

**Subject:** Imfinzi (durvalumab)

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## Overview

This document addresses the use of Imfinzi (durvalumab). Imfinzi is a programmed death-ligand 1 (PD-L1) blocking antibody.

The FDA approved indications for Imfinzi include stage III non-small cell lung cancer (NSCLC), and extensive stage small cell lung cancer (SCLC).

The National Comprehensive Cancer Network (NCCN) provides category 1 and 2A recommendations for use in NSCLC and SCLC also.

### Other Uses

The NCCN panel provides 2A recommendations for use in Stage II NSCLC. The panel noted that a few patients in the PACIFIC trial were Stage II (Antonia SJ et al. 2018; Gray JE et.al 2020; Hui R, et.al. 2019). However, no additional trial data or studies are available to support use in this population.

NCCN provides category 2A and 2B recommendations for use of Imfinzi in several types of bladder cancer. However, their Bladder Cancer guidelines have not been updated since the manufacturer's decision in 2/2021 to withdraw this indication from the FDA label due to Imfinzi's inability to meet the overall survival primary outcome measures in the phase 3 DANUBE confirmatory trials (Powles 2020). The FDA had granted Imfinzi with its bladder cancer indication through the accelerated approval program in 2017, with continued approval contingent upon verification of clinical benefit in confirmatory trials. In the current NCCN compendia, NCCN no longer provides these bladder cancer recommendations.

### Definitions and Measures

**Consolidation therapy:** Any drug or medical treatment that is used to kill remaining cancer cells. Also called intensification therapy or post-remission therapy.

**ECOG or Eastern Cooperative Oncology Group Performance Status:** A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

**Extensive-stage small cell lung cancer:** Cancer has spread to other parts of the body, and could include the fluid around the lungs.

**Immune checkpoint inhibitor:** A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the “brakes” on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2.

**Limited-stage small cell lung cancer:** Cancer is confined to 1 part of the chest, and radiation therapy could be an option.

**Locally advanced cancer:** Cancer that has spread only to nearby tissues or lymph nodes.

**Metastasis:** The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

**Programmed death (PD)-1 proteins:** PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body. Examples of FDA approved anti-PD-1 agents include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).

**Programmed death ligand (PD-L)-1:** The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved anti-PD-L1 agents include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).

## Clinical Criteria

When a drug is being reviewed for coverage under a member’s medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Imfinzi (durvalumab)

Requests for Imfinzi (durvalumab) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Non-Small Cell Lung Cancer (NSCLC) ; **AND**
  - A. Disease is confirmed (histologically or cytologically) stage III locally advanced, unresectable NSCLC disease; **AND**
  - B. Disease has not progressed after definitive chemoradiation; **AND**
  - C. Individual is using as consolidation therapy; **AND**
  - D. Individual is using until disease progression or a maximum of 12 months of treatment (NCCN 2A); **AND**
  - E. Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
  - F. Individual has a current ECOG performance status of 0-2; **AND**
  - G. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;
- OR**
- II. Individual has a diagnosis of extensive stage Small Cell Lung Cancer; **AND**
  - A. Individual is using as first line therapy in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by maintenance Imfinzi monotherapy); **AND**
  - B. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
  - C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Requests for Imfinzi (durvalumab) may not be approved when the above criteria are not met and for all other indications.

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

<b>J9173</b>	Injection, durvalumab, 10 mg [Imfinzi]
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### ICD-10 Diagnosis

<b>C34.00-C34.92</b>	Malignant neoplasm of bronchus and lung
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<b>Z85.110-Z85.118</b>	Personal history of malignant neoplasm of bronchus and lung
<b>Z92.21</b>	Personal history of antineoplastic chemotherapy
<b>Z92.3</b>	Personal history of irradiation

## Document History

Reviewed: 02/25/2022

Document History:

- 02/25/2022 – Annual Review: No changes. Coding Reviewed: No changes.
- 03/15/2021 – Select Review: Update criteria to remove indication for urothelial cancer per FDA label. Coding Reviewed: Removed ICD-10-CM C68.0, C61, C65.1-C65.9, C66.1-C66.9, C67.0-C67.9, Z85.51, Z85.53-Z85.54.
- 02/19/2021 – Annual Review: Updated references. Coding Reviewed: No changes.
- 02/21/2020 – Annual Review: Update criteria to add indication for SCLC per NCCN recommendations. Update criteria regarding conditions that are excluded for consistency. Coding Reviewed: No changes.
- 08/16/2019 – Select Review: Minor wording and formatting changes. Coding Reviewed: No changes.
- 05/17/2019 – Annual Review: Initial review of Imfinzi (durvalumab). Wording and formatting changes. Coding reviewed: Added Z92.21, Z92.3.

## References

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  - b. Small Cell Lung Cancer. V2.2022. Revised November 24, 2021.
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