PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable – Programmed Death-Ligand 1) – Imfinzi Prior Authorization Policy
- Imfinzi® (durvalumab intravenous infusion – AstraZeneca)

REVIEW DATE: 07/20/2022; selected revision 09/21/2022, 11/02/2022, 11/30/2022, 12/21/2022

OVERVIEW

Imfinzi, a programmed cell death ligand 1 (PD-L1) blocking antibody, is indicated for the following uses:[1]

- **Biliary tract cancers**, in combination with gemcitabine and cisplatin for the treatment of adults with locally advanced or metastatic disease.
- **Hepatocellular carcinoma**, in combination with Imjudo® (tremelimumab-actl intravenous infusion) for the treatment of adults with unresectable disease.
- **Non-small cell lung cancer (NSCLC)**, in adults with unresectable Stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- **NSCLC**, in adults with metastatic disease with no sensitizing epidermal growth factor receptor (*EGFR*) mutations or anaplastic lymphoma kinase (*ALK*) genomic tumor aberrations, in combination with Imjudo and platinum-based chemotherapy.
- **Small cell lung cancer**, in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adults with extensive-stage disease.

Guidelines

Imfinzi is addressed in National Comprehensive Cancer Network guidelines:

- **Hepatobiliary Cancers:** Guidelines (version 4.2022 – December 9, 2022) recommend Imfinzi, as monotherapy or in combination with Imjudo, as first-line treatment of hepatocellular carcinoma in patients with unresectable disease who are not transplant candidates, in patients who are inoperable due to performance status or comorbidities, and with metastatic disease.[2,5] Imfinzi is also recommended for the primary and subsequent treatment of unresectable or metastatic biliary tract cancers in combination with cisplatin and gemcitabine.
- **Non-Small Cell Lung Cancer:** Guidelines (version 6.2022 – December 2, 2022) recommend Imfinzi as consolidation therapy for patients with unresectable stage II (category 2A) or stage III (category 1) disease with a performance status of 0 or 1 and no disease progression following definitive chemoradiation.[2,3] Imfinzi is not recommended for patients following definitive surgical resection. The guidelines recommend Imfinzi for the first-line treatment of recurrent, advanced, or metastatic disease with PD-L1 expression ≥ 1% and negative for actionable molecular markers. The guidelines also recommend Imfinzi for disease with PD-L1 expression < 1%, and for disease that is positive for a variety of molecular markers.
- **Small Cell Lung Cancer:** Guidelines (version 2.2022 – November 24, 2021) recommend Imfinzi in combination with etoposide and carboplatin/cisplatin as a preferred primary treatment, followed by Imfinzi as single-agent maintenance therapy (category 1) for patients with extensive stage disease.[2,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Imfinzi. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Imfinzi, as well as the monitoring required for adverse events and long-term efficacy,

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approval requires Imfinzi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Biliary Tract Cancer.** Approve for 1 year 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.** Patient has recurrent disease at least 6 months after surgery and at least 6 months after adjuvant therapy; AND
   - **C)** Patient has ONE of the following (i, ii, or iii):
     - **i.** Gallbladder cancer; OR
     - **ii.** Intrahepatic cholangiocarcinoma; OR
     - **iii.** Extrahepatic cholangiocarcinoma; AND
   - **D)** The medication will be used in combination with cisplatin and gemcitabine; AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

2. **Hepatocellular Carcinoma.** Approve for 1 year 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)** The medication will be used first-line; AND
   - **D)** Patient meets ONE of the following (i or ii):
     - **i.** The medication is used as monotherapy; OR
     - **ii.** The medication is used in combination with Imjudo (tremelimumab-actl intravenous infusion); AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

3. **Non-Small Cell Lung Cancer.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Patient has unresectable Stage II or III disease: Approve for 1 year (total) of therapy if the patient meets ALL of the following criteria (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has not had disease progression following treatment with concurrent platinum-based chemotherapy and radiation therapy; AND
     - **iii.** The medication is prescribed by or in consultation with an oncologist; OR
   - **B)** Patient has recurrent, advanced, or metastatic disease: Approve for 1 year if the patient meets ONE of the following criteria (i, ii, iii, or iv):
     - **i.** Patient meets ALL of the following (a, b, c, and d):
       - **a)** Patient is ≥ 18 years of age; AND

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b) 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*).
c) Patient meets ONE of the following [(1) or (2)]:
(1) Imfinzi is used as first-line therapy; OR
(2) Imfinzi is used as continuation maintenance therapy; AND
d) The medication is prescribed by or in consultation with an oncologist; OR

ii. Patient meets ALL of the following (a, b, c, and d):
a) Patient is ≥ 18 years of age; AND
b) 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
c) Imfinzi is used as first-line therapy; AND
d) The medication is prescribed by or in consultation with an oncologist; OR

iii. Patient meets ALL of the following (a, b, c, and d):
a) Patient is ≥ 18 years of age; AND
b) 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
c) Imfinzi is used as first-line or subsequent therapy; AND
d) The medication is prescribed by or in consultation with an oncologist; OR

iv. Patient meets ALL of the following (a, b, c, d, and e):
a) Patient is ≥ 18 years of age; AND
b) 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
c) 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).
d) Imfinzi is used as subsequent therapy; AND
e) Imfinzi is prescribed by or in consultation with an oncologist.

4. Small Cell Lung Cancer. Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient has extensive stage disease; AND
C) Patient meets ONE of the following (i or ii):
i. The medication is used in combination with etoposide and platinum chemotherapy; OR
Note: Examples of platinum chemotherapy agents include cisplatin and carboplatin.
ii. The medication is used as a single-agent for maintenance after chemotherapy; AND
D) The medication is prescribed by or in consultation with an oncologist.

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CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Imfinzi 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. Imfinzi® 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 13, 2022. Search term: durvalumab.
3. 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.
4. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – November 24, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 7, 2022.
5. The NCCN Hepatocellular 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.

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