Wellmark Advantage Health Plan

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Effective Date: 06/09/2022

Imfinzi® (durvalumab)

HCPCS: J9173

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria
   a. A diagnosis of unresectable stage III non-small cell lung cancer
      i. Prescribed by or in consultation with an oncologist
      ii. FDA approved age
      iii. Have no disease progression following concurrent platinum-based chemotherapy and radiation therapy
      iv. Use as monotherapy
      v. Should not be used if treatment failure has occurred with another PD-L1 inhibitor
      vi. ECOG performance status of 0 – 2
   b. A diagnosis of small cell lung cancer
      i. Prescribed by or in consultation with an oncologist
      ii. FDA approved age
      iii. Must be extensive stage or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan
      iv. Must be used as a first-line agent in combination with etoposide and either carboplatin or cisplatin
      v. ECOG performance status of 0 - 2
   c. Patient is not receiving therapy for a chronic condition, such as autoimmune disease, that requires treatment with a systemic immunosuppressant

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Initial Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for up to 6 months at a time6 months
   c. Renewal Criteria:
      i. Unresectable stage III non-small cell lung cancer: Treatment may be continued until disease progression or until unacceptable toxicity occurs, up to maximum of 12 months
      ii. Extensive stage small cell lung cancer: Treatment may be continued until disease progression or until unacceptable toxicity occurs.

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information

- Imfinzi is indicated for
    - The treatment of adult patients with unresectable stage III non-small cell lung cancer (NSCLC) who's disease has not progressed following concurrent platinum-based chemotherapy and radiation
    - In combination with etoposide and either carboplatin or cisplatin, as first-line treatment of adult patients with extensive stage small cell lung cancer (SCLC)
- Efficacy and safety for Imfinzi in non-small cell lung cancer was determined in the PACIFIC trial, a randomized, double-blind, placebo-controlled phase III study of 713 patients with unresectable stage III NSCLC who completed at least 2 prior cycles of concurrent platinum-based chemotherapy and radiation. Patients were randomized to Imfinzi or placebo for up to 12 months or unacceptable toxicity or progressive disease. Treatment was initiated 6 weeks following completion of chemoradiation. Patients must have had an ECOG performance status of 0 – 1 and were excluded if they required systemic immunosuppression. The primary endpoint was progression free survival which was shown to be statistically significant compared to placebo.
- Safety and efficacy for use in extensive disease small cell lung cancer was assessed in the CASPIAN trial, a phase III, randomized, active-control, open-label study of 537 patients with extensive disease small cell lung cancer. The target population included those with histologically or cytologically documented extensive disease or those with T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan. Eligible patients had an ECOG performance status of 0 – 1 and were suitable to receive platinum-based chemotherapy. Patients could not have received prior therapy and were excluded if they required systemic immunosuppression. The primary endpoint was overall survival of Imfinzi plus chemotherapy versus chemotherapy alone. The Imfinzi plus chemotherapy arm had a statistically significant overall survival rate compared to chemotherapy alone.
- Imfinzi has not been studied as combination therapy when used to treat non-small cell lung cancer.
- There are no studies to support use of a different PD-L1 when treatment failure has occurred with another. The National Comprehensive Cancer Network guidelines also do not support use of a PD-L1 inhibitor following use of one in a prior line of therapy.

References:

1. Imfinzi. [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; July 2021.
2. Express Scripts® Drug Evaluation - Imfinzi™ (durvalumab injection for intravenous use – AstraZeneca Pharmaceuticals LP). Updated July 3, 2017.
3. Antonia SJ, Villegas A, Daniel D, et al. Durvalumab after chemoradiotherapy in stage III non–small-cell lung cancer. NEJM. 2017; 377 (20): 1919 - 29.
4. National Comprehensive Cancer Network. Non-small cell lung cancer (Version 3.2022). 2022 March 16. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed on April 19, 2022.

5. AstraZeneca Media Centre. AstraZeneca reports results from the ARCTIC trial in third-line non-small cell lung cancer. 24 April 2018. Available at: https://www.astrazeneca.com/media-centre/press-releases/2018/astrazeneca-reports-results-from-the-arctic-trial-in-third-line-non-small-cell-lung-cancer-24042018.html. Accessed May 11, 2018.
6. National Comprehensive Cancer Network. Small cell lung cancer (Version 2.2022). 2021 Nov 24. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed on April 19, 2022.
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 randomized, controlled, open-label, phase 3 trial. Lancet. 2019 Nov 23; 394 (10212): 1929 – 39.

Policy History		
#	Date	Change Description
1.1	Effective Date: 06/09/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time
1.0	Effective Date: 01/01/2022	New policy

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*