SmartHealth

Ascension

Durvalumab

(Imfinzi®) J9173 (10 mg)

Covered with prior authorization

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

- Individual has a diagnosis of Non-Small Cell Lung Cancer (NSCLC) ; **AND**
    - Disease is confirmed (histologically or cytologically) stage III locally advanced, unresectable NSCLC disease; **AND**
    - Disease has not progressed after definitive chemoradiation; **AND**
    - Individual is using as consolidation therapy; **AND**
    - Individual is using until disease progression or a maximum of 12 months of treatment (NCCN 2A); **AND**
    - Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
    - Individual has a current ECOG performance status of 0-2; **AND**
    - Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

- Individual has a diagnosis of extensive stage Small Cell Lung Cancer; **AND**
    - 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**
    - Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
    - 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 if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

SmartHealth

Ascension

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Imfinzi® (durvalumab) may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. 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.

Key References Accessed 8/2022:

1. Antonia SJ, Villegas A, Daniel D, et al. Overall survival with Durvalumab after Chemoradiotherapy in Stage III NSCLC. N Engl J Med 2018; 379: 2342-2350.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.

4. Gray JE, Villegas A, Daniel D, et.al. Three-Year Overall Survival with Durvalumab after Chemoradiotherapy in Stage III NSCLCUpdate from PACIFIC. J Thorac Oncol 2020; 15: 288-293.
5. Hui R, Ozguroglu M, Villegas A., et al. Patient-reported outcomes with durvalumab after chemoradiotherapy in stage III, unresectable non-small cell lung cancer (PACIFIC): a randomized, controlled, phase 3 study. Lancet Oncol 2019:20:1670-1680.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. Non-Small Cell Lung Cancer. V1.2022. Revised December 7, 2021.
    b. Small Cell Lung Cancer. V2.2022. Revised November 24, 2021.
8. Powles T, van der Heijden MS, Castellano D, et al; DANUBE study investigators. Durvalumab alone and durvalumab plus tremelimumab versus chemotherapy in previously untreated patients with unresectable, locally advanced or metastatic urothelial carcinoma (DANUBE): a randomized, open-label, multicentre, phase 3 trial. Lancet Oncol. 2020;21(12):1574-1588. doi:10.1016/S1470-2045(20)30541-6.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.