Imfinzi (durvalumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Imfinzi (durvalumab)

APPROVAL CRITERIA

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

I. Individual has diagnosis of Non-Small Cell Lung Cancer (NSCLC) (Label, NCCN 1, 2A); **AND**
   A. Disease type is one of the following:
      1. Disease is confirmed (histologically or cytologically) stage III locally advanced, unresectable NSCLC; **OR**
      2. Disease is confirmed (histologically or cytologically) stage II, unresectable NSCLC;
   B. Disease has not progressed after definitive chemoradiation; **AND**
   C. Individual is using as consolidation therapy; **AND**
   D. Individual is using as a single agent; **AND**
   E. Imfinzi (durvalumab) is being used until disease progression or a maximum of 12 months of treatment (NCCN 2A); **AND**
   F. Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   G. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
   H. 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 NSCLC (Label, NCCN 1, NCCN 2A); **AND**
   A. Individual has recurrent, advanced or metastatic NSCLC disease with no prior chemotherapy or any other systemic therapy; **AND**
   B. Individual is using in combination with Imjudo (tremelimumab-actl) and platinum-based chemotherapy; **AND**
   C. Negative for actionable molecular biomarkers (including but not limited to EGFR, KRAS, ALK, ROS1, BRAF, NTRK 1/23, MET, RET, and ERBB2 (HER2); **AND**
   D. Individual may be KRAS G12C mutation positive; **AND**
   E. Individual has a PD-L1 expression of greater than or equal to 1 to 49%; **AND**
   F. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

G. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

III. Individual has a diagnosis of NSCLC (NCCN 1); **AND**
   A. Individual is using as continuation maintenance therapy in one of the following ways:
      1. As a single agent for recurrent, advanced, or metastatic disease after initial systemic therapy with durvalumab/tremelimumab-actl plus chemotherapy; **OR**
      2. In combination with pemetrexed for recurrent, advanced, or metastatic disease after initial systemic therapy with durvalumab/tremelimumab-actl and platinum-based chemotherapy; **AND**
   B. Individual is using until disease progression or unacceptable toxicity following positive tumor response or stable disease following initial systemic therapy; **AND**
   C. Individual has a ECOG performance status of 0-2;

OR

IV. Individual has a diagnosis of NSCLC (Label, NCCN 1); **AND**
   A. Individual is using as neoadjuvant therapy in combination with platinum-containing chemotherapy; **AND**
   B. Individual has resectable (tumors ≥ 4 cm and/or node positive) NSCLC; **AND**
   C. Individual has no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase rearrangements; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

   OR

   F. Individual is using Imfinzi as single-agent adjuvant therapy; **AND**
   G. Individual is using after initial neoadjuvant use of Imfinzi with platinum-containing chemotherapy for completely resected tumors ≥ 4 cm and/or node positive NSCLC and no known EGFR mutations or ALK rearrangements;

OR

V. Individual has a diagnosis of primary advanced or recurrent endometrial cancer (Label); **AND**
   A. Individual is using in combination with carboplatin and paclitaxel and followed by durvalumab as a single agent; **AND**
   B. Individual has mismatch repair deficient disease (dMMR);

OR

VI. Individual has a diagnosis of limited stage (LS) small-cell lung cancer (Stage I-III) (Label, NCCN 1); **AND**
   A. Individual's disease has not progressed following concurrent platinum-based chemotherapy and radiation; **AND**

B. Individual is using durvalumab as a single agent for up to 24 months (NCCN Small Cell Lung Cancer Guidelines V3.2025); **AND**
C. Individual has an ECOG performance status of 0-1 (NCCN 1);

OR

VII. Individual has a diagnosis of extensive stage Small Cell Lung Cancer (Label, NCCN 1); **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;

OR

VIII. Individual has a diagnosis of locally advanced or metastatic biliary tract cancer (including pancreatobiliary and mixed type disease) (Label, NCCN 1, 2A); **AND**
A. Individual is using in combination with gemcitabine and cisplatin; **AND**
B. Individual has a current ECOG performance status of 0-2; **AND**
C. Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

IX. Individual has a diagnosis of hepatocellular carcinoma (uHCC) (Label, NCCN 1); **AND**
A. Individual is using as first-line therapy in combination with Imjudo (tremelimumab-actl); **AND**
1. Individual has unresectable disease; **OR**
2. Individual has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
3. Individual has metastatic disease or extensive liver tumor burden;

OR

B. Individual is using as first-line therapy as a single agent; **AND**
1. Individual has unresectable disease; **OR**
2. Individual has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
3. Individual has metastatic disease or extensive liver tumor burden;

AND

C. Individual has a current ECOG performance status of 0-1; **AND**
D. Individual has not received treatment with another anti-PD-1 or anti-PDL1 agent; **AND**
E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

X. Individual has a diagnosis of persistent, recurrent, or metastatic small cell neuroendocrine carcinoma of the cervix (NECC) (NCCN 2A); **AND**
   A. Individual is using as first-line, second-line, or subsequent therapy (if not used previously as first-line); **AND**
   B. Individual is using in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by maintenance Imfinzi monotherapy); **AND**
   C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

XI. Individual has a diagnosis of Esophageal and esophagogastric junction cancers or Gastric cancer (NCCN 2A); **AND**
   A. Individual is using as neoadjuvant therapy; **AND**
   B. Individual is using in combination with Imjudo (tremelimumab-actl); **AND**
   C. Individual has a current ECOG performance status of 0-1; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   E. Individual has microsatellite instability-high/deficient mismatch repair (MSI-H/dMMR) tumors.

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

Key References:

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. Cheng Y, Spigel D, Cho BC, et al. Durvalumab after Chemoradiotherapy in Limited-Stage Small-Cell Lung Cancer. N Engl J Med 2024;39;1313-1327.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 27, 2024.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Gray JE, Villegas A, Daniel D, et.al. Three-Year Overall Survival with Durvalumab after Chemoradiotherapy in Stage III NSCLC-Update from PACIFIC. J Thorac Oncol 2020; 15: 288-293.
7. 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.
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
9. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 6, 2024.
   a. Ampullary adenocarcinoma. V1.2024. Revised December 13, 2023.
   b. Biliary Tract Cancers. V3.2024. Revised July 2, 2024.
   c. Cervical Cancer. V3.2024. Revised May 6, 2024.
   d. Esophageal and Esophagogastric Junction Cancers. V1.2024. March 07, 2024.
   e. Gastric Cancer. V2.2024. Revised May 29, 2024.
   f. Hepatocellular Carcinoma. V2.2024. Revised July 2, 2024.

g. Non-Small Cell Lung Cancer. V8.2024. Revised August 23, 2024.
h. Small Cell Lung Cancer. V3.2025. Revised October 29, 2024.
10. 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 randomised, open-label, multicentre, phase 3 trial. *Lancet Oncol*. 2020;21(12):1574-1588. doi:10.1016/S1470-2045(20)30541-6.
11. Spigel DR, et al. ADRIATIC: durvalumab (D) as consolidation treatment (tx) for patients (pts) with limited-stage small-cell lung cancer (LS-SCLC). *J Clin Oncol* 42(suppl 17): LBA5. doi:10.1200/JCO.2024.42.17_suppl.LBA5.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.