Clinical Policy: Durvalumab (Imfinzi)

Reference Number: PA.CP.PHAR.339
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

Description
Durvalumab (Imfinzi®) is a programmed death-ligand 1 (PD-L1) blocking antibody.

FDA approved indication
Imfinzi is indicated for the treatment of patients with:

- Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
  - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with of PA Health and Wellness® that Imfinzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Urothelial Carcinoma (must meet all)**:**

1. Diagnosis of locally advanced or metastatic (Stage IV) urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Failure of or disease progression on platinum-containing chemotherapy;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 10 mg/kg every 2 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of unresectable (Stage III) NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 10 mg/kg every 2 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications:

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via of PA Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 10 mg/kg every 2 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications:

1. Currently receiving medication via of PA Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to PA.CP.PMN.53.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer
RT: radiotherapy

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Urothelial Carcinoma (examples of platinum-containing regimens)		
DDMVAC (dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin)	Varies	Varies
gemcitabine with either cisplatin or carboplatin	Varies	Varies
CMV (cisplatin, methotrexate, and vinblastine)	Varies	Varies
NSCLC (examples of concurrent platinum-containing/radiotherapy regimens)		
cisplatin, etoposide, RT	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
carboplatin, pemetrexed, RT	Varies	Varies
paclitaxel, carboplatin, RT	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Urothelial carcinoma	10 mg/kg IV infusion over 60 minutes every 2 weeks	10 mg/kg per 2 weeks

V. Product Availability

Injection: 500 mg/10mL solution in a single-dose vial
Injection 120 mg/2.4mL solution in a single-dose vial

VI. References

1. Imfinzi Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2018. Available at: https://www.imfinzi.com. Accessed February 8, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 8, 2019.
3. National Comprehensive Cancer Network. Bladder Cancer Version 1.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed February 27, 2018.
4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 3.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed April 18, 2018.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: added new FDA indication for NSCLC; references reviewed and updated.	02.27.18	
2Q 2019 annual review: references reviewed and updated.	04.17.19	