OncoHealth

Imfinzi (Durvalumab)

Effective Date: 9/1/2022
Revision Date(s): n/a
Review Date: 6/14/2022
Policy type: Medical Necessity

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Initial Approval Criteria

Coverage is provided for the following conditions:

Universal Criteria Applied to All Requests

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.
- Member has no history of prior PD-1/PD-L1 use.

Indication Specific Criteria

Hepatobiliary Cancers

- Member has hepatocellular cancer; AND
    - Used as a single agent; AND
    - Used in the first-line setting; AND
    - Member has unresectable disease; AND
    - Member is not a transplant candidate; OR
        - Member has metastatic disease or extensive liver tumor burden; OR
- Member has biliary tract cancer; AND
    - Member has locally advanced, unresectable, recurrent, or metastatic disease; AND
    - Being used in combination with gemcitabine and cisplatin; AND
    - Used in the first-line setting; AND
    - In patients with recurrent disease, members should be at least 6 months post curative surgery; OR
        - Members should be at least 6 months post-completion of adjuvant therapy (chemotherapy and/or radiation)

Non-Small Cell Cancer

- Member has unresectable stage II-III disease; AND
- Being used as consolidative therapy as a single agent; AND
- Member has not had disease progression after definitive concurrent chemoradiation therapy

Small Cell Lung Cancer

- Used in the first-line setting; AND

- Member has extensive-stage disease; AND
- Used in combination with etoposide and either cisplatin or carboplatin followed by single agent maintenance therapy

Billing

Drug Name	HCPCS Code	Description
Imfinzi	J9173	Inj., durvalumab, 10 mg

References

1. Imfinzi. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/. Accessed 6/13/2022
2. Imfinzi [package insert]. AstraZeneca Pharmaceuticals LP, Wilmington, DE. Available at: https://den8dhaj6zs0e.cloudfront.net/50fd68b9-106b-4550-b5d0-12b045f8b184/9496217c-08b3-432b-ab4f-538d795820bd/9496217c-08b3-432b-ab4f-538d795820bd_viewable_rendition__v.pdf
3. Oh Do-Youn, et al. Durvalumab plus Gemcitabine and Cisplatin in Advanced Biliary Tract Cancer. NEJM Evidence June 2022.
4. Hepatobiliary Cancers: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed 6/13/22
5. Non-Small Cell Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed 6/13/22
6. Small Cell Lung Cancer: NCCN Clinical Practice Guidelines in Oncology. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf. Accessed 6/13/22

Disclaimer

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. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

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 OncoHealth, Inc.