POLICY NUMBER UM ONC_1314	SUBJECT Imfinzi™ (durvalumab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 05/03/17, 05/09/18, 05/08/19, 12/11/19, 03/11/20, 05/13/20	APPROVAL DATE May 13, 2020	EFFECTIVE DATE May 29, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 05/03/17, 05/09/18, 05/08/19, 12/11/19, 03/11/20, 05/13/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

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 is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. 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**
    b. 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**
    c. 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**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Urothelial Carcinoma**
    a. **NOTE:** Per NCH policy and NCH pathway, the checkpoint inhibitor of choice is Keytruda over Opdivo, Tecentriq, Bavencio, or Imfinzi. Please refer to the NCH Pathway document.
3. **Non-Small Cell Lung Cancer (NSCLC)**
    a. Imfinzi (durvalumab) will be used as consolidation therapy, after completion of definitive chemoradiation, in members with unresectable stage III disease **AND**
    b. Appropriate imaging studies (e.g. CT or PET/CT) performed after the completion of chemoradiation should have documented one of the following: complete response/partial response/stable disease to the aforementioned chemoradiation.

4. **Small Cell Lung Cancer (Extensive Stage)**

    a. **NOTE:** Per NCH Policy and NCH Pathway, the preferred checkpoint inhibitor for first line therapy of Extensive Stage Small Cell Lung Cancer is Tecentriq. Please refer to the NCH Pathway document.

III. EXCLUSION CRITERIA

1. Disease progression while receiving Imfinzi (durvalumab) or prior checkpoint inhibitor (anti-PD-1 or PD-L1 inhibitor).
2. There is no imaging study available, after the completion of chemoradiation for NSCLC, to confirm complete response/partial response/stable disease.
3. Members with locally advanced non-small cell lung cancer (NSCLC) with disease progression while receiving concurrent chemoradiotherapy or after chemoradiation.
4. Dosing exceeds single dose limit of Imfinzi (durvalumab) 10mg/kg or maximum duration of 12 months for NSCLC consolidation therapy.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Imfinzi PI prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE 2020.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.