AND

B) Patient has adenocarcinoma tumor; AND

C) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND

D) Imjudo is used as neoadjuvant therapy; AND

E) Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion); AND

F) According to the physician, the patient is medically fit for surgery; AND

G) The medication is prescribed by or in consultation with an oncologist.

4. Gastric Cancer. Approve for 30 days if the patient meets ALL of the following (A, B, C, D, E, F, and G):

A) Patient is ≥ 18 years of age; AND

B) Patient has locoregional disease; AND

C) Patient has microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) disease; AND

D) Imjudo is used as neoadjuvant therapy; AND

E) Imjudo is used in combination with Imfinzi (durvalumab intravenous infusion); AND

F) According to the physician, the patient is medically fit for surgery; AND

G) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Imjudo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Imjudo® intravenous infusion [prescribing information]. Wilmington, DE: AstraZeneca; July 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 8, 2024. Search term: tremelimumab.
3. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 3.2024 – September 24, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 8, 2024.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 10.2024 – September 23, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 9, 2024.
5. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 4.2024 – July 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 8, 2024.
6. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – August 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed October 8, 2024.