

Drug Policy:

Imfinzi™ (durvalumab)

POLICY NUMBER UM ONC_1314	SUBJECT Imfinzi™ (durvalumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 4
DATES COMMITTEE REVIEWED 05/03/17, 05/09/18, 05/08/19, 12/11/19, 03/11/20, 05/13/20, 03/10/21, 04/14/21, 11/15/21, 03/09/22, 05/11/22, 10/12/22, 11/09/22, 12/14/22	APPROVAL DATE December 14, 2022	EFFECTIVE DATE December 30, 2022	COMMITTEE APPROVAL DATES 05/03/17, 05/09/18, 05/08/19, 12/11/19, 03/11/20, 05/13/20, 03/10/21, 04/14/21, 11/15/21, 03/09/22, 05/11/22, 10/12/22, 11/09/22, 12/14/22	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Imfinzi (durvalumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. When Health Plans utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, and there is no Health Plan PDL applicable, the [Preferred Drug Guidelines](#) shall follow NCH recommended agents/regimens/preferred drugs **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When applicable, generic alternatives are preferred over brand-name drugs **AND**
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendia or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Biliary Tract Cancer (BTC)

1. Imfinzi (durvalumab) may be used in combination with cisplatin/carboplatin and gemcitabine as first line therapy in members who have not received therapy for unresectable or metastatic biliary tract cancer (e.g., extrahepatic/intrahepatic cholangiocarcinoma, gallbladder carcinoma).

C. Hepatocellular Carcinoma

1. The member has unresectable hepatocellular carcinoma (Child-Pugh Class A score only) with no prior systemic treatment, including prior checkpoint inhibitor (e.g., dostarlimab-gxly, atezolizumab, nivolumab, pembrolizumab, ipilimumab) **AND**
2. Imfinzi (durvalumab) will be used as first line therapy in combination with Imjudo (tremelimumab). Imjudo (tremelimumab) is given for one cycle followed by single agent Imfinzi (durvalumab).

D. Non-Small Cell Lung Cancer (NSCLC)

1. Imfinzi (durvalumab) may be used as a single agent for consolidation therapy (for a total of 1 year), after completion of definitive chemoradiation, in members with unresectable (not amenable to surgical treatment) stage II or stage III disease provided that appropriate imaging studies (e.g., CT or PET/CT) performed after the completion of chemoradiation confirm the lack of disease progression and show one of the following: complete response/partial response/stable disease.
2. Imfinzi (durvalumab) will be used in combination with Imjudo (tremelimumab) and platinum-based chemotherapy for members who have not received prior systemic therapy for metastatic or Stage IV NSCLC and the tumor is negative for EGFR and ALK, regardless of PD-L1 expression.

E. Small Cell Lung Cancer (Extensive Stage)

1. Imfinzi (durvalumab) may be used in combination with [carboplatin/cisplatin + etoposide] followed by single agent maintenance Imfinzi (durvalumab), for members with extensive stage small cell lung cancer.

III. EXCLUSION CRITERIA

- A. Disease progression while receiving Imfinzi (durvalumab) or prior checkpoint inhibitor (PD-1 or PD-L1 inhibitor).
- B. There is no imaging study available, after the completion of chemoradiation for NSCLC, to confirm complete response/partial response/stable disease after chemoradiation.
- C. Members with locally advanced non-small cell lung cancer (NSCLC) with disease progression while receiving concurrent chemoradiotherapy or after chemoradiation.

- D. Dosing exceeds single dose limit of Imfinzi (durvalumab) 10mg/kg (every 2 weeks as a single agent), 20 mg/kg (every 3 weeks when used in combination with chemotherapy), 1,500 mg (every 3 weeks when used in combination with chemotherapy), or 1500 mg (every 4 weeks when used as a single agent), or maximum duration of 12 months for NSCLC consolidation therapy.
- E. For used in combination with Imjudo (tremelimumab): If weight is less than 30 kg, the maximum single dose limit is 20 mg/kg every 4 weeks; for weight 30 kg or more, the maximum single dose limit is 1500 mg every 4 weeks.
- F. Investigational use of Imfinzi (durvalumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
 - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
 - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
 - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
 - 4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
 - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
 - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
 - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Johnson ML, et al. POSEIDON Clinical Trial. Durvalumab With or Without Tremelimumab in Combination With Chemotherapy as First-Line Therapy for Metastatic Non-Small-Cell Lung Cancer: The Phase III POSEIDON Study. *J Clin Oncol*. 2022 Nov 3;JCO2200975.
- B. Abou-Alfa et al HIMALAYA Clinical Trial. Durvalumab plus tremelimumab in unresectable hepatocellular carcinoma. June 6, 2022. *NEJM Evid* 2022;1(8). DOI: <https://doi.org/10.1056/EVIDoa2100070>
- C. Do Yun Oh et al. TOPAZ-1 trial. *NEJM Evidence*. June 1, 2022. DOI: 10.1056/EviDoa2200015
- D. Antonia SJ, et al. PACIFIC trial updated analysis: Overall Survival with Durvalumab after Chemoradiotherapy in Stage III NSCLC. *N Engl J Med*. 2018 Dec 13;379(24):2342-2350.
- E. Antonia SJ, et al. PACIFIC Trial. Durvalumab after Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. *N Engl J Med*. 2017 Nov 16;377(20):1919-1929.
- F. Paz-Ares L, et al. CASPIAN Trial. Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomised, controlled, open-label, phase 3 trial. *Lancet*. 2019 Nov 23;394(10212):1929-1939.
- G. Imfinzi prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE 2020.
- H. Clinical Pharmacology Elsevier Gold Standard 2022.
- I. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2022.
- J. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2022.
- K. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2022.
- L. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol*. 2014 Apr 20;32(12):1277-80.
- M. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- N. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.
- O. NCQA UM 2022 Standards and Elements.