Durvalumab (Imfinzi®)

Prior Authorization Drug Coverage Policy

Effective Date: 3/1/2021
Revision Date: n/a
Review Date: 9/30/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of durvalumab. Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Durvalumab is a human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody that binds to PD-L1 and blocks the interaction of PD-L1 with PD-1 and CD80 (B7.1). Blockade of PD-L1/PD-1 and PDL1/CD80 interactions releases the inhibition of immune responses, without inducing antibody dependent cell-mediated cytotoxicity (ADCC).

FDA Indications[1]

Durvalumab is FDA indicated for the following:

- 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.
- Treatment of patients with extensive-stage small cell lung cancer (ES-SCLC) as first-line in combination with etoposide and either carboplatin or cisplatin.

NCCN Compendium Supported Indications[2]

- Stage II non-small cell lung cancer (NSCLC)

Coverage Determinations[1,2]

Durvalumab will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Non-Small Cell Lung Cancer (NSCLC)

- The member has a diagnosis of unresectable, Stage II **OR** Stage III NSCLC **AND**
- The member completed at least two cycles of platinum-based chemotherapy with concurrent radiation therapy without disease progression as documented by imaging performed after the completion of chemoradiotherapy **AND**
- The member will be using durvalumab as monotherapy

Recommended dosage: 10 mg/kg IV every 2 weeks or 1500 mg IV every 4 weeks

Small Cell Lung Cancer (SCLC)

- The member has a diagnosis of extensive stage SCLC **AND**
- The member is receiving durvalumab as initial treatment in combination with etoposide and either cisplatin or carboplatin, followed by single agent durvalumab maintenance therapy if no disease progression **AND**

Recommended dosage: 1500 mg IV every 3 weeks in combination with chemotherapy, followed by 1500 mg IV every 4-week maintenance

All indications:

- Durvalumab will be approved through clinical review for up to a 6-month duration

Coverage Limitations

Treatment with durvalumab is not considered medically necessary for members with the following concomitant conditions:

- The member has experienced disease progression on durvalumab
- Has received prior therapy with an anti-Programmed Cell Death Receptor 1 (PD-1), anti-Programmed Cell Death Receptor Ligand 1 (PD-L1) or anti-Programmed Cell Death Receptor Ligand 2 (PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (e.g., cytotoxic T-lymphocyte-associated protein 4 (CTLA-4), OX-40, CD137)
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:

- Immune-Mediated Pneumonitis
- Immune-Mediated Hepatitis
- Immune-Mediated Colitis
- Immune-Mediated Endocrinopathies
- Immune-Mediated Nephritis
- Immune-Mediated Dermatologic Reactions
- Infection
- Infusion-Related Reactions
- Embryo-Fetal Toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: Inj., durvalumab 10 mg
- HCPCS codes: J9173

Disclaimer

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from Oncology Analytics, Inc.

References

1. Imfinzi [package insert]. AstraZeneca Pharmaceuticals LP. Wilmington, DE. Available at: http://www.azpicentral.com/pi.html?product=imfinzi&country=us&popup=no
2. Durvalumab. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
3. Massard C, Gordon MS, Sharma S, et al. Safety and Efficacy of Durvalumab (MEDI4736), an Anti–Programmed Cell Death Ligand-1 Immune Checkpoint Inhibitor, in Patients With Advanced Urothelial Bladder Cancer. J Clin Oncol. 2016 Sep 10; 34(26): 3119–3125.
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6. Gray JE, Villegas AE, Daniel DB, et al. Three-year overall survival update from the PACIFIC trial. J Clin Oncol. 2019;37(suppl; abstr 8526). doi: 10.1200/JCO.2019.37.15_suppl.8526. Available at: https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.15_suppl.8526
7. Paz Ares L, Dvorkin M, Chen Y, et al. Durvalumab plus platinum–etoposide versus platinum–etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomised, controlled, open-label, phase 3 trial. Lancet. 2019 Nov 23;394(10212):1929-1939.