Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Imfinzi (durvalumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Imfinzi (durvalumab)

APPROVAL CRITERIA

Requests for Imfinzi (durvalumab) may be approved if the following criteria are met:

I. Individual has diagnosis of Non-Small Cell Lung Cancer (NSCLC); **AND**
   A. Disease is confirmed (histologically or cytologically) stage III locally advanced, unresectable NSCLC; **AND**
   B. Disease has not progressed after definitive chemoradiation; **AND**
   C. Individual is using as consolidation therapy; **AND**
   D. Imfinzi (durvalumab) is being used until disease progression or a maximum of 12 months of treatment (NCCN 2A); **AND**
   E. Individual has not previously received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   F. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2; **AND**
   G. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

II. Individual has a diagnosis of locally advanced or metastatic Urothelial Cancer; **AND**
   A. Disease is confirmed (histologically or cytologically) to be inoperable or metastatic transitional-cell urothelial carcinoma; **AND**
   B. Individual has *one* of the following:
      1. Disease has progressed during or following platinum-containing therapy; **OR**
      2. Disease has progressed within 12 months of neoadjuvant or adjuvant treatment with platinum-containing therapy;

   AND
   C. Individual has a current ECOG performance status of 0-2; **AND**
   D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

III. Individual has a diagnosis of extensive stage Small Cell Lung Cancer (NCCN 1); **AND**
   A. Individual is using as first line therapy in combination with etoposide and either cisplatin or carboplatin for four (4) cycles (followed by maintenance Imfinzi monotherapy); **AND**
   B. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Requests for Imfinzi (durvalumab) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 3, 2020.
   a. Bladder Cancer. V1.2020. Revised November 27, 2019.
   b. Non-Small Cell Lung Cancer. V2.2020. Revised December 23, 2019.
   c. Small Cell Lung Cancer. V2.2020. Revised November 15, 2019.