

# **Fulvestrant:** **Cligavyx™, Faslodex®, Fulvestrant** **(Intramuscular)**

Document Number: IC-0043

**Last Review Date: 08/04/2026**

**Date of Origin: 01/01/2012**

**Dates Reviewed: 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 05/2016, 08/2016, 11/2016, 02/2017, 05/2017, 08/2017, 09/2017, 11/2017, 02/2018, 05/2018, 09/2018, 12/2018, 03/2019, 04/2019, 06/2019, 09/2019, 12/2019, 03/2020, 06/2020, 09/2020, 03/2021, 03/2022, 03/2023, 12/2023, 03/2024, 01/2025, 06/2025, 02/2026, 08/2026**

## **I. Length of Authorization**

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

## **II. Dosing Limits**

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

### **Faslodex & Fulvestrant**

#### **Ovarian Cancer**

- **Loading Dosing:** 20 billable units on day 1 and 10 billable units on days 15 and 29
- **Maintenance Dosing:** 10 billable units every 28 days

#### **All other indications**

- **Loading Dosing:** 20 billable units every 14 days for 3 doses
- **Maintenance Dosing:** 20 billable units every 28 days

### **Cligavyx**

#### **Ovarian Cancer**

- **Loading Dosing:** 500 mg on day 1 and 250 mg on days 15 and 29
- **Maintenance Dosing:** 250 mg every 28 days

#### **All other indications**

- **Loading Dosing:** 500 mg every 14 days for 3 doses
- **Maintenance Dosing:** 500 mg every 28 days

## **III. Initial Approval Criteria <sup>1-3,21</sup>**

Prior authorization validity is provided in the following conditions:

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

**Breast Cancer † ‡ <sup>1-3,4,7,10-13,16-18</sup>**

- Member is postmenopausal, premenopausal with ovarian ablation/suppression, or male (sex assigned at birth) **¥**; **AND**
  - Member has recurrent unresectable (local or regional), advanced, or metastatic disease; **AND**
    - Member has hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease with no visceral crisis; **OR**
    - Member has HR-positive, HER2-positive\* disease as determined by an FDA-approved or CLIA-compliant test **❖ ‡**; **AND**
      - Used as a single agent or in combination with trastuzumab; **OR**
- Member has stage IV (M1) HER2-negative disease with activating HER2 mutation; **AND**
  - Used in combination with trastuzumab AND neratinib or tucatinib as third line and beyond therapy

*¥ When an aromatase inhibitor is used in males, suppression of testicular steroidogenesis with a gonadotropin releasing hormone (GnRH) analog is required.*

#### **Ovarian, Fallopian Tube, and Primary Peritoneal Cancer ‡<sup>4,9,14</sup>**

- Used as single agent therapy; **AND**
- Member has recurrent low-grade serous carcinoma; **AND**
- Member has previously received treatment with an aromatase inhibitor (i.e., letrozole, anastrozole, exemestane)

#### **Endometrial Carcinoma (Uterine Neoplasms) ‡<sup>4,8,15,19</sup>**

- Used as single agent OR in combination with abemaciclib (*for estrogen receptor positive tumors ONLY*); **AND**
- Member has grade 1 or 2 endometrioid adenocarcinoma histology; **AND**
- Will not be used for any of the following:
  - Disease that is not suitable for primary surgery in members with suspected or gross cervical involvement; **OR**
  - Therapy for locoregional recurrence in members with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
  - Therapy after surgical exploration for locoregional recurrence in members with disease confined to the vagina or paravaginal soft tissue

#### **Uterine Sarcoma (Uterine Neoplasms) ‡<sup>4,15,20</sup>**

- Used as single agent therapy; **AND**

- Used for low-grade endometrial stromal sarcoma (ESS) or adenosarcoma without sarcomatous overgrowth (estrogen receptor/progesterone receptor (ER/PR) positive uterine sarcomas)

#### \*HER2-positive overexpression criteria <sup>16</sup>

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

❖ If confirmed using an immunotherapy assay - <http://www.fda.gov/companiondiagnostics>

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

## IV. Renewal Criteria <sup>1-3</sup>

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

- Member continues to meet the 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: bleeding abnormalities, severe injection site reactions (including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy), etc.

## V. Dosage/Administration <sup>1-3,8,9,17,18,19,20,21</sup>

| Indication    | Dose                                                                                                                                                       |
|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Breast Cancer | <b>Loading Dose:</b> <ul style="list-style-type: none"> <li>• Administer 500 mg intramuscularly (IM) on Days 1, 15, 29</li> </ul> <b>Maintenance Dose:</b> |

|                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                       | <ul style="list-style-type: none"> <li>Administer 500 mg IM every 28 days until disease progression or unacceptable toxicity</li> </ul> <p><b>***Note:</b> For premenopausal and perimenopausal women, administer a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards. For men, consider administering a LHRH agonist according to current clinical practice standards.</p>                                                                                       |
| Uterine Sarcoma       | <p><b>Loading Dose:</b></p> <ul style="list-style-type: none"> <li>Administer 500 mg intramuscularly (IM) on Days 1, 15, 29</li> </ul> <p><b>Maintenance Dose:</b></p> <ul style="list-style-type: none"> <li>Administer 500 mg IM every 28 days until disease progression or unacceptable toxicity</li> </ul>                                                                                                                                                                                                        |
| Ovarian Cancer        | <p><b>Loading Dose:</b></p> <ul style="list-style-type: none"> <li>Administer 500 mg intramuscularly (IM) on Day 1 and 250 mg IM on Days 15 and 29</li> </ul> <p><b>Maintenance Dose:</b></p> <ul style="list-style-type: none"> <li>Administer 250 mg IM every 28 days until disease progression or unacceptable toxicity</li> </ul>                                                                                                                                                                                 |
| Endometrial Carcinoma | <p><b>Single Agent:</b><br/>Administer 250 mg intramuscularly (IM) every 4 weeks for at least 8 weeks until disease progression or unacceptable toxicity.</p> <p><b>Combination with abemaciclib:</b><br/><u>Loading Dose:</u></p> <ul style="list-style-type: none"> <li>Administer 500 mg intramuscularly (IM) on Days 1, 15, 29</li> </ul> <p><u>Maintenance Dose:</u></p> <ul style="list-style-type: none"> <li>Administer 500 mg IM every 28 days until disease progression or unacceptable toxicity</li> </ul> |

## VI. Billing Code/Availability Information

### HCPCS Code(s):

- J9395 – Injection, fulvestrant, 25 mg; 1 billable unit = 25 mg
- J9393 – Injection, fulvestrant (teva), not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg
- J9394 – Injection, fulvestrant (fresenius kabi) not therapeutically equivalent to J9395, 25 mg; 1 billable unit = 25 mg
- J9999 – Not otherwise classified, antineoplastic drugs §
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use Only*) §

#### NDC(s):

- Cligavyx 250 mg/5ml single-dose prefilled syringe (Avyxa Pharma): 83831-0159-xx Ψ
- Faslodex 250 mg/5 mL single-dose prefilled syringe: 00310-0720-xx\*
- Fulvestrant 250 mg/5 mL single-dose prefilled syringe (Teva): 00591-5019-xx Ψ
- Fulvestrant 250 mg/5 mL single-dose prefilled syringe (Fresenius Kabi): 63323-0715-xx Ψ

- \* Available generically from multiple manufacturers.
- Ψ Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products may be available from several different manufacturers. For a complete list of all available products and NDCs please reference the FDA website at [National Drug Code Directory](#) for Fulvestrant. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book: [Approved Drug Products with Therapeutic Equivalence Evaluations | Orange Book | FDA](#)
- § Applies to Cligavyx and any other intramuscularly administered fulvestrant products that have received NDA approval by FDA and have not been assigned a classified HCPCS Code.

## VII. References

1. Faslodex [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; January 2021. Accessed January 2026.
2. Fulvestrant [package insert]. North Wales, PA; Teva Pharmaceuticals USA; November 2021. Accessed January 2026.
3. Fulvestrant [package insert]. Lake Zurich, IL; Fresenius Kabi; December 2023. Accessed January 2026.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for fulvestrant. National Comprehensive Cancer Network, 2026. 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 January 2026.
5. Chia S, Gradishar W, Mauriac L, et al. Double-blind, randomized placebo-controlled trial of fulvestrant compared with exemestane after prior nonsteroidal aromatase inhibitor therapy in postmenopausal women with hormone-receptor positive, advanced breast cancer: results from EFFECT. J Clin Oncol 2008; 26:1664-1670.

6. Mauriac L, Romieu G, Bines J. Activity of fulvestrant versus exemestane in advanced breast cancer patients with or without visceral metastases: data from the EFACT trial. *Breast Cancer Res Treat* 2009; 117:69-75.
7. Di Leo A, Jerusalem G, Petruzella L, et al. Results of the CONFIRM phase III trial comparing fulvestrant 250 mg with fulvestrant 500 mg in postmenopausal women with estrogen receptor-positive advanced breast cancer. *J Clin Oncol* 2010; 28:4594-4600.
8. Covens AL, Filiaci V, Gersell D. Phase II study of fulvestrant in recurrent/metastatic endometrial carcinoma: a Gynecologic Oncology Group study. *Gynecol Oncol*. 2011 Feb;120(2):185-8. doi: 10.1016/j.ygyno.2010.10.015. Epub 2010 Nov 13.
9. Argenta PA, Thomas SG, Judson PL, et al. A phase II study of fulvestrant in the treatment of multiply-recurrent epithelial ovarian cancer. *Gynecol Oncol*. 2009 May;113(2):205-209.
10. Robertson JFR, Bondarenko IM, Trishkina E, et al. Fulvestrant 500 mg versus anastrozole 1 mg for hormone receptor-positive advanced breast cancer (FALCON): an international, randomised, double-blind, phase 3 trial. *Lancet*. 2016;388(10063):2997-3005. doi:10.1016/S0140-6736(16)32389-3.
11. Robertson JF, Osborne CK, Howell A, et al. Fulvestrant versus anastrozole for the treatment of advanced breast carcinoma in postmenopausal women: a prospective combined analysis of two multicenter trials. *Cancer*. 2003;98(2):229-238. doi:10.1002/cncr.11468.
12. Cristofanilli M, Turner NC, Bondarenko I, et al. Fulvestrant plus palbociclib versus fulvestrant plus placebo for treatment of hormone-receptor-positive, HER2-negative metastatic breast cancer that progressed on previous endocrine therapy (PALOMA-3): final analysis of the multicentre, double-blind, phase 3 randomised controlled trial [published correction appears in *Lancet Oncol*. 2016 Apr;17 (4):e136] [published correction appears in *Lancet Oncol*. 2016 Jul;17 (7):e270]. *Lancet Oncol*. 2016;17(4):425-439. doi:10.1016/S1470-2045(15)00613-0.
13. Sledge GW Jr, Toi M, Neven P, et al. MONARCH 2: Abemaciclib in Combination With Fulvestrant in Women With HR+/HER2- Advanced Breast Cancer Who Had Progressed While Receiving Endocrine Therapy. *J Clin Oncol*. 2017;35(25):2875-2884. doi:10.1200/JCO.2017.73.7585.
14. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 3.2025. 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 January 2026.
15. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms Version 2.2026. 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 January 2026.

16. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer, Version 1.2026. National Comprehensive Cancer Network, 2026. 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 January 2026.
17. Turner NC, Oliveira M, Howell SJ, et al; CAPItello-291 Study Group. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer. *N Engl J Med*. 2023 Jun 1;388(22):2058-2070. doi: 10.1056/NEJMoa2214131.
18. Turner NC, Im SA, Saura C, et al. Inavolisib-Based Therapy in PIK3CA-Mutated Advanced Breast Cancer. *N Engl J Med*. 2024 Oct 31;391(17):1584-1596. doi: 10.1056/NEJMoa2404625. PMID: 39476340.
19. Green AK, Zhou Q, Iasonos A, et al. A Phase II Study of Fulvestrant plus Abemaciclib in Hormone Receptor-Positive Advanced or Recurrent Endometrial Cancer. *Clin Cancer Res*. 2025 Jun 3;31(11):2088-2096. doi: 10.1158/1078-0432.CCR-24-1999. PMID: 39561275; PMCID: PMC12086264.
20. Trozzi R, Tuyaerts S, Annibali D, et al. An open-label, single-arm, prospective, multi-center, tandem two-stage designed phase II study to evaluate the efficacy of fulvestrant in women with recurrent/metastatic estrogen receptor-positive gynecological malignancies (FUCHSia study). *International Journal of Gynecological Cancer*, Volume 34, Issue 8, 2024, 1217-1224, <https://doi.org/10.1136/ijgc-2023-005229>.
21. Cligavvyx [package insert]. Parsippany-Troy Hills, NJ; Avyxa Pharma, LLC; November 2025. Accessed July 2026.

## 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        | No: PA not a priority |
| 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                                                        |
|---------|---------------------------------------------------------------------------|
| C48.1   | Malignant neoplasm of specified parts of peritoneum                       |
| C48.2   | Malignant neoplasm of peritoneum, unspecified                             |
| C48.8   | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| 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          |
| 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         |

### Medical Necessity Criteria

| ICD-10  | ICD-10 Description                                                      |
|---------|-------------------------------------------------------------------------|
| 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       |
| C54.0   | Malignant neoplasm of isthmus uteri                                     |
| C54.1   | Malignant neoplasm of endometrium                                       |
| C54.2   | Malignant neoplasm of myometrium                                        |
| C54.3   | Malignant neoplasm of fundus uteri                                      |
| C54.8   | Malignant neoplasm of overlapping sites of corpus uteri                 |

#### Medical Necessity Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

| ICD-10 | ICD-10 Description                                               |
|--------|------------------------------------------------------------------|
| C54.9  | Malignant neoplasm of corpus uteri, unspecified                  |
| C55    | Malignant neoplasm of uterus, part unspecified                   |
| C56.1  | Malignant neoplasm of right ovary                                |
| C56.2  | Malignant neoplasm of left ovary                                 |
| C56.3  | Malignant neoplasm of bilateral ovaries                          |
| C56.9  | Malignant neoplasm of unspecified ovary                          |
| C57.00 | Malignant neoplasm of unspecified fallopian tube                 |
| C57.01 | Malignant neoplasm of right fallopian tube                       |
| C57.02 | Malignant neoplasm of left fallopian tube                        |
| C57.10 | Malignant neoplasm of unspecified broad ligament                 |
| C57.11 | Malignant neoplasm of right broad ligament                       |
| C57.12 | Malignant neoplasm of left broad ligament                        |
| C57.20 | Malignant neoplasm of unspecified round ligament                 |
| C57.21 | Malignant neoplasm of right round ligament                       |
| C57.22 | Malignant neoplasm of left round ligament                        |
| C57.3  | Malignant neoplasm of parametrium                                |
| C57.4  | Malignant neoplasm of uterine adnexa, unspecified                |
| C57.7  | Malignant neoplasm of other specified female genital organs      |
| C57.8  | Malignant neoplasm of overlapping sites of female genital organs |
| C57.9  | Malignant neoplasm of female genital organ, unspecified          |
| Z85.3  | Personal history of malignant neoplasm of breast                 |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus  |
| Z85.43 | Personal history of malignant neoplasm of ovary                  |

## 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                           |