Leuprolide Suspension:
Lupron Depot®, Lupron Depot-Ped®, Eligard®, Fensolvi®, Camcevi™, Leuprolide Acetate Depot Ψ
(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
Lupron Depot-Ped 6-Month	45 mg	1 injection	168 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
Leuprolide Acetate Depot	22.5 mg	1 injection	84 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
		Lupron Depot-Ped 45 mg	12	168
		Fensolvi 45 mg Kit	180	168
Prostate Cancer	J1952	Camcevi 42 mg Kit	42	168
Prostate Cancer	J1954	Leuprolide Acetate Depot	3	84
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) [3,6,14,20-22] † Φ (J1950 and J1951)

- 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 [1,2,12] † (J1950)

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

Uterine Leiomyomata (fibroids) [1,2,13,36] † (J1950)

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

Breast Cancer [10,11,15,16] ‡ (J9217 and J1950)

- Patient has invasive or inflammatory disease; **AND**
  - Patient is a premenopausal woman; **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
  - Patient is a male (sex assigned at birth); **AND**
    - Used in combination with aromatase inhibitor therapy

Ovarian Cancer [10,11,18,19] ‡ (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/Fallopian Tube Cancer/Primary Peritoneal Cancer, Mucinous Carcinoma of the Ovary, Clear Cell Carcinoma of the Ovary, Carcinosarcoma (Malignant Mixed Müllerian Tumors), or Grade 1 Endometrioid Carcinoma; **AND**
  - Patient has persistent or recurrent disease (excluding immediate treatment of biochemical relapse); **OR**
- Patient has a diagnosis of Low-Grade Serous Carcinoma; **AND**
  - Patient has disease recurrence

Prostate Cancer [4,5,8-10,11,17] † ‡ (J9217, J1952, and J1954)

Head and Neck Cancer [10,11] ‡ (J9217)

- 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 Hematopoietic Stem Cell Transplant (HCT) [24-27] ‡ (J1950)

- 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 [24-27,37] ‡ (J1950)

- 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) ‡ [28-30] (J1950 and J1951)

- Patient has experienced puberty development to at least Tanner stage 2; **AND**

- 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
    - There are no medical contraindications to treatment

** Definition of a qualified mental health professional [33]
• Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution; AND • For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable; AND • Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity; AND • Are able to assess capacity to consent for treatment; AND • Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity; AND • Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity

§ DSM-V Criteria for Gender Dysphoria [28,29]

• 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 post transitional, 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, severe cutaneous adverse reactions (e.g., Stevens-Johnson syndrome/toxic epidermal necrolysis [SJS/TEN], drug reaction with eosinophilia and systemic symptoms [DRESS], acute generalized exanthematous pustulosis [AGEP]) etc.; **AND**

Prostate Cancer (J9217, J1952, and J1954); Head and Neck Cancer – Salivary Gland Tumors (J9217); Breast and Ovarian Cancer (J9217 and J1950)

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

Central Precocious Puberty (CPP) [3,6,14,20-22] (J1950 and J1951)

- 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, pseudotumor cerebri (idiopathic intracranial hypertension), etc.; **AND**
- Will not be used in combination with growth hormone

Gender Dysphoria [28,29]

- Patient has shown a beneficial response to treatment as evidenced by routine monitoring of clinical pubertal development and applicable laboratory parameters; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: convulsions, development or worsening of psychiatric symptoms, pseudotumor cerebri (idiopathic intracranial hypertension), etc.

Endometriosis (J1950) [1,2]

- 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; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: significant loss of bone mineral density, hypersensitivity reactions, convulsions, new or worsening clinical depression, etc.

Uterine Leiomyomata (fibroids) (J1950)

- Coverage may NOT be renewed

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

- Coverage may NOT be renewed

Fertility Preservation Prior to Chemotherapy (J1950)

- Patient is still receiving treatment with cytotoxic chemotherapy; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: significant loss of bone mineral density, hypersensitivity reactions, convulsions, new or worsening clinical depression, etc.

V. Dosage/Administration [1-9,24,26-27,37]

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: – Dosing for 1-month administration: ▪ >37.5 kg: 15 mg every month (4 weeks) ▪ >25-37.5 kg: 11.25 mg every month (4 weeks) ▪ ≤ 25 kg: 7.5 mg every month (4 weeks) – Dosing for 3-month administration: ▪ 11.25 mg or 30 mg every 3 months (12 weeks) – Dosing for 6-month administration: ▪ 45 mg every 6 months (24 weeks)
Uterine Leiomyomata (fibroids)	Administer 3.75 mg intramuscularly monthly or 11.25 mg intramuscularly as a single dose*. **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 subcutaneously once every 6 months. • Leuprolide Acetate Depot (Cipla) – Administer 22.5 mg intramuscularly once every 12 weeks.
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, and Leuprolide Acetate Depot (Cipla) are administered intramuscularly (IM). Eligard, Fensolvi, and Camcevi are administered subcutaneously (SQ)*
- *Camcevi, Eligard, Fensolvi and Lupron Depot-Ped 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 1-Month	7.5 mg	J1950	00074-2108-xx
Lupron Depot-Ped 1-Month	11.25 mg	J1950	00074-2282-xx
Lupron Depot-Ped 3-Month	11.25 mg	J1950	00074-3779-xx
Lupron Depot-Ped 1-Month	15 mg	J1950	00074-2440-xx
Lupron Depot-Ped 3-Month	30 mg	J1950	00074-9694-xx
Lupron Depot-Ped 6-Month	45 mg	J1950	00074-3575-xx
Eligard	7.5 mg	J9217	62935-0753-xx 62935-0756-xx
Eligard	22.5 mg	J9217	62935-0223-xx 62935-0227-xx
Eligard	30 mg	J9217	62935-0303-xx 62935-0306-xx
Eligard	45 mg	J9217	62935-0453-xx 62935-0461-xx
Fensolvi	45 mg	J1951	62935-0153-xx 62935-0163-xx
Camcevi	42 mg	J1952	69448-0014-xx 69448-0023-xx
Leuprolide Acetate Depot (Cipla) Ψ	22.5 mg	J1954	69097-0909-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
- J1954: Injection, leuprolide acetate for depot suspension (cipla), 7.5 mg Ψ

- ** Some formulations are available as multi-sourced generics.*
- ***Ψ** Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. 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

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

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
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

ICD-10	ICD-10 Description
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
N80.00	Endometriosis of the uterus, unspecified
N80.01	Superficial endometriosis of the uterus
N80.02	Deep endometriosis of the uterus
N80.03	Adenomyosis of the uterus
N80.101	Endometriosis of right ovary, unspecified depth
N80.102	Endometriosis of left ovary, unspecified depth
N80.103	Endometriosis of bilateral ovaries, unspecified depth
N80.109	Endometriosis of ovary, unspecified side, unspecified depth
N80.111	Superficial endometriosis of right ovary
N80.112	Superficial endometriosis of left ovary
N80.113	Superficial endometriosis of bilateral ovaries
N80.119	Superficial endometriosis of ovary, unspecified ovary
N80.121	Deep endometriosis of right ovary
N80.122	Deep endometriosis of left ovary
N80.123	Deep endometriosis of bilateral ovaries
N80.129	Deep endometriosis of ovary, unspecified ovary
N80.201	Endometriosis of right fallopian tube, unspecified depth
N80.202	Endometriosis of left fallopian tube, unspecified depth
N80.203	Endometriosis of bilateral fallopian tubes, unspecified depth
N80.209	Endometriosis of unspecified fallopian tube, unspecified depth

ICD-10	ICD-10 Description
N80.211	Superficial endometriosis of right fallopian tube
N80.212	Superficial endometriosis of left fallopian tube
N80.213	Superficial endometriosis of bilateral fallopian tubes
N80.219	Superficial endometriosis of unspecified fallopian tube
N80.221	Deep endometriosis of right fallopian tube
N80.222	Deep endometriosis of left fallopian tube
N80.223	Deep endometriosis of bilateral fallopian tubes
N80.229	Deep endometriosis of unspecified fallopian tube
N80.30	Endometriosis of pelvic peritoneum, unspecified
N80.311	Superficial endometriosis of the anterior cul-de-sac
N80.312	Deep endometriosis of the anterior cul-de-sac
N80.319	Endometriosis of the anterior cul-de-sac, unspecified depth
N80.321	Superficial endometriosis of the posterior cul-de-sac
N80.322	Deep endometriosis of the posterior cul-de-sac
N80.329	Endometriosis of the posterior cul-de-sac, unspecified depth
N80.331	Superficial endometriosis of the right pelvic sidewall
N80.332	Superficial endometriosis of the left pelvic sidewall
N80.333	Superficial endometriosis of bilateral pelvic sidewall
N80.339	Superficial endometriosis of pelvic sidewall, unspecified side
N80.341	Deep endometriosis of the right pelvic sidewall
N80.342	Deep endometriosis of the left pelvic sidewall
N80.343	Deep endometriosis of the bilateral pelvic sidewall
N80.349	Deep endometriosis of the pelvic sidewall, unspecified side
N80.351	Endometriosis of the right pelvic sidewall, unspecified depth
N80.352	Endometriosis of the left pelvic sidewall, unspecified depth
N80.353	Endometriosis of bilateral pelvic sidewall, unspecified depth
N80.359	Endometriosis of pelvic sidewall, unspecified side, unspecified depth
N80.361	Superficial endometriosis of the right pelvic brim
N80.362	Superficial endometriosis of the left pelvic brim
N80.363	Superficial endometriosis of bilateral pelvic brim
N80.369	Superficial endometriosis of the pelvic brim, unspecified side
N80.371	Deep endometriosis of the right pelvic brim
N80.372	Deep endometriosis of the left pelvic brim
N80.373	Deep endometriosis of bilateral pelvic brim
N80.379	Deep endometriosis of the pelvic brim, unspecified side
N80.381	Endometriosis of the right pelvic brim, unspecified depth
N80.382	Endometriosis of the left pelvic brim, unspecified depth
N80.383	Endometriosis of bilateral pelvic brim, unspecified depth
N80.389	Endometriosis of the pelvic brim, unspecified side, unspecified depth
N80.3A1	Superficial endometriosis of the right uterosacral ligament
N80.3A2	Superficial endometriosis of the left uterosacral ligament
N80.3A3	Superficial endometriosis of the bilateral uterosacral ligament(s)

ICD-10	ICD-10 Description
N80.3A9	Superficial endometriosis of the uterosacral ligament(s), unspecified side
N80.3B1	Deep endometriosis of the right uterosacral ligament
N80.3B2	Deep endometriosis of the left uterosacral ligament
N80.3B3	Deep endometriosis of bilateral uterosacral ligament(s)
N80.3B9	Deep endometriosis of the uterosacral ligament(s), unspecified side
N80.3C1	Endometriosis of the right uterosacral ligament, unspecified depth
N80.3C2	Endometriosis of the left uterosacral ligament, unspecified depth
N80.3C3	Endometriosis of bilateral uterosacral ligament(s), unspecified depth
N80.3C9	Endometriosis of the uterosacral ligament(s), unspecified side, unspecified depth
N80.391	Superficial endometriosis of the pelvic peritoneum, other specified sites
N80.392	Deep endometriosis of the pelvic peritoneum, other specified sites
N80.399	Endometriosis of the pelvic peritoneum, other specified sites, unspecified depth
N80.40	Endometriosis of rectovaginal septum, unspecified involvement of vagina
N80.41	Endometriosis of rectovaginal septum without involvement of vagina
N80.42	Endometriosis of rectovaginal septum with involvement of vagina
N80.50	Endometriosis of intestine, unspecified
N80.511	Superficial endometriosis of the rectum
N80.512	Deep endometriosis of the rectum
N80.519	Endometriosis of the rectum, unspecified depth
N80.521	Superficial endometriosis of the sigmoid colon
N80.522	Deep endometriosis of the sigmoid colon
N80.529	Endometriosis of the sigmoid colon, unspecified depth
N80.531	Superficial endometriosis of the cecum
N80.532	Deep endometriosis of the cecum
N80.539	Endometriosis of the cecum, unspecified depth
N80.541	Superficial endometriosis of the appendix
N80.542	Deep endometriosis of the appendix
N80.549	Endometriosis of the appendix, unspecified depth
N80.551	Superficial endometriosis of other parts of the colon
N80.552	Deep endometriosis of other parts of the colon
N80.559	Endometriosis of other parts of the colon, unspecified depth
N80.561	Superficial endometriosis of the small intestine
N80.562	Deep endometriosis of the small intestine
N80.569	Endometriosis of the small intestine, unspecified depth
N80.A0	Endometriosis in cutaneous scar
N80.A1	Endometriosis of bladder, unspecified depth
N80.A2	Superficial endometriosis of bladder
N80.A41	Deep endometriosis of bladder
N80.A42	Superficial endometriosis of right ureter
N80.A43	Superficial endometriosis of left ureter
N80.A49	Superficial endometriosis of bilateral ureters
N80.A51	Superficial endometriosis of unspecified ureter

ICD-10	ICD-10 Description
N80.A52	Deep endometriosis of right ureter
N80.A53	Deep endometriosis of left ureter
N80.A59	Deep endometriosis of bilateral ureters
N80.A61	Deep endometriosis of unspecified ureter
N80.A62	Endometriosis of right ureter, unspecified depth
N80.A63	Endometriosis of left ureter, unspecified depth
N80.A69	Endometriosis of bilateral ureters, unspecified depth
N80.B1	Endometriosis of unspecified ureter, unspecified depth
N80.B2	Endometriosis of pleura
N80.B31	Endometriosis of lung
N80.B32	Superficial endometriosis of diaphragm
N80.B39	Deep endometriosis of diaphragm
N80.B4	Endometriosis of diaphragm, unspecified depth
N80.B5	Endometriosis of the pericardial space
N80.B6	Endometriosis of the mediastinal space
N80.C0	Endometriosis of cardiothoracic space
N80.C10	Endometriosis of the abdomen, unspecified
N80.C11	Endometriosis of the anterior abdominal wall, subcutaneous tissue
N80.C19	Endometriosis of the anterior abdominal wall, fascia and muscular layers
N80.C2	Endometriosis of the anterior abdominal wall, unspecified depth
N80.C3	Endometriosis of the umbilicus
N80.C4	Endometriosis of the inguinal canal
N80.C9	Endometriosis of extra-pelvic abdominal peritoneum
N80.D0	Endometriosis of other site of abdomen
N80.D1	Endometriosis of the pelvic nerves, unspecified
N80.D2	Endometriosis of the sacral splanchnic nerves
N80.D3	Endometriosis of the sacral nerve roots
N80.D4	Endometriosis of the obturator nerve
N80.D5	Endometriosis of the sciatic nerve
N80.D6	Endometriosis of the pudendal nerve
N80.D9	Endometriosis of the femoral nerve
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
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary

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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate

J1951

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 and J1954

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)

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.

(J1950, J9217, J1952 and J1954)

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6, K	A52453	National Government Services, Inc
J, M	A59160	Palmetto GBA

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