Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2020**
Policy Number: PA.CP.PHAR.339	**Effective Date: 01/2018** **Revision Date: 04/15/2020**
Policy Name: Durvalumab (Imfinzi)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2020 annual review: UC stage III added to encompass NCCN recommended use for locally advanced disease; NCCN recommended use for SCLC added; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Durvalumab (Imfinzi)

Reference Number: PA.CP.PHAR.339
Effective Date: 01/18
Last Review Date: 04/2020 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 adult 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.

- For the treatment of adult patients with 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 adults patients with extensive-stage small cell lung cancer (ES-SCLC).

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 III-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. 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 as first-line treatment with (etoposide with either carboplatin or cisplatin) followed by maintenance Infimzi;
4. Request meets one of the following (a, b, or c):
   a. For body weight ≤ 30 kg, dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 20 mg/kg every 4 weeks as a single agent;
   b. For body weight > 30 kg, dose does not exceed 1500 mg every 3 weeks in combination with chemotherapy for 4 cycles, and then 1500 mg every 4 weeks as a single agent;
   c. 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

D. 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, b, or c):
   a. Urothelial carcinoma, NSCLC: New dose does not exceed 10 mg/kg every 2 weeks;
   b. ES-SCLC: One of the following (i or ii):
      i. For body weight ≤ 30 kg, dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 20 mg/kg every 4 weeks as a single agent;
      ii. For body weight > 30 kg, dose does not exceed 1500 mg every 3 weeks in combination with chemotherapy for 4 cycles, and then 1500 mg every 4 weeks as a single agent;
   c. 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

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		
CMV (cisplatin, methotrexate, and vinblastine)		
NSCLC (examples of concurrent platinum-containing/radiotherapy regimens)		
cisplatin, etoposide, RT	Varies	Varies
carboplatin, pemetrexed, RT		
paclitaxel, carboplatin, RT		
ES-SCLC (regimen examples as included in the NCCN SCLC guidelines)		
(carboplatin or cisplatin) and etoposide and Imfinzi	Carboplatin AUC 5-6 day 1 and etoposide 80-100 mg/m^2 days 1, 2, 3 and Imvinzi 1,500 mg day 1 every 21 days x 4 cycles followed by maintenance Imfinzi 1,500 mg day 1 every 28 days Cisplatin 75-80 mg/m^2 day 1 and etoposide 80-100 mg/m^2 days 1, 2, 3 and Imvinzi 1,500	See dosing regimens

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	mg day 1 every 21 days x 4 cycles followed by maintenance Imfinzi 1,500 mg day 1 every 28 days	

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 NSCLC	10 mg/kg IV infusion over 60 minutes every 2 weeks	10 mg/kg every 2 weeks
ES-SCLC	1500 mg IV in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as a single agent _____ • Patients with body weight ≤ 30 kg must receive weight-based dosing, equivalent to Imfinzi 20 mg/kg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, following by 20 mg/kg every 4 weeks as a single agent until weight increases to > 30 kg. • Administer Imfinzi prior to chemotherapy on the same day. When Imfinzi is administered in combination with chemotherapy, refer to the Prescribing Information for etoposide and carboplatin or cisplatin for dosing information. *[See also Appendix B. Therapeutic Alternatives for NCCN regimens as carboplatin, cisplatin and etoposide are off-label for ES-SCLC.]*	1500 mg every 3 weeks for 4 cycles (combination therapy) 1500 mg every 4 weeks (single agent)

V. Product Availability

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

VI. References

1. Imfinzi Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2019. Available at: https://www.imfinzi.com. Accessed February 10, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 10, 2020.
3. National Comprehensive Cancer Network. Bladder Cancer Version 3.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed February 10, 2020.

4. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 10, 2020.
5. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 3.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 10, 2020.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9999	Injection, not otherwise classified, antineoplastic drugs
C9492	Injection, durvalumab, 10 mg

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	
2Q 2020 annual review: UC stage III added to encompass NCCN recommended use for locally advanced disease; NCCN recommended use for SCLC added; references reviewed and updated.	04/2020	