

PD-1/PD-L1s: Bavencio (Avelumab), Imfinzi (Durvalumab), Jemperli (Dostarlimab), Keytruda (Pembrolizumab), Libtayo (Cemiplimab), Loqtorzi (Toripalimab), Opdivo (Nivolumab), Opdualag (Nivolumab and Relatimab-rmbw), Tecentriq (Atezolizumab), Tevimbra (Tislelizumab), Zynyz (Retifanlimab-dlwr)

Effective Date: 4/1/24

Revision Date(s): 11/1/23, 2/1/24, 2/23/24, 4/16/24, 4/29/24, 7/1/2024

Review Date: 7/1/24

Policy type: Medical Necessity

Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability. **Maximum total length of initial therapy with PD-1/PD-L1 Inhibitor for metastatic non-small cell lung cancer is 2 years^{1,2}.**

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.; **AND**
- Unless otherwise explicitly endorsed in the NCCN Compendia, the use of a PD-1/PD-L1 Inhibitor following disease progression on prior PD-1/PD-L1 Inhibitor therapy is considered investigational and therefore will be subject to an off-label review for medical necessity unless supported by high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Universal Approval Criteria:

Unless otherwise noted above the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.

¹[Sun L, Bleiberg B, Hwang W, et al. Association Between Duration of Immunotherapy and Overall Survival in Advanced Non-Small Cell Lung Cancer. JAMA Oncol. 2023;9\(8\):1075–1082.](#)

²[Herbst RS, Baas P, Kim DW, et al. Pembrolizumab versus docetaxel for previously treated, PD-L1 positive, advanced non-small cell lung cancer \(KEYNOTE-010\): a randomized controlled trial. The Lancet. 2016;387\(10027\):1540-1550.](#)

- NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
- Clinical Pharmacology (Strong For)
- American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
- Thompson Micromedex DrugDex® (Class I and IIa)
- Wolters Kluwer Lexi-Drugs® (Level A)
- Other use of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
 - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
 - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Bavencio	J9023	Inj., avelumab, 10 mg
Imfinzi	J9173	Inj., durvalumab, 10 mg
Jemperli	J9272	Inj., dostarlimab-gxly, 10 mg
Keytruda	J9271	Inj., pembrolizumab, 1 mg
Libtayo	J9119	Inj., cemiplimab, 1 mg
Loqtorzi	J3263	Inj., toripalimab-tpzi, 1 mg
Opdivo	J9299	Inj., nivolumab, 1mg
Opdualag	J9298	Inj., nivolumab and relatlimab-rmbw, 3 mg/1 mg
Tecentriq	J9022	Inj., atezolizumab, 10mg
Zynyz	J9345	Injection, retifanlimab-dlwr, 1 mg
Tevimbra	J9999	Not otherwise classified, antineoplastic drugs

References

1. Bavencio. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
2. Bavencio [package insert]. EMD Serono, Inc., Rockland, MA. Available at: <https://www.bavencio.com/content/dam/web/health-care/biopharma/web/Bavencio/us/redesign/hcp/bavencio-hcp-home/bavencio-pi.pdf>
3. Imfinzi. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/

4. 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
5. Jemperli. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
6. Jemperli [package insert]. GlaxoSmithKline LLC, Philadelphia, PA. Available at: https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Jemperli/pdf/JEMPERLI-PI-MG.PDF
7. Keytruda. NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
8. Keytruda [package insert]. Merck & Co, Inc. Whitehouse Station, NJ. Available at: https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf
9. Libtayo. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
10. Libtayo [package insert]. Regeneron Pharmaceuticals, Inc., Tarrytown, NY. Available at: https://www.regeneron.com/downloads/libtayo_fpi.pdf
11. Loqtorzi [package insert]. Coherus BioSciences, Inc. Redwood City, CA. Available at : <https://loqtorzihcp.com/pdf/prescribing-information.pdf>
12. Opdivo. NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
13. Opdivo [package insert]. Bristol-Myers Squibb Company. Princeton, NJ. Available at: https://packageinserts.bms.com/pi/pi_opdivo.pdf
14. Nivolumab and relatlimab-rmbw. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
15. Opdualag [package insert]. Bristol-Myers Squibb, Princeton, NJ. Available at: https://packageinserts.bms.com/pi/pi_opdualag.pdf
16. Tecentriq. NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
17. Tecentriq [package insert]. Genentech, Inc. South San Francisco, CA. Available at: https://www.gene.com/download/pdf/tecentriq_prescribing.pdf
18. Tevimbra. NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
19. Tevimbra [package insert]. BeiGene USA, Inc., San Mateo, CA. Available at: <https://www.beigene.com/PDF/TEVIMBRAUSPI.pdf>
20. Zynyz. NCCN Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
21. Zynyz [package insert]. Incyte Corporation. Wilmington, DE. Available at: <https://www.zynyz.com/pdf/prescribing-information.pdf>
22. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed April 29th, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

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.

For Internal Use ONLY

Date	Updates
11/1/2023	Combined individual PD-1/PD-L1 policies into a single document Added total therapy limit metastatic NSCLC
2/1/2024	Additional cite
2/23/2024	Updated Universal Criteria
4/16/2024	Updated Universal Criteria
4/29/24	Added Tevimbra
7/1/2024	Updated Loqtorzi HCPCS