PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 11/02/2022; selected revision 11/30/2022, 12/21/2022

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.

- **Hepatobiliary Cancers:** The guidelines (version 4.2022 – December 9, 2022) recommend Imjudo as a preferred first-line treatment in combination with Imfinzi for unresectable or metastatic hepatocellular carcinoma, or in patients who are not surgical candidates.[2,3]
- **Non-Small Cell Lung Cancer:** The guidelines (version 6.2022 – December 2, 2022) 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 criteria (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 unresectable or metastatic disease; OR
ii. According to the prescriber, the patient is not a surgical candidate; 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 criteria (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, *KRAS*, *ROS1*, *BRAF*, *NTRK1/2/3*, *MET*, *RET*, and *ERBB2* (*HER2*).
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) *KRAS G12C* mutation positive; OR
(3) *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 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.

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; November 2022.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 12, 2022. Search term: tremelimumab.
3. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 4.2022 – December 9, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 13, 2022.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 6.2022 – December 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 13, 2022.