I. Policy:
Imfinzi (durvalumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Imfinzi (durvalumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member.  When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age
DESCRIPTION:
Imfinzi (durvalumab) is a human immunoglobulin G1 kappa (IgG1ƙ) monoclonal antibody. IgG1ƙ blocks the interaction between PD-L1 and PD-1/CD80, which stops the inhibition immune responses without inducing antibody dependent cell-mediated cytotoxicity. PD-L1 blockade with durvalumab increased T-cell activation in vitro and decreased tumor size in mouse models.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Imfinzi (durvalumab) will be considered medically necessary when ALL of the following criteria are met:

1. Urothelial Carcinoma
   - Prescription written by a hematologist/oncologist AND
   - Medical record documentation that patient is ≥ 18 years of age AND
   - Medical record documentation of a diagnosis of locally advanced or metastatic urothelial carcinoma AND one of the following:
     - Disease progression during or following platinum-containing chemotherapy OR
     - Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

   AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

2. Non-Small Cell Lung Cancer (NSCLC)
   - Prescription written by a hematologist/oncologist AND
   - Medical record documentation that patient is 18 years of age or older AND
   - Medical record documentation of a diagnosis of unresectable Stage III Non-Small Cell Lung Cancer (NSCLC) AND
   - Medical record documentation that patient has received and has not progressed following a minimum of two cycles of concurrent platinum-based chemotherapy AND radiation therapy

   AUTHORIZATION DURATION (NSCLC): Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval will be for an additional 6 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

   Authorization of Imfinzi for the treatment of non-small cell lung cancer should not exceed the FDA-approved treatment duration of 1 year (12 months). For requests exceeding the above limit, medical record documentation of the following is required:
   - Peer-reviewed literature citing well-designed clinical trials to indicate that the member’s healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/18/17

Revised: 5/15/18 (NSCLC)

Reviewed: 4/22/19, 1/1/20