Goserelin Acetate / Zoladex

Description:

Goserelin Acetate 10.8 mg or Zoladex 3.6 mg is used in men to treat prostate cancer and Zoladex 3.6 mg is used in women to treat certain types of breast cancer or uterine disorders. It is also used in women to thin the lining of the uterus in preparation for surgery. This is an implant that slowly releases hormone into the body and is placed under the skin of the lower abdomen below the navel. The implant completely absorbs into the body over weeks or months.\textsuperscript{3} Initial U.S. approval 1989.

Administrative Criteria:

1. Requires referral from Primary Care Physician (PCP) and supporting medical documentation must accompany request. Documentation must include the following (not all inclusive):
   a. Member’s name
   b. Plan ID#
   c. Radiology or other diagnostic tests results
   d. Applicable ICD-9 and CPT-4 codes
   e. Attending provider’s name
2. Member must have current eligibility on Date of Service
3. Procedure must be performed by a THC contracted provider and at a contracted facility
4. Independent second opinion review with applicable specialist (e.g. oncologist) is required

Prior Authorization Guidelines:

Goserelin Acetate and Zoladex require prior authorization by THC. The final decision rests with the Medical Director. Approval will be based on eligibility, documentation demonstrating medical necessity. THC reserves the right to refer the member for an independent second medical opinion to assist in the decision-making process.

Policy/Criteria:

Total Health Care considers Goserelin Acetate or Zoladex medically necessary for the following FDA approved indications:

- Palliative treatment of advanced carcinoma of the prostate\textsuperscript{1}
- Use in combination with flutamide for the management of locally confined carcinoma of the prostate (stage B2-C)\textsuperscript{1}
- The management of endometriosis\textsuperscript{1}
- Use as an endometrial thinning agent prior to endometrial ablation for dysfunctional uterine bleeding\textsuperscript{1}
- Use in the palliative treatment of advanced breast cancer in premenopausal and perimenopausal women.\textsuperscript{1}
For the purpose of determining if advanced disease or palliative, the treating physician must provide documentation to establish an approved diagnosis. Clinical documentation must be submitted with the request for prior authorization and must include:

- Detailed history and physical, including initial and current stage of the disease
- Physician progress notes
- Prior treatment, including type of treatment, length of treatment trial and patient response

In addition, THC *may* consider requests for Goserelin Acetate/Zoladex for off label uses on a case-by-case basis when submitted documentation demonstrates medical necessity and clinical decision criteria is satisfied. THC utilizes criteria derived from evidenced based medicine and nationally accepted Standards of Care. Additional factors taken into consideration during the clinical review process include (not all inclusive):

a. Age  
b. Pertinent past and current medical history  
c. Current treatment and progress  
d. Prior treatment, including type of treatment, length of treatment trial and patient response  
e. Diagnostic testing including any results related to the condition

Bibliography

1 FDA  
2 WebMD