New Century Health

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, 10/11/23	**APPROVAL DATE** October 11, 2023	**EFFECTIVE DATE** October 27, 2023	**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, 10/11/23
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
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. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

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 and/or Barcelona Clinic Liver Cancer stage B or C) 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).

The Barcelona Clinic Liver Cancer (BCLC) Staging System (60)

BCLC stage	ECOG PS	Liver function: Child-Pugh	Tumor stage
Very early stage (0)	0	A	Single ≤2 cm
Early stage (A)	0	A-B	Single ≤3, nodules ≤3 cm
Intermediate stage (B)	0	A-B	Multinodular
Advanced stage (C)	1-2	A-B	Vascular invasion, extrahepatic spread
Terminal stage (D)	3-4	C	Any

CHILD-PUGH SCORE

Chemical and Biochemical Parameters	Scores (Points) for Increasing Abnormality		
	1	2	3
Encephalopathy (grade)[1]	None	1–2	3–4
Ascites	Absent	Slight	Moderate
Albumin (g/dL)	>3.5	2.8–3.5	<2.8
Prothrombin time[2] Seconds over control INR	 <4 <1.7	 4–6 1.7–2.3	 >6 >2.3
Bilirubin (mg/dL) • For primary biliary cirrhosis	<2 <4	2–3 4–10	>3 >10

Class A = 5–6 points; Class B = 7–9 points; Class C = 10–15 points.

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 amendable 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

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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.

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G. Imfinzi prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE 2020.

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N. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

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