MEDICA®

Medica applies pre-payment claims edits to diagnosis criteria and criteria for maximum units.
Prior authorization criteria *do not apply* for this policy.

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 may be renewed one time only.
- Prevention/Management of Menstrual Bleeding:
  - Coverage will be provided for 6 months and may NOT be renewed.
- Uterine Leiomyomata (fibroids):
  - Coverage will be provided for 3 months and may NOT be renewed.
- Fertility Preservation:
  - Coverage will be provided for 12 months and may be renewed while patient is receiving concomitant cytotoxic chemotherapy.
- All Other Indications: Coverage will be provided for 12 months and may be renewed.

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
Head and Neck Cancer – Salivary Gland Tumors	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	Camcevi 42 mg Kit	(42 mg)	168
Fertility Preservation/ Prevention/Management of Menstrual Bleeding	J1950	Lupron Depot 1-Month 3.75 mg	1	28
Gender Dysphoria	J1950/ J1951	Lupron Depot 1-Month 3.75 mg	1	28
		Lupron Depot 3-Month 11.25 mg	3	84
		Lupron Depot-Ped 11.25 mg	3	28
		Fensolvi 45 mg Kit	180	168

III. Initial Approval Criteria

Coverage is provided in the following conditions:

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

- Onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native growth hormone-releasing hormone (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 premenopausal or is a male with suppression of testicular steroidogenesis; **AND**
- Disease is hormone receptor-positive; **AND**
  - Used in combination with adjuvant endocrine therapy; **OR**
  - Used in combination with endocrine therapy for recurrent unresectable 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 has relapsed disease; **OR**
  - Patient has a diagnosis of Epithelial Ovarian Cancer OR Fallopian Tube Cancer OR Primary Peritoneal Cancer; **AND**
    - Patient has persistent or recurrent disease (excluding immediate treatment of biochemical relapse)

Prostate Cancer [4,5,8,9,15] † (J9217 and J1952 [Camcevi only])

- Patient has advanced disease *(Camcevi only)*

Head and Neck Cancer [8,9] ‡ (J9217 only)

- Patient has salivary gland tumors; **AND**
- Used as a single agent; **AND**
- Patient has androgen-receptor positive recurrent disease; **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 Hematopoetic Stem Cell Transplant (HCT) [22-25] ‡ (J1950 only)

- Patient is premenopausal; **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 premenopausal; **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.)

Gender Dysphoria (formerly Gender Identity Disorder) ‡ [26,27] (J1950 and J1951 [Fensolvi only])

- Patient has a diagnosis of gender dysphoria as confirmed by a qualified mental health professional (MHP)** OR the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) Criteria §; **AND**
- A qualified MHP** has confirmed all of the following:
  - Patient has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); **AND**
  - Gender dysphoria worsened with the onset of puberty; **AND**
  - Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; **AND**
  - Patient has sufficient mental capacity to give informed consent to this (reversible) treatment; **AND**

- Patient has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility; **AND**
- Patient has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process; **AND**
- A pediatric endocrinologist or other clinician experienced in pubertal assessment has confirmed all of the following:
    - Agreement in the indication for treatment; **AND**
    - Puberty has started in the adolescent (e.g., Tanner stage ≥G2/B2); **AND**
    - There are no medical contraindications to treatment

**** Definition of a qualified mental health professional [28]**

- A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should also have documented credentials from the relevant licensing board or equivalent; **AND**
- Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes; **AND**
- Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; **AND**
- Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; **AND**
- Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

§ DSM-V Criteria for Gender Dysphoria [26,27]

- A marked incongruence between one's experienced/expressed gender and natal gender of at least 6mo in duration, as manifested by at least TWO of the following:
    - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
    - A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
    - A strong desire for the primary and/or secondary sex characteristics of the other gender
    - A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
    - A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)

- A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender); **AND**
- The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning; **AND**
- Specify one of the following:
  - The condition exists with a disorder of sex development; **OR**
  - The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

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

IV. Renewal Criteria

Coverage may 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 J1952 [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 of age; **AND**
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), 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

Gender Dysphoria [26,27]

- Patient has shown a beneficial response to treatment as evidenced by routine monitoring of clinical pubertal development and applicable laboratory parameters

Endometriosis (J1950 only)

- 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) (J1950 only)

- Coverage may NOT be renewed

Prevention/Management of Menstrual Bleeding Associated with HCT (J1950 only)

- Coverage may NOT be renewed

Fertility Preservation Prior to Chemotherapy (J1950 only)

- Patient is still receiving treatment with cytotoxic chemotherapy

V. Dosage/Administration [1-7]

Indication	Dose
Endometriosis	Administer 3.75 mg intramuscularly monthly or 11.25 mg intramuscularly 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)	• Fensolvi subcutaneous kit – Administer 45 mg subcutaneously once every 6 months. • Lupron Depot-Ped intramuscular injection: – Weight based: ▪ >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 3.75 mg intramuscularly monthly or 11.25 mg intramuscularly every 3 months*. **The recommended duration of therapy is 3 months or less; retreatment is dependent on the return of symptoms.*
Prostate Cancer	• Lupron Depot & Eligard – 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 – Administer 42 mg subcutaenously 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
Prevention/Management of Menstrual Bleeding Associated with HCT	Administer 3.75 mg intramuscularly 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 Prior to Chemotherapy	Administer 3.75 mg intramuscularly every 4 weeks
Gender Dysphoria	• Lupron Depot injection: – Administer 3.75 mg intramuscularly once a month in combination with transdermal estradiol 1 or 2 mg/day; **OR** – Administer 11.25 mg subcutaneously every 3 months • Fensolvi subcutaneous kit – Administer 45 mg subcutaneously once every 6 months
Note: – *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	J1592	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
*J1952: Leuprolide injectable, camcevi, 1 mg

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

ICD-10	ICD-10 Description
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
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast

ICD-10	ICD-10 Description
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
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
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
Z85.43	Personal history of malignant neoplasm of ovary
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
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified

J1952 (Camcevi only)

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: https://www.cms.gov/medicare-coverage-database/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/new-search/search-results.aspx?keyword=a57655&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 6, K	**NCD/LCD Document (s):** A52453
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52453&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): H	**NCD/LCD Document (s):** A56776
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56776&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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