Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 156.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Imfinzi (durvalumab)

Applicable line of business:

Commercial	X	Medicaid	X
Medicare	X	ACA	X
CHIP	X		

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
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. 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 (IgG1κ) monoclonal antibody. IgG1κ 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 for all lines of business when ALL of the following criteria are met:

1. Neoadjuvant/Adjuvant Non-Small Cell Lung Cancer (NSCLC)
- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation that Imfinzi is being used in the neoadjuvant setting in combination with platinum containing chemotherapy then continued as a single agent in the adjuvant setting following surgery **AND**
- Medical record documentation of no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements.

AUTHORIZATION DURATION (Neoadjuvant/Adjuvant NSCLC): One approval for 18 months or less if the reviewing provider feels it is medically appropriate. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Authorization of Imfinzi for the neoadjuvant/adjuvant treatment of NSCLC should not exceed the FDA-approved treatment duration of 4 cycles of neoadjuvant treatment prior to surgery and 12 cycles of adjuvant treatment following surgery. 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.

2. Stage III 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 (Stage III NSCLC): One approval for 12 months or less if the reviewing provider feels it is medically appropriate. 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

3. Metastatic 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 metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations **AND**
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo) **AND** platinum-based chemotherapy

AUTHORIZATION DURATION (Metastatic NSCLC): 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.

4. Extensive-Stage Small Cell Lung Cancer (ES-SCLC)

- 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 extensive-stage small cell lung cancer (ES-SCLC)* **AND**
- Medical record documentation that Imfinzi will be used as first-line treatment **AND**
- Medical record documentation that Imfinzi will be used in combination with etoposide and either carboplatin or cisplatin

*Note: The National Comprehensive Cancer Network (NCCN) Guidelines defines small cell lung cancer as consisting of two stages:
Limited Stage: Stage I-III (T any, N any, M0) that can be safely treated with definitive radiation doses. Excludes T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.
Extensive Stage: Stage IV (T any, N any, M1a/b), or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan

AUTHORIZATION DURATION (ES-SCLC): 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.

5. Limited Stage Small Cell Lung Cancer (LS-SCLC)

- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of limited-stage small cell lung cancer (LS-SCLC) that has not progressed following concurrent platinum-based chemotherapy and radiation therapy **AND**
- Medical record documentation that Imfinzi will be used as a single-agent

AUTHORIZATION DURATION (LS-SCLC): One approval for 12 months or less if the reviewing provider feels it is medically appropriate. One subsequent approval 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.

Authorization of Imfinzi for the treatment of limited-stage small cell lung cancer should not exceed the FDA-approved treatment duration of 2 years (24 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

6. Unresectable Hepatocellular Carcinoma (uHCC)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of unresectable hepatocellular carcinoma (uHCC) **AND**
- Medical record documentation that Imfinzi will be used in combination with tremelimumab-actl (Imjudo)

AUTHORIZATION DURATION (uHCC): 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.

5. Biliary Tract Cancer (BTC)

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imfinzi is prescribed by a hematologist or oncologist **AND**
- Medical record documentation of locally advanced or metastatic biliary tract cancer (BTC) **AND**
- Medical record documentation that Imfinzi will be used in combination with gemcitabine and cisplatin

AUTHORIZATION DURATION (BTC): 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.

7. dMMR Endometrial Cancer

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation that Imfinzi is prescribed by an oncologist or hematologist **AND**
- Medical record documentation of a diagnosis of primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR) **AND**
- Medical record documentation that Imfinzi will be used in combination with carboplatin and paclitaxel for 6 cycles, followed by continuation of Imfinzi as a single agent

AUTHORIZATION DURATION (dMMR Endometrial Cancer): 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.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

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.

REFERENCES:

1. Imfinzi [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2024.

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

Devised: 7/18/17

Revised: 5/15/18 (NSCLC), 5/19/20 (ES-SCLC), 5/18/21 (urothelial removal), 1/17/23 (Medicaid business segment, LOB carve out, Stage III NSCLC auth duration, mNSCLC, uHCC, BTC), 12/30/23 (references added), 10/18/24 (endometrial [from 8/2024 P&T], neoadjuvant/adjuvant NSCLC, LOB table, taglines), 2/19/25 (LS-SCLC)

Reviewed: 4/22/19, 1/1/20, 5/2/22 (Medicaid PARP statement), 1/9/24

MA UM Committee approval: 12/31/23, 12/31/24