RXADVANCE
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Clinical Policy Title:	durvalumab
Policy Number:	RxA.393
Drug(s) Applied:	Imfinzi™
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Durvalumab (Imfinzi™) is a programmed death-ligand 1 (PD-L1) blocking antibody. Durvalumab is indicated for the treatment of patients with:

- Locally advanced or metastatic urothelial carcinoma who:
  - Have disease progression during or following platinum-containing chemotherapy.
  - 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.

- In combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
durvalumab (Imfinzi ™)	Urothelial carcinoma and NSCLC	10 mg/kg intravenous infusion over 60 minutes every 2 weeks	10 mg/kg per 2 weeks
	ES-SCLC	1500 mg, in combination with carboplatin or cisplatin, every 3 weeks for 4 cycles followed by 1500 mg every 4 weeks as a single agent	1500 mg every 3 weeks

Dosage Forms

- Single-dose vials: 120 mg/2.4 mL, 500 mg/10 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Urothelial Carcinoma (bladder cancer, upper genitourinary tract tumors, urothelial carcinoma of the prostate, primary urethra carcinoma) (must meet all)**:**

1. Diagnosis of locally advanced (stage III) 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. Prescribed as single agent therapy;
5. 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
Commercial: 6 months
Medicaid: 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 (RT);
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
Commercial: 6 months
Medicaid: 6months

C. Extensive-Stage Small Cell Lung Cancer (must meet all):

1. Diagnosis of ES-SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Prescribed in combination with etoposide and either carboplatin or cisplatin;
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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.
2. Member is currently receiving durvalumab for a covered indication and has received this medication for at least 30 days;
3. Member is responding positively to therapy;
4. 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

Commercial: 12 months

Medicaid: 12 months

I. Appendices

APPENDIX A: Abbreviation/Acronym Key

ES-SCLC: Extensive-Stage Small Cell Lung Cancer
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
carboplatin, pemetrexed, RT	Varies	Varies
paclitaxel, carboplatin, RT	Varies	Varies

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None

- Boxed Warning(s):
  - Noe

APPENDIX D: General Information

Not applicable

References

1. Imfinzi Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2020. Available at: https://www.imfinzi.com. Accessed July 23, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July23, 2020.
3. National Comprehensive Cancer Network. Bladder Cancer Version 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed July 23, 2020.
4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 23, 2020.
5. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 4.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed July 23, 2020.
6. Imfinzi. In: Lexicomp Online Drug Database [database on the Internet]. Hudson, Ohio: Lexicomp, Inc.; 2020 [updated July 23, 2020]. Available at: http://online.lexi.com. Subscription required to view. Accessed July 23, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy updated. 1. Formatting updated. 2. Policy Title updated 3. New indication and criteria added. 4. Continued criteria for approval updated. 5. Approval duration updated. 6. Reference updated	07/23/2020	09/14/2020