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	**APPROVAL DATE** March 11, 2020	**EFFECTIVE DATE** March 27, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 05/03/17, 05/09/18, 05/08/19, 12/11/19, 03/11/20	
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: http://pathways.newcenturyhealth.com **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic dug alternatives are preferred over Brand name drugs.

2. **Urothelial Carcinoma**
3. **NOTE: Per NCH Pathways for subsequent therapy of metastatic/recurrent urothelial carcinoma, Keytruda is the preferred checkpoint inhibitor rather than Opdivo, Tecentriq, Bavencio or Imfinzi.**
4. **The member has locally advanced, metastatic, or recurrent urothelial carcinoma and Imfinzi (durvalumab) is being used as a single agent following disease progression during or after platinum-based chemotherapy.**
5. **Non-Small Cell Lung Cancer (NSCLC)**

a. Imfinzi (durvalumab) is being used as consolidation therapy, after completion of definitive chemoradiation, in members with unresectable stage II or III disease **AND**

b. Appropriate imaging studies (e.g. CT or PET/CT) performed after the completion of chemoradiation should have documented a complete response/partial response/stable disease.

III. EXCLUSION CRITERIA

1. Off-label indications for Imfinzi (durvalumab) in small cell lung cancer shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
2. Imfinzi (durvalumab) is being used after disease progression with the same regimen or prior anti-PD-1 or PD-L1 inhibitor.
3. There is no imaging available , after the completion of chemoradiation for NSCLC, to confirm a complete response/partial response/stable disease.
4. Members with locally advanced non-small cell lung cancer (NSCLC) with disease progression while receiving concurrent chemoradiotherapy.
5. Dosing exceeds single dose limit of Imfinzi (durvalumab) 10mg/kg or maximum duration of 12 months for NSCLC consolidation therapy.
6. 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 2019.
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.