



## Prior Authorization Approval Criteria

*Department of Pharmacy Services*

**Generic Name:** abarelix

**Brand Name:** Plenaxis

**FDA Approved Uses:** Palliative treatment of men with advanced symptomatic Prostate Cancer.

**Medication Class:** gonadotropin-releasing hormone antagonist

**Usual Doses:** 100mg SC on days-1, -15, and -29, then every 28days thereafter.

**Duration of Therapy:** The effectiveness of abarelix beyond 12 months has not been established. (see approval for continuation of therapy)

**Approximate yearly cost** (based on ASP 2006): \$8,829.00

**Similar drugs:** Cetrorelix acetate, Ganirelix acetate, Leuprolide acetate, Goserelin, Triptorelin

**Criteria for Use:** *(bullet point below are all inclusive unless otherwise noted)*

If patient meets criteria, the initial approval will be for 3 months. To continue therapy beyond that time the physician must supply documentation stating goals of treatment along with objective and subjective data as to the patient's progress. (please see below under continuation of therapy)

- Only physicians enrolled in the Plenaxis PLUS program (Plenaxis User Safety Program) may prescribe abarelix because of immediate onset allergic reactions.
- Clinically diagnosed advanced prostate cancer.
- Patient unable to take luteinizing hormone-releasing hormone (LHRH) agonists due to at least one or more of the following:
  - Risk of neurological compromise due to metastases
  - Ureteral or bladder outlet obstruction due to local encroachment or metastatic disease
  - Severe bone pain from skeletal metastases persisting on narcotic analgesia.
- Patients in whom surgical castration is not an option.

*Clinical information that must be obtained:*

- Baseline serum testosterone levels and prostate-specific antigen (PSA) levels should be measured prior to treatment.
- Baseline pain score and/or analgesic use.
- Baseline information about Ureteral or bladder obstruction. (ex. does patient have a urinary catheter in place?)
- Baseline information regarding risk of neurological compromise.

**Criteria for Continuation of Therapy:**

- Decrease in testosterone to castrate levels\* ( $\leq 50$ ng/ml).
- Decrease in PSA levels.



- Improvement in pain score and/or analgesic use.
- Improvement in urinary obstruction, hydronephrosis, azotemia and/or removal of urinary catheter.
- Absence of impending neurological compromise with spinal cord compression.

\*In some patients the effectiveness to suppress testosterone to castrate levels declined with increased duration of treatment. The decrease in effectiveness was greater in patients who weighed more than 225 pounds.

- If the patient experiences treatment failure while on Abarelix, therapy will be discontinued.
  - Treatment failure can be detected by:
    - An increase in testosterone levels above 50ng/ml. Serum testosterone should be measured just prior to administration on day 29 and every 8 weeks thereafter. If patient weighs more than 225 pounds strict monitoring is recommended.

**Contraindications:**

- Hypersensitivity reactions to any ingredients in the abarelix injectable suspension.
- Not indicated in women or pediatric patients.

**Not approved if:**

- Patient does not meet the above stated criteria and continuation of therapy criteria.
- Patient has any contraindications to the use of Abarelix.

**Rational:** Most studies observed a 68-79% decrease in testosterone levels to castrate levels of  $\leq 50$ ng/ml by day 8, and about 90-96% by day 29, 85-97% by day 85.<sup>1-8</sup> Failure was defined as any observed serum testosterone concentration greater than 50ng/ml on two consecutive readings at least 2 weeks apart.<sup>5-8</sup> When failure was observed, effectiveness was observed to decline over time. In most studies, patients continued treatment for 24-48 weeks and the maximum was 96 weeks. From day 85 maintenance of medical castration declined.<sup>2, 4-8</sup>

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_