# Clinical Policy: Durvalumab (Imfinzi)

Reference Number: CP.PHAR.339
Effective Date: 07/17
Last Review Date: 07/17
Line of Business: Medicaid

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**
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.

**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 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 urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Failure of or disease progression on platinum-containing chemotherapy;
4. Dose does not exceed 10mg/kg every 2 weeks.

**Approval duration: 6 months**

**B. Other diagnoses/indications:**

1. Refer to CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

2. Documentation of positive response to therapy (e.g.; no disease progression or unacceptable toxicity);
3. Dose does not exceed 10mg/kg every 2 weeks.

**Approval duration: 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 CP.PHAR.57 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## 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 policy – CP.PHAR.57 or evidence of coverage documents.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration

## V. 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 |

## VI. Product Availability

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

## VII. References

1. Imfinzi [Prescribing Information] Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2017. Available at: https://www.imfinzi.com. Accessed May 30, 2017.
2. National Comprehensive Cancer Network. Bladder Cancer. Version 5.2017. Accessed from https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf, June 1, 2017.

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Policy created | 06/17 | 07/17 |

**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.



**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.