Generic Name: Durvalumab

Therapeutic Class or Brand Name: Imfinzi™

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/18/2017

Date Last Reviewed / Revised: 10/16/2023

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:
   A. Non-small cell lung cancer (NSCLC) and criteria 1 OR 2 are met:
      1. Unresectable Stage III NSCLC
         a) Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (RT).
      2. Metastatic NSCLC
         a) Patient has no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
         b) Imfinzi (durvalumab) is used in combination with tremelimumab-actl and platinum-based chemotherapy.
   B. Extensive-stage small cell lung cancer (ES-SCLC):
      1. Imfinzi (durvalumab) is used as first-line treatment in combination with etoposide and either carboplatin or cisplatin.
   C. Locally advanced or metastatic biliary tract cancer (BTC):
      1. Imfinzi (durvalumab) is used in combination with gemcitabine and cisplatin.
   D. Unresectable hepatocellular carcinoma (uHCC):
      1. Imfinzi (durvalumab) is used in combination with tremelimumab-actl.

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to the preferred product(s).

Exclusion Criteria

- Prior treatment with a programmed death receptor-1 (PD-1)-blocking antibody or a programmed death-ligand 1 (PD-L1) blocking antibody (i.e. Bavencio®, Imfinzi™, Jemperli®, Keytruda®, Libtayo®, Opdivo®, Opdualag®, Tecentriq®, or Zynyz®).

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Unresectable, Stage III non-small cell lung cancer (NSCLC):
  - ≥ 30 kg: 10 mg/kg every 2 weeks or 1,500 mg every 4 weeks
  - < 30 kg: 10 mg/kg every 2 weeks
- Metastatic NSCLC:
  - ≥ 30 kg: 1,500 mg every 3 weeks in combination with tremelimumab-actl 75 mg and platinum-based chemotherapy for 4 cycles, and then administer Imfinzi® 1,500 mg every 4 weeks as a single agent with histology-based pemetrexed maintenance therapy every 4 weeks, and a fifth dose of tremelimumab-actl 75 mg in combination with Imfinzi® dose 6 at week 16
  - < 30 kg: 20 mg/kg every 3 weeks in combination with tremelimumab-actl 1 mg/kg and platinum-based chemotherapy, and then administer Imfinzi® 20 mg/kg every 4 weeks as a single agent with histology-based pemetrexed therapy every 4 weeks, and a fifth dose of tremelimumab-actl 1 mg/kg in combination with Imfimzi® dose 6 at week 16
- Extensive-stage small cell lung cancer (ES-SCLC): With etoposide and either carboplatin or cisplatin.
  - ≥ 30 kg: 1,500mg every 3 weeks in combination with chemotherapy for 4 cycles, followed by 1500mg every 4 weeks as a single agent
  - < 30 kg: 20 mg/kg in combination with chemotherapy every 3 weeks for 4 cycles, followed by 10 mg/kg every 2 weeks as a single agent
- Locally advanced or metastatic biliary tract cancer (BTC): With gemcitabine and cisplatin.
  - ≥ 30 kg: 1,500 mg in combination with chemotherapy every 3 weeks up to 8 cycles followed by 1,500 mg every 4 weeks as a single agent
  - < 30 kg: 20 mg/kg in combination with chemotherapy every 3 weeks up to 8 cycles followed by 20 mg/kg every 4 weeks as a single agent
- Unresectable hepatocellular carcinoma (uHCC):
  - ≥ 30 kg: 1,500 mg following a single dose of tremelimumab-actl at Day 1 of Cycle 1; followed by 1,500 mg as a single agent every 4 weeks

- < 30 kg: 20 mg/kg following a single dose of tremelimumab-actl at Day 1 of Cycle 1; followed by 20 mg/kg as a single agent every 4 weeks

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.
  - Unresectable stage III NSCLC: The patient may receive a maximum of 12 months treatment.

Appendix

N/A

References

1. Imfinzi. Prescribing information. AstraZeneca Pharmaceuticals LP; 2023. Accessed October 7, 2023. https://www.azpicentral.com/imfinzi/imfinzi.pdf#page=1.
2. NCCN Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer V.3.2023. Updated April 13, 2023. Accessed September 10, 2023. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.
3. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer V.1.2024. Updated September 5, 2023. Accessed October 1, 2023. https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.
4. NCCN Clinical Practice Guidelines in Oncology. Biliary Tract Cancers V.2.2023. Updated May 10, 2023. Accessed September 4,2023. https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf.
5. NCCN Clinical Practice Guidelines in Oncology. Hepatocellular Carcinoma V.2.2023. Updated September 14, 2023. Accessed September 20, 2023. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.