Zoladex® (goserelin acetate)

**Effective:** 9/1/15

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<th>Clinical documentation and prior authorization required</th>
<th>✓</th>
<th>Type of review – case management</th>
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<td>Fax: 617-673-0988</td>
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<td>MED/RX</td>
<td>Department to review</td>
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**OVERVIEW**

**FDA-APPROVED INDICATIONS**

Zoladex (goserelin acetate implant) is indicated for:

- Use in combination with flutamide for the management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate. Treatment with Zoladex and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy.
- The palliative treatment of advanced carcinoma of the prostate.
- The management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with Zoladex for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months.
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.
- Use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women.

**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of Zoladex (goserelin acetate implant) for members when all the following criteria are met and limitations do not apply:

1. The medication is being prescribed for one of the following diagnoses:
   - Prostate carcinoma
   - Breast carcinoma
   - Endometriosis
   - Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.

**LIMITATIONS**

1. Initial requests will be approved for the following quantity limits and durations:
   - Prostate carcinoma or Breast carcinoma: One 3.6 mg depot per month for 1 year duration.
   - B2-C Prostatic Carcinoma: One 3.6 mg depot per month or 10.8 mg depot per 3 months for 1 year.
   - Endometriosis: One 3.6 mg depot per month for 6 months.
   - Endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding: Two 3.6 mg depots.

2. Renewal requests will be approved as follows:
   - Prostate carcinoma or Breast carcinoma: One 3.6 mg depot per month for 1 year duration.
   - B2-C Prostatic Carcinoma: One 3.6 mg depot per month or 10.8 mg depot per 3 months for 1 year.

**CODES**

The following HCPCS/CPT code(s) are:

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<th>Code</th>
<th>Description</th>
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<tr>
<td>J9202</td>
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**REFERENCES**


**APPROVAL HISTORY**

- 8/12/14: Reviewed by the Pharmacy and Therapeutics Committee.
- 8/11/11: No changes.

**BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION**

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.