Drug Policy:
Imfinzi™ (durvalumab)

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. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND

4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND

5. When available, generic alternatives are preferred over brand-name drugs.

B. 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.

C. Small Cell Lung Cancer (Extensive Stage)

1. NOTE: Per NCH Policy and NCH Pathway, the preferred checkpoint inhibitor for first line therapy of Extensive Stage Small Cell Lung Cancer is Tecentriq (atezolizumab). Please refer to the NCH Pathway document. This recommendation is based on the lack of Level 1 evidence (randomized trial and/or meta-analysis) to support superior outcomes with Imfinzi (durvalumab) based therapy over Tecentriq (atezolizumab) based therapy, in first line treatment of extensive-stage small cell lung cancer.

2. Imfinzi (durvalumab) may be used in combination with [carboplatin + etoposide], for members with extensive stage small cell lung cancer, if there is a history of intolerance to Tecentriq (atezolizumab).

III. EXCLUSION CRITERIA

A. Disease progression while receiving Imfinzi (durvalumab) or prior checkpoint inhibitor (anti-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), 20 mg/kg (every 3 weeks), or 1500 mg (every 4 weeks), or maximum duration of 12 months for NSCLC consolidation therapy.

E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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


