

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), Tecentriq Hybreza, 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, 7/1/24, 7/30/2024, 9/4/2024, 10/2/2024

Review Date: 10/2/2024

Policy type: Medical Necessity

Line of Business: Commercial

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are 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 Approval Criteria:

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

- National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence; **OR**
- United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with all components of the product labeling; **OR**
- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be considered if determined to be medically necessary per one or more of the following compendia:
 - Clinical Pharmacology (Strong For); **OR**
 - Wolters Kluwer Lexi-Drugs® (Level A); **OR**
- Other uses of drugs and biologics may be considered medically necessary if supported as safe and effective according to peer-reviewed articles from one of the following journals:

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.](#)

- 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;
- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

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
Tevimbra	J9329	Injection, tislelizumab-jsgr, 1 mg
Zynyz	J9345	Injection, retifanlimab-dlwr, 1 mg
Tecentriq Hybreza	J9999	Not otherwise classified, antineoplastic drugs

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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
7/1/24	Updated Loqtorzi HCPCS
7/30/2024	Annual Review – Update to Universal Criteria, auth span, disclaimer
9/4/2024	Updated Tevimbra HCPCS
10/2/2024	Addition of Tecentriq Hybreza