# Gonadotropin-Releasing Hormone (GnRH) Agonists

**Included Products:** Camcevi (leuprolide mesylate), Eligard (leuprolide in Atrigel), Fensolvi (leuprolide), Leuprolide Acetate, Lupron (leuprolide), Lupron Depot (leuprolide), Lupron Depot-PED (leuprolide), Supprelin LA (histrelin implant), Trelstar (triptorelin), Vantas (histrelin implant), Zoladex (goserelin implant)

***Lupron and Lupaneta may be covered with PA on the outpatient benefit. All others are nonformulary on outpatient benefit. PA for all required for medical benefit.***

*Created:* 01/11/2018 *Revised:* 11/09/23 *Reviewed:* 11/09/23 *Updated:* 12/01/2023

## All Diagnoses

| Initial Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Is the diagnosis a type of cancer? | Continue to cancer criteria. | Continue to #2. |
| **2.** | Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age? | Continue to #3. | Do not approve. |
| **3.** | Has the treatment been initiated by or is an appropriate specialist currently supervising it?<br>a. Cancer: Hematologist/Oncologist<br>b Endometriosis: Obstetrician/Gynecologist<br>c Gender Dysphoria: Pediatric Endocrinologist<br>d. Leiomyoma: Obstetrician/Gynecologist<br>e. Precocious Puberty: Pediatric Endocrinologist | Continue to #4. | Do not approve. |
| **4.** | Proceed to specific criteria for the submitted indication. | | |

## Cancer

| Initial Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Is the medication being prescribed by an oncologist for a cancer diagnosis? | Continue to #2. | Do not approve. |
| **2.** | Is the member new to CareOregon and already receiving the medication for a cancer diagnosis? | Continue to #6. | Continue to #3. |

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| **3.** | Is the treatment supported for the diagnosis in the NCCN guidelines? | Continue to #5. | Continue to #4. |
| **4.** | Is the treatment being used according to the FDA indication for the requested product? | Continue to #5. | Do not approve. |
| **5.** | Does the request meet criteria for treatment coverage specified in Guideline Note 12 of the Prioritized List of Health Services, considering treatment of cancer with little or no benefit? | Continue to #6. | Do not approve. |
| **6.** | Approve for 12 months. | | |
| **Renewal Criteria** | | **If yes** | **If no** |
| **1.** | Is the requested medication being continued by an oncologist for a cancer diagnosis? | Continue to #2. | Do not approve. |
| **2.** | Approve for 12 months. | | |

## Endometriosis

| Initial Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Does the member have a detailed operative description or histologic diagnosis of endometriosis? | Continue to #2. | Do not approve. |
| **2.** | Has the member tried and failed or have contraindications to hormonal therapies (combined oral contraceptives, progestins, or levonorgestrel IUD)? | Continue to #3. | Do not approve. |
| **3.** | Is the request for initial treatment (member is treatment naïve)? | Continue to #5. | Continue to #4. |
| **4.** | Is the request for Lupaneta or is norethindrone add-back therapy also prescribed? | Continue to #5. | Do not approve. |
| **5.** | Approve for 6 months. | | |
| **Renewal Criteria** | | **If yes** | **If no** |
| **1.** | Is the request for Lupaneta or is norethindrone add-back therapy also prescribed? | Continue to #2. | Do not approve. |

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| **2.** | Has the total length of use of GnRH agonist therapy been less than 12 months? | Continue to #3. | Do not approve. |
| **3.** | Approve for 6 months. | | |

## Gender Dysphoria

| Initial Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Is the request for use in delaying the onset of puberty and/or continued pubertal development in a child or adolescent (younger than 18 years of age) with a diagnosis of gender dysphoria? | Continue to #2. | Continue to #7. |
| **2.** | Is the use for delaying the onset of puberty? | Continue to #3. | Continue to #4. |
| **3.** | Has the member reached Tanner stage 2, with documentation that the first physical changes of puberty have occurred? | Continue to #8. | Continue to #7. |
| **4.** | Is the request for continued delay of pubertal development in an adolescent who started titrating cross-sex hormones before age 18 but after reaching Tanner stage 5 in the gender they were assigned at birth? | Continue to #5. | Continue to #7. |
| **5.** | Has it been more than two years from initiation of cross-sex hormones? | Continue to #7. | Continue to #6. |
| **6.** | Has it been more than one year from initiation of cross-sex hormones? | Approve until two years of cross-sex hormone therapy has been completed. | Continue to #8. |
| **7.** | This case is identified as possibly not being aligned with standards of care. CareOregon will review with a specialist with expertise in gender-affirming care. Based on that review, is this use consistent with standards of care? | Approve until the appropriate duration as specified in the review or requested | Do not approve. |
| **8.** | Approve for 12 months. | | |
| **Renewal Criteria** | | **If yes** | **If no** |
| **1.** | Is the use for delaying the onset of puberty? | Continue to #2. | Continue to #4. |

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|---|---|---|---|
| **2.** | Is the member age less than 17? | Continue to #8. | Continue to #3. |
| **3.** | Is member age less than 18? | Approve until the member turns 18. | Continue to #7. |
| **4.** | Is the request for continued delay of pubertal development in an adolescent who started titrating cross-sex hormones before age 18 but after reaching Tanner stage 5 in the gender they were assigned at birth? | Continue to #5. | Continue to #7. |
| **5.** | Has it been more than two years from initiation of cross-sex hormones? | Continue to #7. | Continue to #6. |
| **6.** | Has it been more than one year from initiation of cross-sex hormones? | Approve until two years of cross-sex hormone therapy has been completed. | Continue to #8. |
| **7.** | This case is identified as possibly not being aligned with standards of care. CareOregon will review with a specialist with expertise in gender-affirming care. Based on that review, is this use consistent with standards of care? | Approve until the appropriate duration as specified in the review or requested | Do not approve. |
| **8.** | Approve for 12 months. | | |

## Leiomyoma (Uterine Fibroids)

| Initial Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Does the member have a diagnosis of uterine leiomyoma (fibroids)? | Continue to #2. | Do not approve. |
| **2.** | Is the request for preoperative hematologic treatment of anemia caused by fibroids? | Continue to #3. | Do not approve. |
| **3.** | Is the request for initial treatment (member is treatment naïve)? | Continue to #4. | Do not approve. |
| **4.** | Approve for 3 months. | | |

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# Precocious Puberty

| Initial Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Is the request for a leuprolide containing product? | Continue to #3. | Continue to #2. |
| **2.** | Has a leuprolide product been tried and failed or is there a clinical reason to avoid leuprolide? | Continue to #3. | Do not approve. |
| **3.** | Is the request for Fensolvi? | Continue to #4. | Continue to #5. |
| **4.** | Is there a reason why Lupron can't be used? | Continue to #5. | Do not approve. |
| **5.** | Is the request being initiated by or supervised by a pediatric endocrinologist? | Continue to #6. | Do not approve. |
| **6.** | Does the member have a diagnosis of central precocious puberty? | Continue to #7. | Do not approve. |
| **7.** | Is the member age less than 11 for females and 12 for males? | Continue to #8. | Do not approve. |
| **8.** | Approve up to 12 months until age 11 for females and age 12 for males. | | |

| Renewal Criteria | | If yes | If no |
|---|---|---|---|
| **1.** | Does the member have a diagnosis of central precocious puberty? | Continue to #2. | Do not approve. |
| **2.** | Is the member age less than 11 for females and 12 for males? | Continue to #3. | Do not approve. |
| **3.** | Approve up to 12 months until age 11 for females and age 12 for males. | | |