

Leuprolide Suspension:

Lupron Depot[®], Lupron Depot-Ped[®], Eligard[®], Fensolvi[®], Camcevi[™] (Intramuscular/Subcutaneous)

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I. Length of Authorization

- Endometriosis: Coverage will be provided for 6 months and is eligible for renewal one time only
- Menses Suppression and Control: Coverage will be provided for 6 months and may not be renewed
- Uterine leiomyomata (fibroids): Coverage will be provided for 3 months and is not eligible for renewal
- Fertility Preservation: Coverage will be provided for 12 months and is eligible for renewal while patient is receiving concomitant cytotoxic chemotherapy
- All other indications: Coverage will be provided for 12 months and is eligible for renewal.

II. Dosing Limits

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

| Drug Name | Strength | Quantity | Days Supply |
|--------------------------|----------|-------------|-------------|
| Lupron Depot 1-Month | 3.75 mg | 1 injection | 28 days |
| Lupron Depot 1-Month | 7.5 mg | 1 injection | 28 days |
| Lupron Depot 3-Month | 11.25 mg | 1 injection | 84 days |
| Lupron Depot 3-Month | 22.5 mg | 1 injection | 84 days |
| Lupron Depot 4-Month | 30 mg | 1 injection | 112 days |
| Lupron Depot 6-Month | 45 mg | 1 injection | 168 days |
| Lupron Depot-Ped 1-month | 7.5 mg | 1 injection | 28 days |
| Lupron Depot-Ped 1-month | 11.25 mg | 1 injection | 28 days |
| Lupron Depot-Ped 3-Month | 11.25 mg | 1 injection | 84 days |
| Lupron Depot-Ped 1-month | 15 mg | 1 injection | 28 days |
| Lupron Depot-Ped 3-Month | 30 mg | 1 injection | 84 days |
| Eligard | 7.5 mg | 1 injection | 28 days |
| Eligard | 22.5 mg | 1 injection | 84 days |
| Eligard | 30 mg | 1 injection | 112 days |
| Eligard | 45 mg | 1 injection | 168 days |
| Fensolvi | 45 mg | 1 injection | 168 days |

| | | | |
|---------|-------|-------------|----------|
| Camcevi | 42 mg | 1 injection | 168 days |
|---------|-------|-------------|----------|

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

| Diagnosis | HCPCS | Product(s) | Billable Units | Days Supply |
|--------------------------------------------------------------------|------------------|----------------------------------------|----------------|-------------|
| Prostate/Breast/ Ovarian Cancer | J9217 | Lupron Depot 1-Month & Eligard 7.5 mg | 1 | 28 |
| | | Lupron Depot 3-Month & Eligard 22.5 mg | 3 | 84 |
| | | Lupron Depot 4-Month & Eligard 30 mg | 4 | 112 |
| | | Lupron Depot 6-Month & Eligard 45 mg | 6 | 168 |
| Salivary Gland Tumors of the Head and Neck | J9217 | Lupron Depot 1-month & Eligard 7.5 mg | 1 | 28 |
| | | Lupron Depot 3-Month & Eligard 22.5 mg | 3 | 84 |
| Breast/Ovarian Cancer; Endometriosis; Uterine Fibroids | J1950 | Lupron Depot 1-Month 3.75 mg | 1 | 28 |
| | | Lupron Depot 3-Month 11.25 mg | 3 | 84 |
| Central Precocious Puberty | J1950/ J1951 | Lupron Depot-Ped 7.5 mg | 2 | 28 |
| | | Lupron Depot-Ped 11.25 mg | 3 | 28 |
| | | Lupron Depot-Ped 15 mg | 4 | 28 |
| | | Lupron Depot-Ped 30 mg | 8 | 84 |
| | | Fensolvi 45 mg Kit | 180 | 168 |
| Prostate Cancer | J1952/ J9999* | Camcevi 42 mg Kit | (42 mg) | 168 |
| Fertility Preservation/ Menses Suppression and Control | J1950 | Lupron Depot 1-Month 3.75 mg | 1 | 28 |

**Note: J1952 is effective 01/01/2022 with a corresponding billable unit equivalent to 1 mg. (Discontinue J9999 01/01/2022)*

III. Initial Approval Criteria

- Coverage for Deseret Protect members is limited to oncology uses ONLY.

Coverage is provided in the following conditions:

- Patient is 18 years or older (unless otherwise specified); **AND**

Central Precocious Puberty (CPP) ^{3,6,12,18-20} † Φ (J1950 and J1951 [Fensolvi only])

- Patient is less than 13 years old; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid level and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**

- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor) ; **AND**
- Will not be used in combination with growth hormone

Endometriosis ^{1,2,10} † (J1950 only)

- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine Leiomyomata (fibroids) ^{1,2,11} † (J1950 only)

- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
- Documentation patient is receiving iron therapy

Breast Cancer ^{8,9,13,14} ‡ (J9217 and J1950)

- Patient is pre-menopausal or is a male with suppression of testicular steroidogenesis; **AND**
- Disease is hormone receptor positive; **AND**
 - Used in combination with adjuvant endocrine therapy; **OR**
 - Endocrine therapy for recurrent or metastatic disease

Ovarian Cancer ^{8,9,16,17} ‡ (J9217 and J1950)

- Used as a single agent; **AND**
 - Patient has a diagnosis of stage II-IV granulosa cell tumors of the ovary; **AND**
 - Patient's disease has relapsed; **OR**
 - Patient has a diagnosis of Epithelial Ovarian Cancer OR Fallopian Tube Cancer OR Primary Peritoneal Cancer; **AND**
 - Patient's disease is persistent or recurrent (excluding immediate treatment of biochemical relapse)

Prostate Cancer ^{4,5,8,9,15} † (J9217 and J9999 [Camcevi only])

- Patient has advanced disease (*Camcevi only*)

Head and Neck Cancer ^{8,9} ‡ (J9217 only)

- Patient has a diagnosis of androgen-receptor positive recurrent salivary gland tumor; **AND**
 - Patient has distant metastases with a performance status score of 0-3; **OR**
 - Patient has unresectable locoregional recurrence or second primary with prior radiation therapy

Prevention/Management of Menstrual Bleeding Associated with Hematopoietic Stem Cell Transplant (HCT) ²²⁻²⁵ ‡ (J1950 only)

- Patient is pre-menopausal; **AND**
 - Patient will receive conditioning myeloablative treatment with cytotoxic chemotherapy; **OR**
 - Patient has menorrhagia due to thrombocytopenia related to delayed platelet engraftment

Fertility Preservation Prior to Chemotherapy ²²⁻²⁵ ‡ (J1950 only)

- Patient is pre-menopausal; **AND**
- Patient is receiving treatment with cytotoxic chemotherapy with the potential to cause ovarian damage/toxicity (e.g., cyclophosphamide, melphalan, procarbazine, vinblastine, imatinib, etc.); **AND**
- Patient has failed or is not a candidate for other fertility preservation methods (e.g., cryopreservation, etc.)

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

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: tumor flare, hyperglycemia/diabetes, cardiovascular disease (myocardial infarction, sudden cardiac death, stroke), QT/QTc prolongation, convulsions, etc.; **AND**

Prostate Cancer (J9217 and J9999 [Camcevi only]);

Head and Neck Cancer – Salivary Gland Tumors (J9217 only);

Breast and Ovarian Cancer (J9217 or J1950 only)

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

Central Precocious Puberty (CPP) ^{3,6,12,18-20} (J1950 and J1951 [Fensolvi only])

- Patient is less than 13 years old; **AND**
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: convulsions, development or worsening of psychiatric symptoms, etc.; **AND**
- Will not be used in combination with growth hormone

Endometriosis (J1950 only)

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- Patient has not received a total of 12 months of therapy of a GnRH-agonist (i.e., leuprolide acetate, etc.); **AND**
- Patient continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
- Patient will have bone density assessment prior to retreatment; **AND**
- Extended GnRH-agonist treatment will be used in combination with norethindrone add-back therapy

Uterine leiomyomata (fibroids)/Menses suppression/control associated with HCT (J1950 only)

- May not be renewed

Fertility Preservation (J1950 only)

- Patient is still receiving treatment with cytotoxic chemotherapy

V. Dosage/Administration ¹⁻⁷

| Indication | Dose |
|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Endometriosis | Administer, intramuscularly, 3.75 mg monthly or 11.25 mg every 3 months for a duration of 6 months only. |
| Breast/Ovarian Cancer | Administer, intramuscularly or subcutaneously, 3.75 mg every/7.5 mg monthly or 11.25 mg/22.5 mg every 3 months. |
| Central Precocious Puberty (CPP) | <ul style="list-style-type: none"> • Fensolvi subcutaneous kit <ul style="list-style-type: none"> – Administer 45 mg subcutaneously once every six months. • Lupron Depot-Ped intramuscular injection: <ul style="list-style-type: none"> – Weight based <ul style="list-style-type: none"> ▪ >37.5 kg: 15 mg every 4 weeks ▪ >25-37.5 kg: 11.25 mg every 4 weeks ▪ ≤ 25 kg: 7.5 mg every 4 weeks; OR – Ages 2 to 11 yrs: 11.25 mg or 30 mg every 12 weeks |
| Uterine leiomyomata (fibroids) | Administer, intramuscularly, 3.75 mg monthly or 11.25 mg every 3 months. The recommended duration of therapy is 3 months or less; retreatment depends on return of symptoms. |
| Prostate Cancer | <ul style="list-style-type: none"> • Lupron Depot & Eligard <ul style="list-style-type: none"> – Administer intramuscularly or subcutaneously, 7.5 mg every 4 weeks, 22.5 mg every 12 weeks, 30 mg every 16 weeks, 45 mg every 24 weeks, or 42 mg every 24 weeks. • Camcevi subcutaneous kit <ul style="list-style-type: none"> – Administer subcutaneously 42 mg once every 6 months. |
| Salivary Gland tumors of the Head and Neck | Administer, intramuscularly or subcutaneously, 7.5 mg every 4 weeks, 22.5 mg every 12 weeks |

| | |
|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Menstrual Bleeding Prevention or Management in HCT | Administer intramuscularly 3.75 mg once every 4 weeks up to 6 months (Therapy should be started 4-5 weeks prior to conditioning chemotherapy and continued as required until platelets are >50,000 post HCT) |
| Fertility Preservation | Administer intramuscularly 3.75 mg once every 4 weeks |

- *Lupron Depot is administered intramuscularly (IM), Eligard, Fensolvi, and Camcevi are administered subcutaneously (SQ)*
- *Camcevi must be administered by a healthcare provider.*
- *Do not use concurrently a fractional dose, or a combination of doses of this or any depot formulation due to different release characteristics.*

VI. Billing Code/Availability Information

| Drug Name | Strength | HCPCS* | NDC |
|--------------------------|----------|----------------------------------------------------------------|---------------|
| Lupron Depot 1-Month | 3.75 mg | J1950 | 00074-3641-xx |
| Lupron Depot 1-Month | 7.5 mg | J9217 | 00074-3642-xx |
| Lupron Depot 3-Month | 11.25 mg | J1950 | 00074-3663-xx |
| Lupron Depot 3-Month | 22.5 mg | J9217 | 00074-3346-xx |
| Lupron Depot 4-Month | 30 mg | J9217 | 00074-3683-xx |
| Lupron Depot 6-Month | 45 mg | J9217 | 00074-3473-xx |
| Lupron Depot-Ped | 7.5 mg | J1950 | 00074-2108-xx |
| Lupron Depot-Ped | 11.25 mg | J1950 | 00074-2282-xx |
| Lupron Depot-Ped 3-Month | 11.25 mg | J1950 | 00074-3779-xx |
| Lupron Depot-Ped | 15 mg | J1950 | 00074-2440-xx |
| Lupron Depot-Ped 3-Month | 30 mg | J1950 | 00074-9694-xx |
| Eligard | 7.5 mg | J9217 | 62935-0753-xx |
| Eligard | 22.5 mg | J9217 | 62935-0223-xx |
| Eligard | 30 mg | J9217 | 62935-0303-xx |
| Eligard | 45 mg | J9217 | 62935-0453-xx |
| Fensolvi | 45 mg | J1951 | 62935-0153-xx |
| Camcevi | 42 mg | J9999 (discontinue 01/01/2022) J1592 (effective 01/01/2022) | 72851-0042-xx |

*J1950: Injection, leuprolide acetate (for depot suspension), per 3.75 mg

*J9217: Leuprolide acetate (for depot suspension), 7.5 mg

*J1951: Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg

*J9999: Not otherwise classified, antineoplastic drugs (*Camcevi only*) (*Discontinue use on 01/01/2022*)

*J1952: Leuprolide injectable, camcevi, 1 mg (*Effective 01/01/2022*)

VII. References

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Appendix 1 – Covered Diagnosis Codes

J1950

| 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 female breast |
| C50.022 | Malignant neoplasm of nipple and areola, left female breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified female 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 |
| 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 |

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| ICD-10 | ICD-10 Description |
|---------|-----------------------------------------------------------------------|
| 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 |
| 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 |
| D25.0 | Submucous leiomyoma of uterus |

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| ICD-10 | ICD-10 Description |
|--------|--------------------------------------------------------------------------------------|
| D25.1 | Intramural leiomyoma of uterus |
| D25.2 | Subserosal leiomyoma of uterus |
| D25.9 | Leiomyoma of uterus, unspecified |
| E30.1 | Precocious puberty |
| E30.8 | Other disorders of puberty |
| N80.0 | Endometriosis of uterus |
| N80.1 | Endometriosis of ovary |
| N80.2 | Endometriosis of fallopian tube |
| N80.3 | Endometriosis of pelvic peritoneum |
| N80.4 | Endometriosis of rectovaginal septum and vagina |
| N80.5 | Endometriosis of intestine |
| N80.6 | Endometriosis in cutaneous scar |
| N80.8 | Other endometriosis |
| N80.9 | Endometriosis, unspecified |
| N93.8 | Other specified abnormal uterine and vaginal bleeding |
| N94.89 | Other specified conditions associated with female genital organs and menstrual cycle |
| T86.09 | Other complications of bone marrow transplant |
| Z31.84 | Encounter for fertility preservation procedure |

J9217

| ICD-10 | ICD-10 Description |
|---------|---------------------------------------------------------------------------|
| C06.9 | Malignant neoplasm of mouth, unspecified |
| C07 | Malignant neoplasm of parotid gland |
| C08.0 | Malignant neoplasm of submandibular gland |
| C08.1 | Malignant neoplasm of sublingual gland |
| C08.9 | Malignant neoplasm of major salivary gland, unspecified |
| 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 female breast |
| C50.022 | Malignant neoplasm of nipple and areola, left female breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified female 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 |

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| ICD-10 | ICD-10 Description |
|---------|-------------------------------------------------------------------------|
| 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 |
| 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 |

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| ICD-10 | ICD-10 Description |
|---------|---------------------------------------------------------------------|
| 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 |
| 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 |
| C61 | Malignant neoplasm of prostate |
| Z85.46 | Personal history of malignant neoplasm of prostate |

J1951 (Fensolvi only)

| ICD-10 | ICD-10 Description |
|--------|----------------------------|
| E30.1 | Precocious puberty |
| E30.8 | Other disorders of puberty |

J9999 (Camcevi only) (Discontinue use on 01/01/2022); J1952 (Camcevi only) (Effective on 01/01/2022)

| ICD-10 | ICD-10 Description |
|--------|----------------------------------------------------|
| C61 | Malignant neoplasm of prostate |
| Z85.46 | Personal history of malignant neoplasm of prostate |

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

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 Determination (NCD), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

Lupron Depot/Lupron Depot-Ped (J1950) & Lupron Depot/Eligard (J9217)

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Jurisdiction(s): N | NCD/LCD Document (s): A57655 |
| https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57655&bc=gAAAAAAAAAAAA& | |
| Jurisdiction(s): 6, K | NCD/LCD Document (s): A52453 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52453&bc=gAAAAAAAAAAAA& | |
| Jurisdiction(s): H | NCD/LCD Document (s): A56776 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56776&bc=gAAAAAAAAAAAA& | |

| 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, LLC |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| 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) |

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Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|---------------------|--------------------------------------|-------------------------|
| 15 | KY, OH | CGS Administrators, LLC |