Clinical Policy: Durvalumab (Imfinzi)
Reference Number: CP.PHAR.339
Effective Date: 07.01.17
Last Review Date: 05.19
Line of Business: Medicaid, HIM-Medical Benefit

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Durvalumab (Imfinzi®) is a programmed death-ligand 1 (PD-L1) blocking antibody.

FDA Approved Indication(s)
Imfinzi is indicated for the treatment of patients with:
- Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
  - This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.
- Unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Imfinzi is medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Urothelial Carcinoma (must meet all):
   1. Diagnosis of locally advanced or metastatic (Stage IV) urothelial carcinoma;
   2. Prescribed by or in consultation with an oncologist;
   3. Failure of or disease progression on platinum-containing chemotherapy;
   4. Request meets one of the following (a or b):
      a. Dose does not exceed 10 mg/kg every 2 weeks;
      b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   Approval duration: 6 months
B. Non-Small Cell Lung Cancer (must meet all):
   1. Diagnosis of unresectable (Stage III) NSCLC;
   2. Prescribed by or in consultation with an oncologist;
   3. Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (RT);
   5. Request meets one of the following (a or b):
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Durvalumab

a. Dose does not exceed 10 mg/kg every 2 weeks;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 6 months

C. Other diagnoses/indications:
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy
A. All Indications in Section I (must meet all):
1. Currently receiving medication via Centene benefit, or member has previously met initial approval criteria, or documentation supports that member is currently receiving Imfinzi for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 10 mg/kg every 2 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration:
NSCLC: up to a total duration of 12 months
All other indications: 12 months

B. Other diagnoses/indications:
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NSCLC: non-small cell lung cancer
RT: radiotherapy
Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urothelial Carcinoma (examples of platinum-containing regimens)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DDMVAC (dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>gemcitabine with either cisplatin or carboplatin</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>CMV (cisplatin, methotrexate, and vinblastine)</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>NSCLC (examples of concurrent platinum-containing/radiotherapy regimens)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>cisplatin, etoposide, RT</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>carboplatin, pemetrexed, RT</td>
<td>Varies</td>
<td>Varies</td>
</tr>
<tr>
<td>paclitaxel, carboplatin, RT</td>
<td>Varies</td>
<td>Varies</td>
</tr>
</tbody>
</table>

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urothelial carcinoma NSCLC</td>
<td>10 mg/kg IV infusion over 60 minutes every 2 weeks</td>
<td>10 mg/kg per 2 weeks</td>
</tr>
</tbody>
</table>

VI. Product Availability

Single-dose vials: 120 mg/2.4 mL, 500 mg/10 mL

VII. References


Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.
**CLINICAL POLICY**

**Durvalumab**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>J9999</td>
<td>Injection, not otherwise classified, antineoplastic drugs</td>
</tr>
<tr>
<td>C9492</td>
<td>Injection, durvalumab, 10 mg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P &amp; T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>06.17</td>
<td>07.17</td>
</tr>
<tr>
<td>2Q 2018 annual review: added new FDA indication for NSCLC with total duration of therapy of 12 months only per trial design and NCCN guideline; HIM added; references reviewed and updated.</td>
<td>04.24.18</td>
<td>05.18</td>
</tr>
<tr>
<td>2Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>12.19.19</td>
<td>05.19</td>
</tr>
</tbody>
</table>

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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