Ixempra® (ixabepilone)
(Intravenous)

-E-

Document Number: OHSU HEALTHSERVICES-0472

Date Reviewed: 09/2025
Date of Origin: 07/01/2019
Dates Approved: 07/2019, 06/2020, 06/2021, 06/2022, 06/2023, 06/2024, 10/2024,10/02/2025

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter.

II. Dosing Limits

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

- 90 billable units every 21 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

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

Universal Criteria [1]

- Patient does not have a history of a severe hypersensitivity to agents containing Cremophor® EL or its derivatives (e.g., polyoxyethylated castor oil); **AND**
- If used in combination with capecitabine, the patient must not have an AST or ALT > 2.5 x ULN or bilirubin > 1 x ULN; **AND**

Breast Cancer † ‡ [1-4,1e,2e,4e,6e,8e,14e,15e,17e,21e]

- Used for recurrent unresectable (local or regional) or metastatic (stage IV [M1]) disease OR inflammatory breast cancer with no response to preoperative systemic therapy ‡; **AND**
  - Patient has human epidermal growth factor receptor 2 (HER2)-negative* disease as confirmed by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used as a single agent; **AND**

- Patient has hormone-receptor positive disease with visceral crisis or refractory to endocrine therapy; **AND**
  - Used as first-line therapy if no germline BRCA 1/2 mutation and/or HER2 IHC 0+, 1+, or 2+/ISH negative; **AND**
    - Patient was previously treated with an anthracycline; **AND**

    - Use of ixabepilone will be restricted to patients with a contraindication or intolerance to a generically available agent/regimen (e.g., paclitaxel, capecitabine, etc.) [*see NCCN Breast Cancer guidelines for complete list of alternatives*]; **OR**
  - Used as second-line therapy if not a candidate for fam-trastuzumab deruxtecan; **AND**

    - Patient must demonstrate an inadequate response in second-line therapy to a generically available agent or regimen (e.g., paclitaxel, capecitabine, etc.) [*see NCCN Breast Cancer guidelines for complete list of alternatives*], unless there is a contraindication or intolerance, prior to approval of ixabepilone; **OR**
  - Used as third-line therapy and beyond; **AND**
    - Patient previously failed an anthracycline, a taxane, and capecitabine; **OR**
- Patient has triple-negative breast cancer (TNBC) **Ψ**; **AND**
  - Used as first-line therapy if PD-L1 CPS <10 and no germline BRCA 1/2 mutation; **AND**
    - Patient was previously treated with an anthracycline; **AND**

    - Use of ixabepilone will be restricted to patients with a contraindication or intolerance to a generically available agent/regimen (e.g., paclitaxel, capecitabine, etc.) [*see NCCN Breast Cancer guidelines for complete list of alternatives*]; **OR**
  - Used as second-line therapy; **AND**

    - Patient must demonstrate an inadequate response to a generically available agent or regimen (e.g., paclitaxel, capecitabine, etc.) [*see NCCN Breast Cancer guidelines for complete list of alternatives*], unless there is a contraindication or intolerance, prior to approval of ixabepilone; **OR**
  - Used as third-line therapy and beyond; **AND**
    - Patient previously failed an anthracycline, a taxane, and capecitabine; **OR**

- Patient has HER2-positive** disease as confirmed by an FDA-approved or CLIA-compliant test❖; **AND**

- Used in combination with trastuzumab as fourth-line therapy and beyond‡; **AND**

  - Patient must demonstrate an inadequate response to one of the following, unless there is a contraindication or intolerance, prior to approval of ixabepilone in combination with trastuzumab:
    - Trastuzumab in combination with a generically available agent (e.g., trastuzumab/docetaxel, etc.) [*see NCCN Breast Cancer guidelines for complete list of alternatives*]
    - Lapatinib/capecitabine
    - Lapatinib/trastuzumab; **OR**

- Used for locally advanced or metastatic disease †; **AND**
  - Patient has failed or is resistant*** to treatment with an anthracycline and a taxane OR patient is taxane resistant and further anthracycline therapy is contraindicated; **AND**
    - Used in combination with capecitabine; **AND**
      - Patients must demonstrate an inadequate response to a generically available multi-agent chemotherapy regimen (e.g., gemcitabine/vinorelbine, etc.), unless there is a contraindication or intolerance, prior to approval of ixabepilone [*see NCCN Breast Cancer guidelines for complete list of alternatives*]; **OR**
    - Used as a single agent after failure on capecitabine

****Note: Anthracycline resistance is defined as progression while on therapy or within 6 months in the adjuvant setting or 3 months in the metastatic setting. Taxane resistance is defined as progression while on therapy or within 12 months in the adjuvant setting or 4 months in the metastatic setting.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

***HER2-negative expression criteria: [5,6]**

- Immunohistochemistry (IHC) assay is 0 or 1+; **OR**
- Dual-probe in situ hybridization (ISH) assay indicating (Group 5) HER2/CEP17 ratio <2.0 AND average HER2 copy number <4.0 signals/cell; **OR**
- Concurrent dual-probe ISH and IHC assay results indicating one of the following:
  - (Group 2) HER2/CEP17 ratio ≥2.0 AND average HER2 copy number <4.0 signals/cell and concurrent IHC 0-1+ or 2+; OR
  - (Group 3) HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥6.0 signals/cell and concurrent IHC 0-1+; OR
  - (Group 4) HER2/CEP17 ratio <2.0 AND average HER2 copy number ≥4.0 and <6.0 signals/cell and concurrent IHC 0-1+ or 2+

Ψ ER/PR-negative expression criteria: [7]

- Immunohistochemistry (IHC) assay: Sample is considered ER/PR negative if the percentage of cancer cells staining on evaluation is <1% OR 0% of tumor cell nuclei are immunoreactive.

  Note: A sample may be deemed uninterpretable for ER or PR if the sample is inadequate (insufficient cancer or severe artifacts present, as determined at the discretion of the pathologist), if external and internal controls (if present) do not stain appropriately, or if pre-analytic variables have interfered with the assay's accuracy.

Ψ ER Scoring Interpretation *(following ER testing by validated IHC assay)*

Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive

**Note: Invasive cancers with between 1%–10% ER positivity are considered ER-low–positive. However, this group is noted to be heterogeneous and the biologic behavior of ER-low–positive cancers may be more similar to ER-negative cancers. This should be considered in decision making for other adjuvant therapy and overall treatment pathway.*

****HER2-positive overexpression criteria: [5,6]**

- Immunohistochemistry (IHC) assay 3+; **OR**
- Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR**
- Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  - HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  - HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**

- HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

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

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

IV. Renewal Criteria [1]

Prior authorization validity may be renewed based on the following criteria:

- Patient continues to meet the 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: peripheral neuropathy (sensory and motor neuropathy), myelosuppression (e.g., neutropenia, leukopenia, anemia, thrombocytopenia, etc.), toxicity in patients with hepatic impairment, hypersensitivity reactions (including anaphylaxis), cardiac adverse reactions (e.g., myocardial ischemia and ventricular dysfunction), etc.

V. Dosage/Administration [1-4,8,9]

Indication	Dose
Breast Cancer	Administer 40 mg/m² intravenously (IV) over 3 hours every 21 days until disease progression or unacceptable toxicity. (*Doses for patients with a BSA > 2.2 m^2 should be calculated based on 2.2 m^2*)

VI. Billing Code/Availability Information

HCPCS Code:

- J9207 – Injection, ixabepilone, 1mg: 1mg = 1 billable unit

NDC(s):

- Ixempra 15 mg single-dose vial for injection: 70020-1910-xx
- Ixempra 45 mg single-dose vial for injection: 70020-1911-xx

VII. References (STANDARD)

1. Ixempra [package insert]. Princeton, NJ; R-Pharm US LLC; January 2023. Accessed September 2025.

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for ixabepilone. National Comprehensive Cancer Network, 2025. 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 September 2025.
3. Thomas ES, Gomez HL, Li RK, et al. Ixabepilone plus capecitabine for metastatic breast cancer progressing after anthracycline and taxane treatment. J Clin Oncol. 2007 Nov 20;25(33):5210-7. doi: 10.1200/JCO.2007.12.6557.
4. Perez EA, Lerzo G, Pivot X, et al. Efficacy and safety of ixabepilone (BMS-247550) in a phase II study of patients with advanced breast cancer resistant to an anthracycline, a taxane, and capecitabine. J Clin Oncol. 2007 Aug 10;25(23):3407-14. doi: 10.1200/JCO.2006.09.3849.
5. Wolff AC, Hammond MEH, Allison KH, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018 Nov;142(11):1364-1382. doi: 10.5858/arpa.2018-0902-SA. Epub 2018 May 30. Arch Pathol Lab Med. 2018. PMID: 29846104.
6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer, Version 4.2025. National Comprehensive Cancer Network, 2025. 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 Guidelines, go online to NCCN.org. Accessed September 2025.
7. Allison KH, Hammond EH, Dowsett M, et al. Estrogen and Progesterone Receptor Testing in Breast Cancer: ASCO/CAP Guideline Update. J Clin Oncol 38:1346-1366.
8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ixabepilone: Breast Cancer Chemotherapy Order Template, BRS64. 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 Guidelines, go online to NCCN.org. Accessed September 2025.
9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ixabepilone + Trastuzumab: Breast Cancer Chemotherapy Order Template, BRS152. 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 Guidelines, go online to NCCN.org. Accessed September 2025.

VIII. References (ENHANCED)

1e. Roché H, Yelle L, Cognetti F, et al. Phase II clinical trial of ixabepilone (BMS-247550), an epothilone B analog, as first-line therapy in patients with metastatic breast cancer previously treated with anthracycline chemotherapy. J Clin Oncol. 2007 Aug 10;25(23):3415-20.

2e. Thomas E, Tabernero J, Fornier M, et al. Phase II clinical trial of ixabepilone (BMS-247550), an epothilone B analog, in patients with taxane-resistant metastatic breast cancer. J Clin Oncol. 2007 Aug 10;25(23):3399-406.

3e. Rugo HS, Barry WT, Moreno-Aspitia A, et al. Randomized Phase III Trial of Paclitaxel Once Per Week Compared With Nanoparticle Albumin-Bound Nab-Paclitaxel Once Per Week or Ixabepilone With Bevacizumab As First-Line Chemotherapy for Locally Recurrent or Metastatic Breast Cancer: CALGB 40502/NCCTG N063H (Alliance). J Clin Oncol. 2015;33(21):2361–2369.

4e. Sledge GW, Neuberg D, Bernardo P, et al. Phase III trial of doxorubicin, paclitaxel, and the combination of doxorubicin and paclitaxel as front-line chemotherapy for metastatic breast cancer: an intergroup trial (E1193). J Clin Oncol. 2003 Feb 15;21(4):588-92.

5e. Jones SE, Erban J, Overmoyer B, et al. Randomized Phase III Study of Docetaxel Compared With Paclitaxel in Metastatic Breast Cancer. Journal of Clinical Oncology 2005 23:24, 5542-5551.

6e. Fumoleau P, Largillier R, Clippe C, et al. Multicentre, phase II study evaluating capecitabine monotherapy in patients with anthracycline- and taxane-pretreated metastatic breast cancer. Eur J Cancer. 2004 Mar;40(4):536-42.

7e. Blackstein M, Vogel CL, Ambinder R, et al. Gemcitabine as first-line therapy in patients with metastatic breast cancer: a phase II trial. Oncology. 2002;62(1):2-8.

8e. Martín M, Ruiz A, Muñoz M, et al. Gemcitabine plus vinorelbine versus vinorelbine monotherapy in patients with metastatic breast cancer previously treated with anthracyclines and taxanes: final results of the phase III Spanish Breast Cancer Research Group (GEICAM) trial. Lancet Oncol. 2007 Mar;8(3):219-25.

9e. Jones S, Winer E, Vogel C, et al. Randomized comparison of vinorelbine and melphalan in anthracycline-refractory advanced breast cancer. J Clin Oncol. 1995 Oct;13(10):2567-74.

10e. Thomas ES, Gomez HL, Li RK, et al. Ixabepilone plus capecitabine for metastatic breast cancer progressing after anthracycline and taxane treatment. J Clin Oncol. 2007 Nov 20;25(33):5210-7.

11e. Albain KS, Nag SM, Calderillo-Ruiz G, et al. Gemcitabine plus Paclitaxel versus Paclitaxel monotherapy in patients with metastatic breast cancer and prior anthracycline treatment. J Clin Oncol. 2008 Aug 20;26(24):3950-7.

12e. Mavroudis D, Papakotoulas P, Ardavanis A, et al. Randomized phase III trial comparing docetaxel plus epirubicin versus docetaxel plus capecitabine as first-line treatment in women with advanced breast cancer. Ann Oncol. 2010 Jan;21(1):48-54.

13e. Langley RE, Carmichael J, Jones AL, et al. Phase III trial of epirubicin plus paclitaxel compared with epirubicin plus cyclophosphamide as first-line chemotherapy for metastatic breast cancer:

United Kingdom National Cancer Research Institute trial AB01. J Clin Oncol. 2005 Nov 20;23(33):8322-30.

14e. Tolaney SM, Najita J, Sperinde J, et al. A phase II study of ixabepilone and trastuzumab for metastatic HER2-positive breast cancer. Ann Oncol. 2013;24(7):1841–1847.

15e. Baselga J, Cortés J, Kim SB, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med. 2011;366(2):109-19.

16e. Swain SM, Baselga J, Kim SB, et al. Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. N Engl J Med. 2015;372(8):724-34.

17e. Andersson M, et al. Phase III Randomized Study Comparing Docetaxel Plus Trastuzumab With Vinorelbine Plus Trastuzumab As First-Line Therapy of Metastatic or Locally Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: The HERNATA Study. Journal of Clinical Oncology 2011 29:3, 264-271.

18e. Anthony Ellis P, et al. Phase III, randomized study of trastuzumab emtansine (T-DM1) ± pertuzumab (P) vs trastuzumab + taxane (HT) for first-line treatment of HER2-positive MBC: Primary results from the MARIANNE study. Journal of Clinical Oncology 2015 33:15_suppl, 507-507.

19e. Verma S, Miles D, Gianni L, et al. Trastuzumab emtansine for HER2-positive advanced breast cancer. N Engl J Med. 2012;367(19):1783-91.

20e. Cameron D, Casey M, Oliva C, Newstat B, Imwalle B, Geyer CE. Lapatinib plus capecitabine in women with HER-2-positive advanced breast cancer: final survival analysis of a phase III randomized trial. Oncologist. 2010;15(9):924-934. doi:10.1634/theoncologist.2009-0181.

21e. Blackwell KL, Burstein HJ, Storniolo AM, et al. Randomized study of Lapatinib alone or in combination with trastuzumab in women with ErbB2-positive, trastuzumab-refractory metastatic breast cancer. J Clin Oncol. 2010;28(7):1124-1130. doi:10.1200/JCO.2008.21.4437.

22e. Kaufman PA, Awada A, Twelves C, et al. Phase III open-label randomized study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with an anthracycline and a taxane. J Clin Oncol. 2015;33(6):594-601. doi:10.1200/JCO.2013.52.4892.

23e. Gradishar WJ, Tjulandin S, Davidson N, et al. Phase III trial of nanoparticle albumin-bound paclitaxel compared with polyethylated castor oil-based paclitaxel in women with breast cancer. J Clin Oncol. 2005;23(31):7794-7803. doi:10.1200/JCO.2005.04.937.

24e. von Minckwitz G, du Bois A, Schmidt M, et al. Trastuzumab beyond progression in human epidermal growth factor receptor 2-positive advanced breast cancer: a german breast group 26/breast international group 03-05 study. J Clin Oncol. 2009 Apr 20;27(12):1999-2006. doi: 10.1200/JCO.2008.19.6618. Epub 2009 Mar 16.

25e. Perez EA, Vogel CL, Irwin DH, et al. Multicenter phase II trial of weekly paclitaxel in women with metastatic breast cancer. J Clin Oncol. 2001 Nov 15;19(22):4216-23. doi: 10.1200/JCO.2001.19.22.4216. PMID: 11709565.

26e. Murthy RK, Loi S, Okines A, et al. Tucatinib, Trastuzumab, and Capecitabine for HER2-Positive Metastatic Breast Cancer. N Engl J Med. 2020 Feb 13;382(7):597-609. doi: 10.1056/NEJMoa1914609. Epub 2019 Dec 11. Erratum in: N Engl J Med. 2020 Feb 6;382(6):586. PMID: 31825569.

27e. Saura C, Oliveira M, Feng YH, et al. Neratinib Plus Capecitabine Versus Lapatinib Plus Capecitabine in HER2-Positive Metastatic Breast Cancer Previously Treated With ≥ 2 HER2-Directed Regimens: Phase III NALA Trial. J Clin Oncol 2020; 38:3138.

28e. Rugo HS, Im SA, Cardoso F, et al. Efficacy of Margetuximab vs Trastuzumab in Patients With Pretreated ERBB2-Positive Advanced Breast Cancer: A Phase 3 Randomized Clinical Trial. JAMA Oncol 2021; 7:573.

29e. Modi S, Saura C, Yamashita et al. Trastuzumab Deruxtecan in Previously Treated HER2-Positive Breast Cancer. N Engl J Med. 2020 Feb 13;382(7):610-621. doi: 10.1056/NEJMoa1914510. Epub 2019 Dec 11.

30e. Cortés J, Kim SB, Chung WP, et al. Trastuzumab deruxtecan (T-DXd) vs trastuzumab emtansine (T-DM) in patients (Pts) with HER2+ metastatic breast cancer (mBC): results of the randomized phase III DESTINY-Breast03 study. Presented at: European Society for Medical Oncology Annual Congress 2021. September 16-21, 2021; virtual. Abstract LBA1.

31e. Rugo HS, Bardia A, Marme F, et al. Sacituzumab Govitecan in Hormone Receptor-Positive/Human Epidermal Growth Factor Receptor 2-Negative Metastatic Breast Cancer. J Clin Oncol. 2022 Oct 10;40(29):3365-3376. doi: 10.1200/JCO.22.01002. Epub 2022 Aug 26.

32e. Robert N, Leyland-Jones B, Asmar L, et al. Randomized phase III study of trastuzumab, paclitaxel, and carboplatin compared with trastuzumab and paclitaxel in women with HER-2-overexpressing metastatic breast cancer.

33e. Aditya Bardia, Jhaveri K, Im SA, et al. Datopotamab Deruxtecan Versus Chemotherapy in Previously Treated Inoperable/Metastatic Hormone Receptor–Positive Human Epidermal Growth Factor Receptor 2–Negative Breast Cancer: Primary Results From TROPION-Breast01. J Clin Oncol. 2025 Jan 20;43(3):285-296. doi: 10.1200/JCO.24.00920.

34e. Pistilli K, Jhaveri K, Im S, et al. VP1-2025: Datopotamab deruxtecan (Dato-DXd) vs chemotherapy (CT) in previously-treated inoperable or metastatic hormone receptor-positive, HER2-negative (HR+/HER2–) breast cancer (BC): Final overall survival (OS) from the phase III TROPION-Breast01 trial. ESMO virtual plenary abstract. Volume 36, Issue 3. p348-350. March 2025

35e. Prime Therapeutics Management. Ixempra Clinical Literature Review Analysis. Last updated September 2025. Accessed September 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast

ICD-10	ICD-10 Description
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
Z85.3	Personal history of malignant neoplasm of breast

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