Gonadotropin-Releasing Hormone Agonists

Goal(s):

- Restrict pediatric use of gonadotropin-releasing hormone (GnRH) agonists to medically appropriate conditions funded under the Oregon Health Plan (e.g., central precocious puberty or gender dysphoria)
- Promote use that is consistent with medical evidence and product labeling

Length of Authorization:

- Up to 6 months

Requires PA:

- GnRH agonists prescribed for pediatric patients less than 18 years of age
- Non-preferred products

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is the diagnosis funded by OHP?	**Yes:** Go to #3	**No:** Current age ≥ 21 years: Pass to RPh. Deny; not funded by the OHP. Current age < 21 years: Go to #3
3. Is the prescriber a pediatric endocrinologist?	**Yes:** Go to #4	**No:** Go to #8
4. What diagnosis is being treated and what is the age and gender of the patient assigned at birth?	Record ICD10 code. Record age and gender assigned at birth	
5. Is the diagnosis central precocious puberty (ICD10 E30.1, E30.8) or other endocrine disorder (E34.9)?	**Yes:** Approve for up to 6 months	**No:** Go to #6
6. Is the diagnosis gender dysphoria (ICD10 F64.2, F64.1)?	**Yes:** Go to #7	**No:** Go to #12

Approval Criteria		
7. Does the request meet **all** of the following criteria? • Diagnosis of gender dysphoria made by a mental health professional with experience in gender dysphoria. • Onset of puberty confirmed by physical changes and hormone levels, but no earlier than Tanner Stages 2. • The prescriber agrees criteria in the Guideline Notes on the OHP List of Prioritized Services have been met.* *From Guideline Note 127: To qualify for cross-sex hormone therapy, the patient must: A) have persistent, well-documented gender dysphoria B) have the capacity to make a fully informed decision and to give consent for treatment C) have any significant medical or mental health concerns reasonably well controlled D) have a comprehensive mental health evaluation provided in accordance with Version 7 of the World Professional Association for Transgender Health (WPATH) Standards of Care (www.wpath.org).	**Yes:** Approve for up to 6 months.	**No:** Pass to RPh; deny for medical appropriateness
8. Is this request for treatment of breast cancer or prostate cancer?	**Yes:** Approve up to 1 year	**No:** Go to #9
9. Is this request for leuprolide for the management of preoperative anemia due to uterine fibroids (leiomyoma)?	**Yes:** Approve for up to 3 months	**No:** Go to #10
10. Is this request for management of moderate to severe pain associated with endometriosis in a woman ≥18 years of age?	**Yes**: Go to #11	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
11. Has the patient tried and failed an adequate trial of preferred first line endometriosis therapy options including administration of combined hormonal contraceptives or progestins (oral, depot injection, or intrauterine) alone? -or- Does the patient have a documented intolerance, FDA-labeled contraindication, or hypersensitivity the first-line therapy options?	**Yes:** Approve for 6 months. *Note maximum recommended duration of therapy for nafarelin, leuprolide, and goserelin is 6 months. If requesting continuation of therapy beyond 6 months, pass to RPh. Deny; medical appropriateness.	**No:** Pass to RPh. Deny; medical appropriateness *First-line therapy options such as hormonal contraceptives or progestins do not require PA
12. RPh only: All other indications need to be evaluated as to whether it is funded under the OHP. Refer unique situations to Medical Director of DMAP. If unfunded and current age is <21, provider must submit documentation for the following: • Medical necessity including documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc). If documentation is not provided, deny; medical necessity. • FDA-approved or compendia-supported indication based on medical literature. If medical literature is not provided, deny; medical appropriateness.		

P&T / DUR Review: *12/21 (DM); 3/19 (DM); 5/15*
Implementation: *1/1/22; 5/1/19*