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: 05/01/2021**
Policy Number: PA.CP.PHAR.339	**Effective Date: 01/2018** **Revision Date: 04/2021**
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2Q 2021 annual review: removed criteria for bladder cancer as the FDA labeled indication was withdrawn by the manufacturer based on confirmatory trial results; added coverage for stage II NSCLC per NCCN 2A recommendation; revised dosing for all indications per updated FDA label; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Durvalumab (Imfinzi)

Reference Number: PA.CP.PHAR.339
Effective Date: 01/18
Last Review Date: 04/2021 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 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. Non-Small Cell Lung Cancer (must meet all):

1. Diagnosis of unresectable, stage II-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, b, or c):*
   a. For body weight < 30 kg, dose does not exceed 10 mg/kg every 2 weeks;
   b. For body weight ≥ 30 kg, dose does not exceed 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks;
   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

B. 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 and either carboplatin or cisplatin followed by maintenance with Infimzi as a single agent;
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 10 mg/kg every 2 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, 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

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, b, or c):
   a. NSCLC (i or ii):
      i. For body weight < 30 kg, new dose does not exceed 10 mg/kg every 2 weeks;
      ii. For body weight ≥ 30 kg, new dose does not exceed 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks;
   b. ES-SCLC (i or ii):
      i. For body weight < 30 kg, new dose does not exceed 20 mg/kg every 3 weeks in combination with chemotherapy for 4 cycles, then 10 mg/kg every 2 weeks as a single agent;
      ii. For body weight ≥ 30 kg, new dose does not exceed 1500 mg every 3 weeks in combination with chemotherapy for 4 cycles, 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
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 mg day 1 every 21 days x 4 cycles followed by maintenance Imfinzi 1,500 mg day 1 every 28 days	See dosing regimens

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.

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information
On February 22, 2021, AstraZeneca announced the voluntary withdrawal of the indication for Imfinzi for second-line treatment of locally advanced or metastatic bladder cancer. Imfinzi was approved for this indication under the accelerated pathway in 2017, based on study results that showed positive tumor response rates and duration of response. In its announcement, AstraZeneca pointed to results from the DANUBE confirmatory trial, in which Imfinzi failed to meet its key primary endpoint of overall survival.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	Weight ≥ 30 kg: 10 mg/kg IV every 2 weeks or 1,500 mg every 4 weeks Weight < 30 kg: 10 mg/kg IV every 2 weeks	See regimen; maximum duration of 12 months

Indication	Dosing Regimen	Maximum Dose
ES-SCLC	Weight ≥ 30 kg: 1,500 mg IV in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, followed by 1,500 mg every 4 weeks as a single agent Weight < 30 kg: 20 mg/kg IV in combination with chemotherapy* every 3 weeks (21 days) for 4 cycles, following by 10 mg/kg every 2 weeks as a single agent *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.]*	See regimen

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; February 2021. Available at: https://www.imfinzi.com. Accessed February 23, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 23, 2021.
3. National Comprehensive Cancer Network. Non-Small Cell Lung Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 15, 2021.
4. National Comprehensive Cancer Network. Small Cell Lung Cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed January 15, 2021.

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	

Reviews, Revisions, and Approvals	Date	Approval Date
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	
2Q 2021 annual review: removed criteria for bladder cancer as the FDA labeled indication was withdrawn by the manufacturer based on confirmatory trial results; added coverage for stage II NSCLC per NCCN 2A recommendation; revised dosing for all indications per updated FDA label; references reviewed and updated.	04/2021	