

## Trelstar® (triptorelin pamoate) (Intramuscular)

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### I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months (365 days), unless otherwise specified.
  - Endometriosis/Uterine Leiomyomata (fibroids): Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 12 months (365 days) thereafter, unless otherwise specified.
  - Endometriosis/Uterine Leiomyomata (fibroids): Prior authorization validity may NOT be renewed.
  - Fertility Preservation: Prior authorization validity may be renewed every 12 months (365 days) thereafter, while member is receiving concomitant cytotoxic chemotherapy.

### II. Dosing Limits

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

- Prostate Cancer: 6 billable units (22.5 mg) every 168 days
- Gender Dysphoria: 1 billable unit (3.75 mg) at weeks 0, 2, and 4 and up to 6 billable units (22.5 mg) every 168 days thereafter
- Breast Cancer, Head and Neck Cancer: 3 billable units (11.25 mg) every 84 days
- All Other Indications: 1 billable unit (3.75 mg) every 28 days

### III. Initial Approval Criteria

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age (unless otherwise specified); **AND**

**Prostate Cancer † ‡<sup>1,2</sup>**

**Central Precocious Puberty (CPP) † ‡<sup>9-12,16</sup>**

- Member 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 gonadotropin-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

### **Gender Dysphoria (formerly Gender Identity Disorder) ‡<sup>13,17,18</sup>**

- Member has experienced puberty development to at least Tanner stage 2 (*Note: this applies only to members <18 yrs of age*); **AND**
- Member 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, Text Revision (DSM-5-TR) Criteria §; **AND**
- A qualified MHP\*\* has confirmed all of the following:
  - Member 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 member's situation and functioning are stable enough to start treatment; **AND**
  - Member has sufficient mental capacity to give informed consent to this (reversible) treatment; **AND**
- Member 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**
- Member 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**
- For adolescent members, 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 <sup>18</sup>**

- 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-5-TR Criteria for Gender Dysphoria in Adolescents and Adults <sup>17</sup>**

- 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

#### **Endometriosis ‡ <sup>3,4</sup>**

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

### **Uterine Leiomyomata (fibroids) ‡<sup>8,19</sup>**

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

### **Breast Cancer ‡<sup>2,23</sup>**

- Member 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 (local or regional) or stage IV (M1) disease; **OR**
- Member is a male (sex assigned at birth); **AND**
  - Used in combination with aromatase inhibitor therapy

### **Fertility Preservation While Receiving Chemotherapy ‡<sup>2,20</sup>**

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

### **Head and Neck Cancer ‡<sup>2,21</sup>**

- Member has salivary gland tumors; **AND**
- Used in combination with abiraterone and prednisone; **AND**
- Member has androgen-receptor positive recurrent disease with one of the following:
  - Distant metastases
  - Unresectable locoregional recurrence with prior radiation therapy (RT)
  - Unresectable second primary with prior RT

### **Uterine Neoplasms – Uterine Sarcoma ‡<sup>2</sup>**

- Member has a diagnosis of low-grade stage II-IV endometrial stromal sarcoma (ESS) or adenosarcoma without sarcomatous overgrowth; **AND**
- Member has estrogen receptor/progesterone receptor positive (ER/PR+) disease; **AND**

- Member is premenopausal and not suitable for surgery (i.e. bilateral salpingo-oophorectomy); **AND**
- Used for members with small tumor volume or an indolent growth pace as additional therapy following total hysterectomy; **AND**
- Used in combination with anastrozole, letrozole or exemestane

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

#### IV. **Renewal Criteria** <sup>1</sup>

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

- Member continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Duration of authorization has not been exceeded (*refer to Section I*); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions, tumor flare, severe QT/QTc interval prolongation, metabolic syndrome (hyperglycemia, diabetes mellitus, hyperlipidemia), cardiovascular diseases (e.g., myocardial infarction, stroke, etc.), convulsions, severe cutaneous adverse reactions (including Stevens-Johnson syndrome/toxic epidermal necrolysis [SJS/TEN], drug reaction with eosinophilia and systemic symptoms [DRESS], and acute generalized exanthematous pustulosis [AGEP]), etc.; **AND**

#### **Prostate Cancer; Head and Neck Cancer; Breast Cancer; Uterine Neoplasms – Uterine Sarcoma** <sup>1,2</sup>

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

#### **Central Precocious Puberty (CPP)** <sup>9-12,16</sup>

- Member 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, and a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction

#### **Gender Dysphoria** <sup>13,17</sup>

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

#### **Fertility Preservation While Receiving Chemotherapy** <sup>2,20</sup>

- Member is still receiving treatment with cytotoxic chemotherapy

## V. Dosage/Administration<sup>1,2,18,22,23</sup>

| Indication                          | Dose                                                                                                                                              |
|-------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Prostate Cancer                     | 3.75 mg intramuscularly (IM) once every 4 weeks, 11.25 mg IM once every 12 weeks, or 22.5 mg IM once every 24 weeks                               |
| Breast Cancer, Head and Neck Cancer | 3.75 mg intramuscularly (IM) every 4 weeks or 11.25 mg IM every 12 weeks                                                                          |
| Gender Dysphoria                    | 3.75 mg intramuscularly (IM) at weeks 0, 2, 4 and every 4 weeks thereafter, OR 11.25 mg IM once every 12 weeks, OR 22.5 mg IM once every 24 weeks |
| All other indications               | 3.75 mg intramuscularly (IM) every 4 weeks                                                                                                        |

## VI. Billing Code/Availability Information

### HCPCS Code:

- J3315 – Injection, triptorelin pamoate, 3.75 mg; 1 billable unit = 3.75 mg

### NDC(s):

- Trelstar 3.75 mg single-dose injection kit: 74676-5902-xx
- Trelstar 11.25 mg single-dose injection kit: 74676-5904-xx
- Trelstar 22.5 mg single-dose injection kit: 74676-5906-xx

## VII. References

1. Trelstar [package insert]. Ewing, NJ; Verity Pharmaceuticals, Inc; September 2025. Accessed May 2026.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for triptorelin pamoate. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2026.
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## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription

Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

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

## Appendix 1 – Covered Diagnosis Codes

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

#### Medical Necessity Criteria

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|         |                                                                                 |
|---------|---------------------------------------------------------------------------------|
| 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               |
| C50.A0  | Malignant inflammatory neoplasm of unspecified breast                           |
| C50.A1  | Malignant inflammatory neoplasm of right breast                                 |
| C50.A2  | Malignant inflammatory neoplasm of left breast                                  |
| C54.0   | Malignant neoplasm of isthmus uteri                                             |
| C54.1   | Malignant neoplasm of endometrium                                               |
| C54.2   | Malignant neoplasm of myometrium                                                |
| C54.3   | Malignant neoplasm of fundus uteri                                              |
| C54.8   | Malignant neoplasm of overlapping sites of corpus uteri                         |
| C54.9   | Malignant neoplasm of corpus uteri, unspecified                                 |
| C55     | Malignant neoplasm of uterus, part unspecified                                  |
| C61     | Malignant neoplasm of prostate                                                  |
| D25.0   | Submucous leiomyoma of uterus                                                   |
| D25.1   | Intramural leiomyoma of uterus                                                  |
| D25.2   | Subserosal leiomyoma of uterus                                                  |
| D25.9   | Leiomyoma of uterus, unspecified                                                |
| D37.031 | Neoplasm of uncertain behavior of the sublingual salivary glands                |
| D37.032 | Neoplasm of uncertain behavior of the submandibular salivary glands             |
| D37.039 | Neoplasm of uncertain behavior of the major salivary glands, 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 ( <i>Discontinued effective 10/1/26</i> ) |
| F64.A   | Gender identity disorder, in remission ( <i>Effective 10/1/26</i> )             |
| N80.00  | Endometriosis of the uterus, unspecified                                        |

#### Medical Necessity Criteria

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|         |                                                                |
|---------|----------------------------------------------------------------|
| 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 |
| 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          |

#### Medical Necessity Criteria

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|         |                                                                            |
|---------|----------------------------------------------------------------------------|
| 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)         |
| 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                        |

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|         |                                                                                   |
|---------|-----------------------------------------------------------------------------------|
| 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                           |
| N80.6   | Endometriosis in cutaneous scar                                                   |

|         |                                                                          |
|---------|--------------------------------------------------------------------------|
| N80.9   | Endometriosis, unspecified                                               |
| N80.A0  | Endometriosis of bladder, unspecified depth                              |
| N80.A1  | Superficial endometriosis of bladder                                     |
| N80.A2  | Deep endometriosis of bladder                                            |
| N80.A41 | Superficial endometriosis of right ureter                                |
| N80.A42 | Superficial endometriosis of left ureter                                 |
| N80.A43 | Superficial endometriosis of bilateral ureters                           |
| N80.A49 | Superficial endometriosis of unspecified ureter                          |
| N80.A51 | Deep endometriosis of right ureter                                       |
| N80.A52 | Deep endometriosis of left ureter                                        |
| N80.A53 | Deep endometriosis of bilateral ureters                                  |
| N80.A59 | Deep endometriosis of unspecified ureter                                 |
| N80.A61 | Endometriosis of right ureter, unspecified depth                         |
| N80.A62 | Endometriosis of left ureter, unspecified depth                          |
| N80.A63 | Endometriosis of bilateral ureters, unspecified depth                    |
| N80.A69 | Endometriosis of unspecified ureter, unspecified depth                   |
| N80.B1  | Endometriosis of pleura                                                  |
| N80.B2  | Endometriosis of lung                                                    |
| N80.B31 | Superficial endometriosis of diaphragm                                   |
| N80.B32 | Deep endometriosis of diaphragm                                          |
| N80.B39 | Endometriosis of diaphragm, unspecified depth                            |
| N80.B4  | Endometriosis of the pericardial space                                   |
| N80.B5  | Endometriosis of the mediastinal space                                   |
| N80.B6  | Endometriosis of cardiothoracic space                                    |
| N80.C0  | Endometriosis of the abdomen, unspecified                                |
| N80.C10 | Endometriosis of the anterior abdominal wall, subcutaneous tissue        |
| N80.C11 | Endometriosis of the anterior abdominal wall, fascia and muscular layers |
| N80.C19 | Endometriosis of the anterior abdominal wall, unspecified depth          |
| N80.C2  | Endometriosis of the umbilicus                                           |
| N80.C3  | Endometriosis of the inguinal canal                                      |
| N80.C4  | Endometriosis of extra-pelvic abdominal peritoneum                       |
| N80.C9  | Endometriosis of other site of abdomen                                   |

#### Medical Necessity Criteria

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|        |                                                                 |
|--------|-----------------------------------------------------------------|
| N80.D0 | Endometriosis of the pelvic nerves, unspecified                 |
| N80.D1 | Endometriosis of the sacral splanchnic nerves                   |
| N80.D2 | Endometriosis of the sacral nerve roots                         |
| N80.D3 | Endometriosis of the obturator nerve                            |
| N80.D4 | Endometriosis of the sciatic nerve                              |
| N80.D5 | Endometriosis of the pudendal nerve                             |
| N80.D6 | Endometriosis of the femoral nerve                              |
| N80.D9 | Endometriosis of other pelvic nerve                             |
| Z31.84 | Encounter for fertility preservation procedure                  |
| Z85.3  | Personal history of malignant neoplasm of breast                |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus |
| 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.

| 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 |

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