OVERVIEW

Imfinzi is a human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that binds to programmed cell
death ligand-1 (PD-L1). By binding, it blocks the interaction of PD-L1 with PD-1 and CD80, thereby
releasing the inhibition of immune responses without inducing antibody dependent cell-mediated
cytotoxicity.

Imfinzi is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who
have a) disease progression during or following platinum-containing chemotherapy; or b) have disease
progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
Imfinzi is also indicated for the treatment of patients with unresectable Stage III non-small cell lung cancer
(NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation
therapy.

The recommended dose of Imfinzi is 10 mg/kg administered as an intravenous infusion over 60 minutes every
2 weeks, until disease progression or unacceptable toxicity, for both indications. For NSCLC, the dosing is
limited to a maximum of 12 months. Management of AEs may require that Imfinzi be withheld or
discontinued, as determined by the prescribing physician. No dose reductions are recommended.

Imfinzi is available as 120 mg/2.4 mL (50 mg/mL) and 500 mg/10 mL (50 mg/mL) clear to opalescent
solution in a single-dose vial.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on bladder cancer (version 3.2019 – April
23, 2019) recommends Imfinzi as one of the options for subsequent therapy (category 2A), as an alternative
preferred regimen for the treatment of locally advanced or metastatic urothelial carcinoma after progression
on platinum-based chemotherapy or disease that has progressed within 12 months of neoadjuvant or adjuvant
platinum-containing chemotherapy.2 Imfinzi can be used regardless of PD-L1 expression levels. The NCCN
Compendium3 recommends Imfinzi for urothelial carcinoma of the bladder for clinical stage T4b or T2-4a,
N1-3 disease, or for recurrence post cystectomy, or for metastatic disease, as a single agent for subsequent
systemic therapy post-platinum (alternative preferred regimen). It is also recommended as subsequent
systemic, post-platinum therapy for upper genitourinary tract tumors (metastatic disease); urothelial
carcinoma of the prostate (metastatic disease); and for primary carcinoma of the urethra (recurrent or
metastatic disease).

The NCCN guidelines on NSCLC (version 4.2019 – April 29, 2019) recommends Imfinzi (category 1) as
consolidation therapy for patients with unresectable Stage III disease with a performance status of 0 or 1.4
Imfinzi can be used regardless of the PD-L1 status in patients who have not progressed after two or more
cycles of definitive concurrent platinum-based chemoradiation therapy.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Imfinzi. Approval is recommended for
those who meet the conditions of coverage in the Criteria and Dosing for the listed indication(s). Extended
approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Imfinzi, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Imfinzi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**RECOMMENDED AUTHORIZATION CRITERIA**
Coverage of Imfinzi is recommended in those who meet one of the following criteria:

**FDA-Approved Indications**

1. **Non-Small Cell Lung Cancer (NSCLC).** Approve for 1 year (total) of therapy if the patient meets the following criteria (A, B, and C):
   A) Imfinzi is prescribed by or in consultation with an oncologist; AND
   B) Patient has unresectable Stage III NSCLC; AND
   C) Patient has not had disease progression following treatment with concurrent platinum-based chemotherapy and radiation therapy.

   **Dosing.** Approve up to 10 mg/kg administered as an intravenous infusion once every 2 weeks.1

2. **Urothelial Carcinoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) Imfinzi is prescribed by or in consultation with an oncologist; AND
   B) Patient has locally advanced or metastatic urothelial carcinoma; AND
   C) Patient has tried platinum-containing chemotherapy (cisplatin or carboplatin).

   **Dosing.** Approve up to 10 mg/kg administered as an intravenous infusion once every 2 weeks.1

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

1. **Other Indications (Non-Cancer).** Coverage is not recommended for circumstances not listed in the Authorization Criteria (FDA-approved indications and Other Uses with Supportive Evidence). Criteria will be updated as new published data are available.
REFERENCES
1. Imfinzi® injection for intravenous use [prescribing information]. Wilmington, DE: AstraZeneca; February 2018.

HISTORY

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes*</th>
<th>Approval Date</th>
</tr>
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<tbody>
<tr>
<td>New policy</td>
<td>Deleted “Initial/Extended Approval,” “Duration of Therapy,” “Labs/Diagnositics,” “Patient has been started on Imfinzi,” “Other Cancer Indications,” and “Waste Management for All Indications”.</td>
<td>05/23/2018</td>
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<tr>
<td>Annual revision</td>
<td>Deleted criteria “Imfinzi will be used as a single agent.” Added “Approval duration to criteria added for “up to 1 year (total).” In Dosing section, deleted “As a single agent, the recommended dose is” and the infusion time of 60 minutes. Specified “Approve up to” 10 mg/kg “once” every 2 weeks.</td>
<td>06/18/2019</td>
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<td></td>
<td>Non-Small Cell Lung Cancer: Deleted criteria “Imfinzi will be used as a single agent.” Added “Approval for up to 1 year.” In Dosing section, deleted “As a single agent, the recommended dose is” and deleted infusion time of 60 minutes. Specified “Approve up to” 10 mg/kg “once” every 2 weeks. Re-worded to state patient “has tried” platinum-containing chemotherapy; previously it stated patient “has disease progression during or after trying” chemotherapy.</td>
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