

Tecentriq HybrezaTM (atezolizumab and hyaluronidase-tqjs) (Subcutaneous)

Document Number: IC-0769

Last Review Date: 10/03/2024

Date of Origin: 10/03/2024

Dates Reviewed: 10/2024

I. Length of Authorization ^{Δ 1}

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Adjuvant therapy in Non-Small Cell Lung Cancer (NSCLC) can be renewed up to a maximum of 12 months of therapy.*

**Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.*

Dosing Frequency	Maximum length of therapy	Maximum number of doses
3 weeks	1 year	18 doses

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Tecentriq 1,875 mg and 30,000 units/15 mL in a single-dose vial: 1 vial per 21 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 375 billable units every 21 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, tislelizumab, etc.) unless otherwise specified ^Δ (Note: Not applicable when used as switch-therapy with intravenous atezolizumab); **AND**
- Therapy will not be used concomitantly with intravenous atezolizumab; **AND**
- Patients <62 kg should use the IV formulation of Tecentriq; **AND**

Non-Small Cell Lung Cancer (NSCLC) † 1,5,6,8,11,12,17,23

- Used for metastatic disease; **AND**
 - Used as first-line therapy; **AND**
 - Used as a single agent; **AND**
 - Patients has tumors that are negative for actionable molecular markers* (EGFR or ALK genomic tumor aberrations) and PD-L1 ≥ 50% (*PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]*), as determined by an FDA-approved test or CLIA-compliant test❖; **OR**
 - Used in combination with one of the following:
 - Carboplatin, paclitaxel, and bevacizumab
 - Carboplatin and albumin-bound paclitaxel; **AND**
 - Used for non-squamous disease; **AND**
 - Patients have tumors that are negative for actionable molecular markers* (EGFR or ALK genomic tumor aberrations); **OR**
 - Used as subsequent therapy during or after platinum-containing chemotherapy; **AND**
 - Used as a single agent; **AND**
 - Patients who are positive for one of the following molecular biomarkers and received prior targeted therapy§: EGFR or ALK rearrangement,; **OR**
- Used as adjuvant therapy as a single agent; **AND**
 - Tumor expresses PD-L1 ≥1% as determined by an FDA-approved test or CLIA-compliant test❖; **AND**
 - Used following resection and previous adjuvant chemotherapy; **AND**
 - Patient has stage II to IIIA disease †;

**Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2). Complete genotyping for EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), via biopsy and/or plasma testing. If a clinically actionable marker is found, it is reasonable to start therapy based on the identified marker. Treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Small Cell Lung Cancer (SCLC) † Φ 1,6,14,18

- Patient has extensive stage disease (ES-SCLC); **AND**
- Used as first-line therapy in combination with etoposide and carboplatin

Hepatocellular Carcinoma (HCC) † Φ 1,6,15,16,21,28

- Used in combination with bevacizumab; **AND**

- Used as first-line therapy for unresectable or metastatic disease †

Cutaneous Melanoma † ‡ Φ ^{1,6,19,20,29}

- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test❖; **AND**
- Used in combination with cobimetinib and vemurafenib; **AND**
- Patient has unresectable or metastatic disease

Alveolar Soft Part Sarcoma (ASPS) † ^{1,6,26}

- Patient has unresectable or metastatic disease; **AND**
- Used as a single agent

❖ If confirmed using an FDA approved assay – <http://www.fda.gov/companiondiagnostics>

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

§ Genomic Aberration/Mutational Driver Targeted Therapies (Note: not all inclusive, refer to guidelines for appropriate use)			
EGFR exon 19 deletion or exon 21 L858R tumors	EGFR S768I, L861Q, and/or G719X mutation positive tumors	EGFR exon 20 insertion mutation positive tumors	NTRK1/2/3 gene fusion positive tumors
<ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab 	<ul style="list-style-type: none"> – Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab 	<ul style="list-style-type: none"> – Amivantamab 	<ul style="list-style-type: none"> – Larotrectinib – Entrectinib – Repotrectinib
ALK rearrangement-positive tumors	ROS1 rearrangement-positive tumors	BRAF V600E-mutation positive tumors	ERBB2 (HER2) mutation positive tumors
<ul style="list-style-type: none"> – Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib 	<ul style="list-style-type: none"> – Ceritinib – Crizotinib – Entrectinib – Lorlatinib – Repotrectinib 	<ul style="list-style-type: none"> – Dabrafenib ± trametinib – Encorafenib + binimetinib – Vemurafenib 	<ul style="list-style-type: none"> – Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine
PD-L1 tumor expression ≥ 1%	MET exon-14 skipping mutations	RET rearrangement-positive tumors	KRAS G12C mutation positive tumors
<ul style="list-style-type: none"> – Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab 	<ul style="list-style-type: none"> – Capmatinib – Crizotinib – Tepotinib 	<ul style="list-style-type: none"> – Selpercatinib – Cabozantinib – Pralsetinib 	<ul style="list-style-type: none"> – Sotorasib – Adagrasib

IV. Renewal Criteria ^{Δ 1,6}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis/renal dysfunction, rash/dermatitis [including Stevens-Johnson syndrome (SJS), drug rash with eosinophilia and systemic symptoms (DRESS), and toxic epidermal necrolysis (TEN)], myocarditis, pericarditis, vasculitis, solid organ transplant rejection, etc.), severe infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.

NSCLC (adjuvant treatment)

- Patient has not exceeded a maximum of twelve (12) months of therapy

^Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration ^{Δ 1,14,27,28}

Indication	Dose
All Indications	<p>The recommended dosage of Tecentriq Hybreza is one 15 mL injection (containing 1,875 mg of atezolizumab and 30,000 units of hyaluronidase administered subcutaneously every 3 weeks, until disease progression or unacceptable toxicity.</p> <ul style="list-style-type: none"> – When used as combination therapy, administer prior to chemotherapy when given on the same day. – For adjuvant treatment of NSCLC, duration of therapy is up to one year, unless there is disease recurrence or unacceptable toxicity – For treatment of Melanoma, prior to initiating Tecentriq Hybreza, patients should receive the following 28-day treatment cycle of cobimetinib and vemurafenib: <ul style="list-style-type: none"> ○ Days 1 to 21: cobimetinib 60 mg orally once daily in combination with 960 mg of oral vemurafenib twice daily. ○ Days 22 to 28: withhold cobimetinib and administer vemurafenib 720 mg orally twice daily.

Tecentriq Hybreza must be administered by a healthcare professional

Note:

- Tecentriq Hybreza has different recommended dosage and administration than intravenous atezolizumab products.
- Patients who are treated with IV atezolizumab can switch to SQ Tecentriq Hybreza at their next scheduled dose; or patients who are treated with Tecentriq Hybreza can switch to IV atezolizumab at their next scheduled dose.
- Tecentriq Hybreza is for subcutaneous use in the thigh only administered over approximately 7 minutes.

VI. Billing Code/Availability Information

HCPCS Code:

- J9024 – Injection, atezolizumab, 5 mg and hyaluronidase-tqjs; 1 billable unit = 5 mg (*Effective 04/01/2025*)
- J9999 – Not otherwise classified, antineoplastic drugs (*Discontinue use on 04/01/2025*)
- C9399 – Unclassified drugs or biologicals (hospital outpatient use only) (*Discontinue use on 04/01/2025*)

NDC(s):

- Tecentriq 1,875 mg and 30,000 units/15 mL in a single-dose vial: 50242-0933-xx

VII. References

1. Tecentriq Hybreza [package insert]. South San Francisco, CA; Genentech, Inc; September 2024. Accessed September 2024.
2. Ventana Product Library, Roche Pharmaceuticals. VENTANA PD-L1 [SP142] Assay. <http://www.ventana.com/ventana-pd-l1-sp142-assay-2/> and product label https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160006C.pdf. Accessed July 2023.
3. U.S. Food and Drug Administrations (FDA). Division of Drug Information. Health Alert. <http://s2027422842.t.en25.com/e/es?s=2027422842&e=88882&elqTrackId=B1F0B909CCF90C71B9C490C37BFE6647&elq=3f0714083e82421a8af346a664bedbfb&elqaid=3588&elqat=1>. Accessed May 2018.
4. Balar AV, Galsky MD, Rosenberg JE, et al. Atezolizumab as first-line therapy in cisplatin-ineligible patients with locally advanced and metastatic urothelial carcinoma: a single-arm, multicentre, phase 2 trial. *Lancet*. 2017 January 07; 389(10064): 67–76. doi:10.1016/S0140-6736(16)32455-2.
5. Socinski MA, Jotte RM, Cappuzzo F, et. al. Atezolizumab for First-Line Treatment of Metastatic Nonsquamous NSCLC. *N Engl J Med* 2018; 378:2288-2301. DOI: 10.1056/NEJMoa1716948.
6. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) atezolizumab. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the

National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.

7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Bladder Cancer. Version 4.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Non-Small Cell Lung Cancer. Version 5.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
9. Gupta S, Bellmunt J, Plimack ER, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). *J Clin Oncol*. 2022 June 1;40(16_suppl):4577.
10. Rosenberg JE, Hoffman-Censits J, Powles T, et al. Atezolizumab in patients with locally advanced and metastatic urothelial carcinoma who have progressed following treatment with platinum-based chemotherapy: a single-arm, multicentre, phase 2 trial. *Lancet*. 2016 May 7;387(10031):1909-20. doi: 10.1016/S0140-6736(16)00561-4. Epub 2016 Mar 4.
11. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab-paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol*. 2019 Jul;20(7):924-937. doi: 10.1016/S1470-2045(19)30167-6. Epub 2019 May 20.
12. Rittmeyer A, Barlesi F, Waterkamp D, et al. Atezolizumab versus docetaxel in patients with previously treated non-small-cell lung cancer (OAK): a phase 3, open-label, multicentre randomised controlled trial. *Lancet*. 2017 Jan 21;389(10066):255-265. doi: 10.1016/S0140-6736(16)32517-X. Epub 2016 Dec 13.
13. Schmid P, Adams S, Rugo HS, et al. Atezolizumab and Nab-Paclitaxel in Advanced Triple-Negative Breast Cancer. *N Engl J Med*. 2018 Nov 29;379(22):2108-2121. doi: 10.1056/NEJMoa1809615. Epub 2018 Oct 20.
14. Horn L, Mansfield AS, Szczesny A, et al. First-Line Atezolizumab plus Chemotherapy in Extensive-Stage Small-Cell Lung Cancer. *N Engl J Med*. 2018 Dec 6;379(23):2220-2229. doi: 10.1056/NEJMoa1809064. Epub 2018 Sep 25.
15. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Hepatocellular Carcinoma. Version 1.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.

16. Pishvaian MJ, Lee MS, Ryoo B, et al. Updated safety and clinical activity results from a Phase Ib study of atezolizumab + bevacizumab in hepatocellular carcinoma (HCC). ESMO 2018 Congress. Munich, Germany; 2018.
17. De Marinis F, Jassem J, Spigel DR, et al. 480TiP IMpower110: Phase III study on 1L atezolizumab (atezo) in PD-L1–selected chemotherapy (chemo)-naïve NSCLC patients (pts). *Annals of Oncology*. 2016 Dec 1;27(suppl_9).
18. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Cell Lung Cancer. Version 3.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
19. Gutzmer R, Stroyakovskiy D, Gogas H, et al. Atezolizumab, vemurafenib, and cobimetinib as first-line treatment for unresectable advanced BRAFV600 mutation-positive melanoma (IMspire150): primary analysis of the randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet*. 2020;395(10240):1835-1844. doi:10.1016/S0140-6736(20)30934-X.
20. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Melanoma: Cutaneous. Version 2.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.
21. Finn RS, Qin S, Ikeda M, et al; IMbrave150 Investigators. Atezolizumab plus Bevacizumab in Unresectable Hepatocellular Carcinoma. *N Engl J Med*. 2020 May 14;382(20):1894-1905.
22. Bellmunt, J. (2024). Treatment of metastatic urothelial cancer of the bladder and urinary tract. In Lerner SP, Shah S (Eds.), *UptoDate*. Last updated April 11, 2024. Accessed June 2024. Available from https://www.uptodate.com/contents/treatment-of-metastatic-urothelial-cancer-of-the-bladder-and-urinary-tract?search=cisplatin%20ineligible&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1.
23. Felip E, Altorki N, Zhou C, et al. Adjuvant atezolizumab after adjuvant chemotherapy in resected stage IB-IIIA non-small-cell lung cancer (IMpower010): a randomised, multicentre, open-label, phase 3 trial. *Lancet*. 2021 Oct 9;398(10308):1344-1357. doi: 10.1016/S0140-6736(21)02098-5. Epub 2021 Sep 20.
24. Raghav KPS, Overman MJ, Liu S, et al. A phase II trial of atezolizumab and bevacizumab in patients with relapsed/refractory and unresectable malignant peritoneal mesothelioma. *Journal of Clinical Oncology* 2020 38:15_suppl, 9013-9013.
25. De Santis M, Bellmunt J, Mead G, et al. Randomized phase II/III trial assessing gemcitabine/carboplatin and methotrexate/carboplatin/vinblastine in patients with advanced urothelial cancer "unfit" for cisplatin-based chemotherapy: phase II--results of EORTC study 30986. *J Clin Oncol*. 2009 Nov 20;27(33):5634-9. doi: 10.1200/JCO.2008.21.4924. Epub 2009 Sep 28.

26. Naqash AR, O'Sullivan Coyne GH, Moore N, et al. Phase II study of atezolizumab in advanced alveolar soft part sarcoma (ASPS). *Journal of Clinical Oncology* 2021 39:15_suppl, 11519-11519.
27. Raghav K, Liu S, Overman MJ, et al. Efficacy, Safety, and Biomarker Analysis of Combined PD-L1 (Atezolizumab) and VEGF (Bevacizumab) Blockade in Advanced Malignant Peritoneal Mesothelioma. *Cancer Discov.* 2021 Nov;11(11):2738-2747. doi: 10.1158/2159-8290.CD-21-0331.
28. Qin S, Chen M, Cheng AL, Kaseb AO, et al. Atezolizumab plus bevacizumab versus active surveillance in patients with resected or ablated high-risk hepatocellular carcinoma (IMbrave050): a randomised, open-label, multicentre, phase 3 trial. *Lancet.* 2023 Nov 18;402(10415):1835-1847. doi: 10.1016/S0140-6736(23)01796-8.
29. Ascierto PA, Stroyakovskiy D, Gogas H, et al. Overall survival with first-line atezolizumab in combination with vemurafenib and cobimetinib in BRAFV600 mutation-positive advanced melanoma (IMspire150): second interim analysis of a multicentre, randomised, phase 3 study. *Lancet Oncol* 2023;24:33-44.
30. Kicken, M.P., Deenen, M.J., Moes, D.J.A.R. et al. An Evidence-Based Rationale for Dose De-escalation of Subcutaneous Atezolizumab. *Targ Oncol* 19, 779–787 (2024). <https://doi.org/10.1007/s11523-024-01087-4>.
31. Morrissey KM, Marchand M, Patel H, et al. Alternative dosing regimens for atezolizumab: an example of model-informed drug development in the postmarketing setting. *Cancer Chemother Pharmacol.* 2019 Dec;84(6):1257-1267. doi: 10.1007/s00280-019-03954-8. Epub 2019 Sep 21. PMID: 31542806; PMCID: PMC6820606.
32. Liu SN, Marchand M, Liu X, et al. Extension of the Alternative Intravenous Dosing Regimens of Atezolizumab into Combination Settings through Modeling and Simulation. *The Journal of Clinical Pharmacology*, 10.1002, 62,11, (1393-1402), Nov. 2022.
33. Cody J. Peer, Keith T. Schmidt, Oluwatobi Arisa, William J. Richardson, Koosha Paydary, Daniel A. Goldstein, James L. Gulley, William D. Figg, Mark J. Ratain, In Silico Re-Optimization of Atezolizumab Dosing Using Population Pharmacokinetic Simulation and Exposure–Response Simulation, *The Journal of Clinical Pharmacology*, 10.1002/jcph.2203, 63, 6, (672-680), (2023).
34. Wesevich A, Goldstein DA, Paydary K, et al. Interventional pharmacoeconomics for immune checkpoint inhibitors through alternative dosing strategies. *British Journal of Cancer.* 2023 Oct;129(9):1389-1396. DOI: 10.1038/s41416-023-02367-y. PMID: 37542109; PMCID: PMC10628132.
35. Maritaz, C., Broutin, S., Chaput, N. et al. Immune checkpoint-targeted antibodies: a room for dose and schedule optimization?. *J Hematol Oncol* 15, 6 (2022). <https://doi.org/10.1186/s13045-021-01182-3>

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.0	Liver cell carcinoma

ICD-10	ICD-10 Description
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C33	Malignant neoplasm of trachea
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk

ICD-10	ICD-10 Description
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C7A.1	Malignant poorly differentiated neuroendocrine tumors
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC