VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Imfinzi Utilization Review Medical Policy
- Imfinzi® (durvalumab injection for intravenous use – AstraZeneca)

REVIEW DATE: 07/15/2020

OVERVIEW

Imfinzi, a programmed cell death ligand 1 (PD-L1) blocking antibody, is indicated for the treatment of the following conditions:

- **Non-small cell lung cancer (NSCLC)**, in adult patients with unresectable Stage III disease that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
- **Small cell lung cancer**, in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of adult patients with extensive-stage disease.
- **Urothelial carcinoma,** in adult patients with locally advanced or metastatic disease with a) disease progression during or following platinum-containing chemotherapy; or b) have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

The recommended dose of Imfinzi is 10 mg/kg administered as an intravenous infusion over 60 minutes every 2 weeks, until disease progression or unacceptable toxicity, for both urothelial carcinoma and NSCLC. For NSCLC, the dosing is limited to a maximum of 12 months. For small cell lung cancer, the dose is 1,500 mg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1,500 mg every 4 weeks as a single agent. Management of AEs may require that Imfinzi be withheld or discontinued, as determined by the prescribing physician. No dose reductions are recommended.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on bladder cancer (version 5.2020 – May 12, 2020) recommends Imfinzi as one of the options for subsequent therapy (category 2A), as an alternative preferred regimen for the treatment of locally advanced or metastatic urothelial carcinoma after progression on platinum-based chemotherapy or disease that has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.[2] Imfinzi can be used regardless of PD-L1 expression levels.

The NCCN guidelines on NSCLC (version 6.2020 – June 15, 2020) recommends Imfinzi (category 1) as consolidation therapy for patients with unresectable Stage III disease with a performance status of 0 or 1.[3,4] Imfinzi can be used regardless of the PD-L1 status in patients who have not progressed after two or more cycles of definitive concurrent platinum-based chemoradiation therapy. Imfinzi is not recommended for patients following definitive surgical resection.

The NCCN guidelines for small cell lung cancer (version 4.2020 – July 7, 2020) recommends the use of Imfinzi in combination with etoposide and carboplatin/cisplatin as "preferred" first-line treatment option (category 1).[3,5] Imfinzi is used in maintenance setting, after 4 cycles in combination with chemotherapy, as single-agent once every 28 days until disease progression or unacceptable toxicity.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Imfinzi. Approval is recommended for those who meet the conditions of coverage in the **Criteria** and **Dosing** for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the 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, approval requires Imfinzi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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1. Non-Small Cell Lung Cancer. Approve for 1 year (total) of therapy if the patient meets the following criteria (A, B, and C):

- **A)** Patient has unresectable Stage III disease; AND
- **B)** Patient has not had disease progression following treatment with concurrent platinum-based chemotherapy and radiation therapy; AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.[1]

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2. Small Cell Lung Cancer. Approve for 1 year if the patient meets the following criteria (A and B):

- **A)** Patient meets one of the following (i or ii):
  - **i.** The medication is used in combination with etoposide and platinum chemotherapy (cisplatin or carboplatin); OR
  - **ii.** The medication is used as single-agent for maintenance after chemotherapy; AND
- **B)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 1,500 mg administered as an intravenous infusion not more frequently than once every 3 weeks.

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3. Urothelial Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):

- **A)** Patient has locally advanced or metastatic urothelial carcinoma; AND
- **B)** Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin); AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 10 mg/kg administered as an intravenous infusion not more frequently than once every 2 weeks.[1]

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 Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Imfinzi® injection for intravenous use [prescribing information]. Wilmington, DE: AstraZeneca; June 2020.
2. The NCCN Bladder Cancer Clinical Practice Guidelines in Oncology (Version 5.2020 – May 12, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 10, 2020.
3. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 10, 2020. Search term: durvalumab.
4. The NCCN Non-Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 6.2020 – June 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 10, 2020.
5. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 4.2020 – July 7, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed July 10, 2020.

HISTORY

Type of Revision	Summary of Changes	Review Date
New policy	New criteria	05/23/2018
Annual revision	• Deleted "Initial/Extended Approval," "Duration of Therapy," "Labs/Diagnositics," "Patient has been started on Imfinzi," "Other Cancer Indications," and "Waste Management for All Indications". • **Non-Small Cell Lung Cancer:** Deleted criteria "Imfinzi will be used as a single agent." Added "Approval duration to criteria added for "up to 1 year (total)." In Dosing section, deleted "As a single agent, the recommended dose is" and the infusion time of 60 minutes. Specified "Approve up to" 10 mg/kg "once" every 2 weeks. • **Urothelial Carcinoma:** Deleted criteria "Imfinzi will be used as a single agent." Added "Approve for up to 1 year." In Dosing section, deleted "As a single agent, the recommended dose is" and deleted infusion time of 60 minutes. Specified "Approve up to" 10 mg/kg "once" every 2 weeks. Re-worded to state patient "has tried" platinum-containing chemotherapy; previously it stated patient "has disease progression during or after trying" chemotherapy.	06/18/2019
Annual revision	• For Dosing, added "not more frequently than" in reference to duration. • For all conditions, instead of "Imfinzi is prescribed by…" changed it to "The medication is prescribed by". • **Small Cell Lung Cancer:** Added new approval condition based on FDA-approval. • **Conditions Not Recommended For Approval:** Deleted "Other Indications (Non-Cancer)".	07/15/2020