Policy Title:	Imfinzi (durvalumab) Intravenous		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/18/2019		
Revision Date:	12/18/2019		

Purpose: To support safe, effective and appropriate use of Imfinzi (durvalumab).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement: Imfinzi (durvalumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure: Coverage of Imfinzi (durvalumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient must be at least 18 years old; AND
- Used as a single agent; AND
- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, etc.) unless otherwise specified; AND

Bladder Cancer/Urothelial Carcinoma

- Must be used as subsequent therapy after previous platinum treatment*; AND
- Patient has a diagnosis of one of the following:
  - Locally advanced or metastatic Urothelial Carcinoma; OR
  - Disease recurrence post-cystectomy; OR
  - Metastatic Upper Genitourinary Tract Tumors; OR
  - Metastatic Urothelial Carcinoma of the Prostate; OR
  - Recurrent or metastatic Primary Carcinoma of the Urethra AND
    - Patient does not have recurrent stage T3-4 disease or palpable inguinal lymph nodes.

Non-Small Cell Lung Cancer (NSCLC)

- Must be used as consolidation therapy; AND
- Patient has unresectable stage III disease; AND
- Disease did not progress after at least 2 cycles of definitive chemoradiation; AND
- Patient has a performance status (PS) of 0-1.

*If platinum treatment occurred greater than 12 months ago, the patient should be re-treated with platinum-based therapy. Patients with comorbidities (e.g., hearing loss, neuropathy, poor PS, renal insufficiency, etc.) may not be eligible for cisplatin. Carboplatin may be substituted for cisplatin particularly in those patients with a GFR< 60mL/min or a PS of 2.

***Continuation of Therapy Criteria*:**

- Patient continues to meet initial criteria; AND
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe infusion reactions, immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, skin, etc.); AND
- For NSCLC, patient has not exceeded a maximum of twelve months of therapy.

Coverage durations:

- Initial & Renewal coverage = 6 months
    - NSCLC can be authorized up to a maximum of 12 months of therapy.

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	**Dose (1 billable unit = 10mg)**	**Maximum Units (1 billable unit = 10mg)**
All indications	10mg/kg every 2 weeks	112 billable units (1120 mg) every 14 days

Investigational Use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes: Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J9173	Injection, durvalumab, 10 mg

References:

1. Imfinzi [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; February 2018.
2. Massard C, Gordon MS, Sharma S, et al. Safety and Efficacy of Durvalumab (MEDI4736), an Anti-Programmed Cell Death Ligand-1 Immune Checkpoint Inhibitor, in Patients With Advanced Urothelial Bladder Cancer. J Clin Oncol. 2016 Sep 10;34(26):3119-25.
3. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) durvalumab. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
4. Antonia SJ, Villegas A, Daniel D, et al. Durvalumab after Chemoradiotherapy in Stage III Non-Small-Cell Lung Cancer. N Engl J Med. 2017 Sep 8.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 1.2019. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.
6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 5.2018. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed November 2018.