Clinical Policy: Durvalumab (Imfinzi)

Reference Number: CP.PHAR.339
Effective Date: 07.01.17
Last Review Date: 05.20
Line of Business: HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

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

It is the policy of health plans affiliated with Centene Corporation® 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 (Stages 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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 (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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. Other diagnoses/indications:
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit, or member has previously met initial approval criteria, or documentation supports that member is currently receiving Imfinzi for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
NSCLC: up to a total duration of 12 months
All other indications: 12 months

B. Other diagnoses/indications:

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

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

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. 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 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.

V. 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	1500 mg every 3 weeks for 4 cycles

Indication	Dosing Regimen	Maximum Dose
	• 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.]*	(combination therapy) 1500 mg every 4 weeks (single agent)

VI. Product Availability

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

VII. References

1. Imfinzi Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2020. Available at: https://www.imfinzi.com. Accessed April 27, , 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 27, 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 April 27, 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	P& T Approval Date
Policy created	06.17	07.17
2Q 2018 annual review: added new FDA indication for NSCLC with total duration of therapy of 12 months only per trial design and NCCN guideline; HIM added; references reviewed and updated.	04.24.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	12.19.19	05.19
No significant changes; revised formatting only.	07.08.19	
2Q 2020 annual review: HIM line of business added; UC stage III added to encompass NCCN recommended use for locally advanced disease; NCCN recommended use for SCLC added; references reviewed and updated.	02.11.20	05.20
FDA new indication added for ES-SCLC; references reviewed and updated.	04.27.20	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.