### PRIOR AUTHORIZATION CRITERIA

**Gonadotropin-Releasing Hormone (GnRH) Agonists**

<table>
<thead>
<tr>
<th>Medication Class:</th>
<th>GONADOTROPINS</th>
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<tr>
<td>Review Date:</td>
<td>7/24/2020</td>
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<tr>
<td>Available Through:</td>
<td>X Medical Benefit</td>
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- Gonadotropin-releasing hormone (GnRH) agonists may be indicated for **1 or more** of the following:
  - Assisted reproductive technology (eg, female patient undergoing in vitro fertilization)[17](18)(19)(20)
  - Cancer, as indicated by **1 or more** of the following:
    - Adjuvant therapy needed, [8] and **ALL** of the following[27](28)[34]:
      - Administered in combination with tamoxifen or an aromatase inhibitor (eg, exemestane)
      - Lymph node-positive disease that is either estrogen receptor-positive or progesterone receptor-positive
      - Patient is premenopausal.
    - Advanced disease, [8] and **ALL** of the following[1]:
      - Palliative treatment
      - Patient is premenopausal or perimenopausal.
  - Prostate cancer, as indicated by **1 or more** of the following[3](35)(37)(38)(39):
    - Intermediate-risk, high-risk, or very high-risk disease, as indicated by **1 or more** of the following[45](46)(47)(48):
      - International Society of Urological Pathology (ISUP) Grade Group 2 to 5 (Gleason score of 7 to 10)[49]
      - Pretreatment PSA of 10 ng/mL (mcg/L) or greater
      - Stage T2b/T2c, stage T3a/T3b, or stage 4 prostate cancer
    - Metastatic prostate cancer (ie, bone or other metastasis)[50](51)(52)(53)(55)
  - Central precocious puberty, as indicated by **ALL** of the following[2](56)(57)(59)(62)(66)(67):
    - Advanced bone age or accelerated growth velocity[1]
    - Precocious puberty signs or symptoms, as indicated by **1 or more** of the following[76]:
      - Female with **ALL** of the following:
        - Age between 2 and 8 years when signs or symptoms of precocious puberty appear
        - Breast development Tanner stage 2 or greater
        - Increased uterine volume (longitudinal diameter 3.4 cm or greater) on pelvic ultrasound[5]

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- Menstrual bleeding or vaginal discharge
- No pregnancy
- No undiagnosed abnormal vaginal bleeding
  - Male with ALL of the following:
    - Age between 2 and 9 years when signs or symptoms of precocious puberty appear
    - Signs and symptoms, as indicated by 1 or more of the following:
      - Acne
      - Erections
      - Nocturnal emissions
      - Oily skin
    - Testicular volume 4 mL or greater
      - Other causes of precocious puberty ruled out by appropriate hormonal and imaging studies (eg, congenital adrenal hyperplasia)(5)
      - Pubertal gonadal sex steroid levels(5)
      - Pubertal LH response to stimulation by native GnRH(77)
  - Dysfunctional uterine bleeding, as indicated by ALL of the following(5)(1)(78):
    - Prior to planned endometrial ablation for definitive treatment
    - No current breast-feeding
    - No pregnancy currently or anticipated while receiving medication
    - Other causes of symptoms or bleeding ruled out (eg, by endometrial biopsy)
  - Endometriosis, as indicated by ALL of the following(6)(1)(2)(79)(80)(81)(82):
    - Age 18 years or older
    - Endometriosis symptoms, as indicated by 1 or more of the following:
      - Dysmenorrhea
      - Dyspareunia
      - Pelvic pain
      - Failure of NSAIDs and oral contraceptives to control symptoms
      - No current breast-feeding
      - No pregnancy currently or anticipated while receiving medication
      - No vaginal bleeding of unknown cause
  - Gender dysphoria, as indicated by ALL of the following(85)(86)(87):
    - Confirmed diagnosis of gender dysphoria by mental health professional with expertise in child and adolescent psychology(90)
    - Laboratory testing confirms pubertal levels of gonadotropins or sex steroids (eg, estradiol in female or testosterone in male).
    - Pubertal development of Tanner stage 2 or greater
  - Uterine leiomyomas (fibroids), as indicated by ALL of the following(79)(91):
    - Age 18 years or older
    - Goal to reduce leiomyoma (fibroid) size or bleeding prior to operative intervention(94)

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- Leiomyoma symptoms, as indicated by 1 or more of the following:
  - Abnormal uterine bleeding
  - Bulk-related symptoms (eg, pelvic pain or pressure, dyspareunia, urinary symptoms)
  - Iron deficiency anemia
- No current breast-feeding
- No pregnancy currently or anticipated while receiving medication
- Other causes of symptoms or bleeding ruled out (eg, by endometrial biopsy)

### CPT-Codes/HCPCS Codes/ICD-10 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
</tr>
<tr>
<td>J1950</td>
<td>Injection, leuprolide acetate (for depot suspension), per 3.75 mg</td>
</tr>
<tr>
<td>J3315</td>
<td>Injection, triptorelin pamoate, 3.75 mg</td>
</tr>
<tr>
<td>J3316</td>
<td>Injection, triptorelin, extended-release, 3.75 mg</td>
</tr>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J9202</td>
<td>Goserelin acetate implant, per 3.6 mg</td>
</tr>
<tr>
<td>J9217</td>
<td>Leuprolide acetate (for depot suspension), 7.5 mg</td>
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<tr>
<td>J9218</td>
<td>Leuprolide acetate, per 1 mg</td>
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<tr>
<td>J9219</td>
<td>Leuprolide acetate implant, 65 mg</td>
</tr>
<tr>
<td>J9226</td>
<td>Histrelin implant (supprelin la), 50 mg</td>
</tr>
<tr>
<td>S9560</td>
<td>Home injectable therapy; hormonal therapy (e.g.; leuprolide, goserelin), including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem</td>
</tr>
</tbody>
</table>

### REFERENCES:

1. Zoladex (goserelin acetate implant) 3.6 mg. Physician Prescribing Information [Internet] AstraZeneca Pharmaceuticals LP. 2019 Feb Accessed at: https://www.zoladex.com/. [created 1989; accessed 2019 Nov 22] [ Context Link 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 ]

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36. Ishizuka O, et al. Comparison of efficacy and safety of 1- and 3-month luteinizing hormone-releasing hormone agonist depot as initial therapies for prostate cancer. International

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42. Ostergren PB, et al. Luteinizing hormone-releasing hormone agonists are superior to subcapsular orchiectomy in lowering testosterone Levels of Men with Prostate Cancer: Results from a Randomized Clinical Trial. Journal of Urology 2017;197(6):1441-1447. DOI: 10.1016/j.juro.2016.12.003. [Context Link 1] [View abstract...]


46. Sasse AD, Sasse E, Carvalho AM, Macedo LT. Androgenic suppression combined with radiotherapy for the treatment of prostate adenocarcinoma: a systematic review. BMC Cancer 2012;12:54. DOI: 10.1186/1471-2407-12-54. [Context Link 1] [View abstract...]

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61. Silverman LA, et al. Long-term continuous suppression with once-yearly histrelin subcutaneous implants for the treatment of central precocious puberty: A final report of a phase 3 multicenter trial. Journal of Clinical Endocrinology and Metabolism 2015;100(6):2354-63. DOI: 10.1210/jc.2014-3031. [Context Link](1, 2) [View abstract...](1, 2)


63. Triptorelin (Triptodur) for central precocious puberty. Medical Letter on Drugs and Therapeutics 2018;60(1537):7-8. [Context Link](1) [View abstract...](1)


68. Long D. Precocious puberty. Pediatrics in Review 2015;36(7):319-21. DOI: 10.1542/pir.36-7-319. [Context Link](1) [View abstract...](1)


71. Li P, Li Y, Yang CL. Gonadotropin releasing hormone agonist treatment to increase final stature in children with precocious puberty: a meta-analysis. Medicine 2014;93(27):e260. DOI: 10.1097/MD.0000000000002620. [Context Link](1) [View abstract...](1)

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78. Tan YH, Lethaby A. Pre-operative endometrial thinning agents before endometrial destruction for heavy menstrual bleeding. Cochrane Database of Systematic Reviews 2013, Issue 11. Art. No.: CD010241. DOI: 10.1002/14651858.CD010241.pub2. [ Context Link 1, 2 ] View abstract...
81. Dysmenorrhea and endometriosis in the adolescent: ACOG Committee Opinion No. 760. Obstetrics & Gynecology 2018;132(6):e249-e258. DOI: 10.1097/AOG.0000000000002978. (Reaffirmed 2019 Jan) [ Context Link 1, 2 ] View abstract...

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