Generic Name: Durvalumab

Therapeutic Class or Brand Name: Imfinzi™

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 5/18/2017

Date Last Reviewed / Revised: 4/24/2025

PRIOR AUTHORIZATION CRITERIA

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

I. Documentation of one of the following diagnoses A through M and must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Non-small cell lung cancer (NSCLC) and criteria 1, 2, or 3 are met:

1. Unresectable Stage III NSCLC

a) Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy (RT).

b) Imfinzi (durvalumab) is used as single-agent therapy.

2. Metastatic NSCLC

a) Documentation that the patient has no sensitizing epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) genomic tumor aberrations and criteria 1 or 2 is met:

(1) First-line therapy

(a) Imfinzi (durvalumab) is used in combination with Imjudo(tremelimumab-actl) and platinum-based chemotherapy i, ii, or iii:

(i) Albumin-bound paclitaxel and carboplatin

(ii) Pemetrexed and either carboplatin or cisplatin for non-squamous cell histology

(iii) Gemcitabine and either carboplatin or cisplatin for squamous cell histology

(2) Continuation maintenance therapy and criteria a or b is met:

(a) Imfinzi (durvalumab) is used as a single agent in patients who achieved tumor response or stable disease following first-line therapy with Imfinzi (durvalumab), Imjudo (tremelimumab-actl) plus chemotherapy.

(b) Imfinzi (durvalumab) is used in combination with pemetrexed in patients who achieved a response or stable disease following initial systemic therapy with Imfinzi (durvalumab), Imjudo (tremelimumab-actl),

pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology.

3. Resectable NSCLC
    a) Tumors ≥ 4 cm and/or node-positive
    b) Patient has no sensitizing EGFR mutations or ALK genomic tumor aberrations.
    c) Imfinzi (durvalumab) is used in combination with platinum-containing chemotherapy as neoadjuvant treatment, followed by use as a single agent as adjuvant treatment after surgery.

B. Small cell lung cancer (ES-SCLC) and criteria 1 or 2 is met:
    1. Documentation of extensive-stage SCLC (ES-SCLC).
        a) Imfinzi (durvalumab) is used as first-line treatment in combination with etoposide and either carboplatin or cisplatin, followed by use as single-agent maintenance therapy.
    2. Documentation of limited-stage SCLC (LS-SCLC)
        a) Imfinzi (durvalumab) is used as a single agent for LS-SCLC that has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

C. Biliary tract cancer (gallbladder cancer, intrahepatic or extrahepatic cholangiocarcinoma)
    1. Imfinzi (durvalumab) is used as primary treatment in combination with gemcitabine and cisplatin, and criteria a or b is met:
        a) Documentation of locally advanced, unresectable, resected gross residual (R2) disease or metastatic disease
        b) Documentation of recurrent disease > 6 months after surgery with curative intent and > 6 months after completion of adjuvant therapy

D. Hepatocellular carcinoma (uHCC):
    1. Imfinzi (durvalumab) is used as first-line therapy in combination with Imjudo (tremelimumab-actl) at cycle 1, continued as a single agent.
    2. Documentation disease is unresectable, and patient is deemed ineligible for transplant.

E. Endometrial cancer
    1. Documentation of primary advanced or recurrent disease
    2. Tumor is mismatch repair deficient (dMMR).
    3. Imfinzi (durvalumab) is used in combination with carboplatin and paclitaxel, followed by use as a single agent.

F. Muscle invasive bladder cancer (MIBC)
    1. Imfinzi (durvalumab) is used as neo-adjuvant therapy in combination with gemcitabine and cisplatin, followed by single-agent Imfinzi (durvalumab) after radical cystectomy.

Other Uses With Supportive Evidence

G. NSCLC

H. Biliary tract cancer (gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma)

I. Unresectable hepatocellular carcinoma (uHCC)

J. Ampullary adenocarcinoma

K. Cervical cancer

L. Esophageal cancer and esophagogastric junction cancers

M. Gastric cancer

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
    - Maximum treatment duration: 12 months
- Metastatic NSCLC
    - ≥ 30 kg: 1,500 mg every 3 weeks in combination with Imjudo (tremelimumab-actl) 75 mg and platinum-based chemotherapy for 4 cycles, 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 Imfinzi dose 6 at week 16

- Resectable NSCLC
  - ≥ 30 kg:
    - Neoadjuvant: 1,500 mg in combination with chemotherapy every 3 weeks for up to 4 cycles prior to surgery
    - Adjuvant: 1,500 mg as a single agent every 4 weeks for up to 12 cycles after surgery
  - < 30 kg
    - Neoadjuvant: 20 mg/kg every 3 weeks in combination with chemotherapy for up to 4 cycles prior to surgery
    - Adjuvant: 20 mg/kg every 4 weeks as a single agent for up to 12 cycles after surgery
- Extensive-stage small cell lung cancer (ES-SCLC)
  - ≥ 30 kg: 1,500mg every 3 weeks in combination with etoposide and either carboplatin or cisplatin for 4 cycles, followed by 1500mg every 4 weeks as a single agent
  - < 30 kg: 20 mg/kg in combination with etoposide and either carboplatin or cisplatin every 3 weeks for 4 cycles, followed by 10 mg/kg every 2 weeks as a single agent
- Limited-stage small cell lung cancer (LS-SCLC)
  - ≥ 30 kg: 1,500 mg every 4 weeks
  - < 30 kg: 20 mg/kg every 4 weeks
  - Maximum treatment duration: 24 months
- Biliary tract cancer (gallbladder cancer, intrahepatic or extrahepatic cholangiocarcinoma)
  - ≥ 30 kg: 1,500 mg in combination with gemcitabine and cisplatin 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 gemcitabine and cisplatin 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 Imjudo (tremelimumab-actl) on Day 1 of Cycle 1, followed by 1,500 mg as a single agent every 28 days

- < 30 kg: 20 mg/kg following a single dose of Imjudo (tremelimumab-actl) on Day 1 of Cycle 1, followed by 20 mg/kg as a single agent every 28 days

- Mismatch repair deficient endometrial cancer:
  - ≥ 30 kg: 1,120 mg in combination with carboplatin and paclitaxel every 3 weeks for 6 cycles, followed by 1,500 mg every 4 weeks as a single agent
  - < 30 kg: 15 mg/kg in combination with carboplatin and paclitaxel every 3 weeks for 6 cycles, followed by 20 mg/kg every 4 weeks as a single agent
- Muscle invasive bladder cancer (MIBC)
  - ≥ 30 kg
    - Neoadjuvant: 1,500 mg in combination with gemcitabine and cisplatin every 3 weeks for 4 cycles prior to surgery
    - Adjuvant: 1,500 mg every 4 weeks as a single agent for up to 8 cycles after surgery
  - > 30 kg
    - Neoadjuvant: 20 mg/kg in combination with gemcitabine and cisplatin every 3 weeks for 4 cycles prior to surgery
    - Adjuvant: 20 mg/kg every 4 weeks as a single agent for up to 8 cycles after surgery

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization**: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

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