Field Name	Field Description
Prior Authorization Group Description	**Gonadotropin Releasing Hormone Agonists (GNRH)** ****IF DIAGNOSIS IS CANCER, USE ONCOLOGY CRITERIA****
Drug(s)	**Preferred GNRH Agonist(s) for their respective indications:** Lupron Depot (leuprolide acetate) and Lupron Depot-Ped (leuprolide acetate) **Non-Preferred GNRH Agonist(s):** Fensolvi (leuprolide acetate), Supprelin LA (histrelin acetate), Trelstar (triptorelin pamoate), Triptodur (triptorelin pamoate), and any newly marketed GnRH agonist**.**
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), the American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	See "Other Criteria"
Age Restrictions	According to package insert if not detailed in "Other Criteria"
Prescriber Restrictions	Prescriber must be a specialist in the field to treat the member's condition.
Coverage Duration	If all of the conditions are met, the request will be approved for up to 12 months if diagnosis is central precocious puberty, and up to 3-6 months as indicated below for other indications as recommended per FDA approved indications and/or as defined by the medical compendium or standard of care guidelines.
Other Criteria	**INITIAL AUTHORIZATION for ALL REQUESTS:** • The medication is being prescribed for an FDA approved/standard of care guideline indication and within FDA approved/standard of care dosing guidelines. AND the member meets the following for the respective diagnosis: Central precocious puberty (CPP) • Onset of secondary sexual characteristics occurred when member was aged less than 8 years for females or aged less than 9 years for males • Diagnosis is confirmed by a pubertal response to a GnRH stimulation test and/or measurement of gonadotropins (FSH/LH), and bone age advanced beyond chronological age. o Patients with low or intermediate basal levels of LH should have a GnRH stimulation test to clarify the diagnosis.

	▪ *If basal levels of LH are markedly elevated [e.g. more than 0.3mlU/ml (where IU- International units)] in a child with precocious puberty, then a diagnosis of CPP can be made without proceeding to a GnRH stimulation test*. • Brain magnetic resonance imaging (MRI) has been performed for all boys with CPP and for girls with onset of secondary sexual characteristics before the age of six years of age to rule out a tumor. • If the request is for any agent other than Lupron Depot-Ped the member has had a documented trial and failure with Lupron Depot-Ped or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot-Ped <u>Endometriosis</u> • For all therapies except Lupron, Lupron Depot, or Lupron Depot-Ped, member is ≥ 18 years of age • Member has a confirmed diagnosis (e.g. laparoscopy, etc.) • Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with combined estrogen progestin oral contraceptive pills (OCPs): o If one of the following drugs has been tried previously, a trial of OCPs is not required: progestins, Orilissa (elagolix), danazol, or aromatase inhibitors (e.g. anastrozole, letrozole) • If the request is for any agent other than Lupron Depot/Ped the member has had a documented trial and failure with the preferred agents or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use these medications • Approval is 6 months <u>Uterine leiomyomas (Fibroids)</u> • Member has a confirmed diagnosis (e.g. pelvic examination, etc.) • If the request is for any agent other than Lupron Depot the member has had a documented trial and failure with Lupron Depot or a documented medical reason (e.g. intolerance, hypersensitivity, contraindication) was submitted why the member is not able to use Lupron Depot • Approval is 3 months <u>Endometrial thinning</u> • Member has a confirmed diagnosis (e.g. pelvic examination, etc.)

	• Documentation indicates patient is scheduled for endometrial ablation for dysfunctional uterine bleeding. • Approval is 3 months **<u>REAUTHORIZATION for all requests:</u>** • The medication is being prescribed for an FDA approved indication and within FDA approved dosing guidelines. • Documentation was provided supporting continued treatment (e.g. patient still has symptoms), and medication is being continued as recommended in package insert or standard of care guidelines. <u>AND meets the following per diagnosis:</u> <u>Central precocious puberty (CPP)</u> • If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR a documented medical reason to continue treatment was provided with request, and includes current height and bone age <u>Endometriosis</u> • Provider has evaluated patient for osteoporosis (e.g. Dexascan), and patient is receiving "add back" hormonal therapy (norethindrone acetate 5 mg daily alone or with conjugated estrogen therapy) or an oral bisphosphonate AND calcium and vitamin D supplementation. • The patient has not received cumulative doses of the GnRH agonist greater than 12 months of therapy. <u>Fibroids</u> • The patient has not received cumulative doses of the GnRH agonist greater than 6 months of therapy **NOTE: Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**
Review Date 11/2024	