



Medical Policy Manual **Approved: Do Not Implement Until 12/12/09**

Degarelix Acetate

DESCRIPTION

Degarelix acetate is a gonadotropin releasing hormone (GnRH) receptor antagonist. It binds reversibly to the pituitary GnRH receptors resulting in decreased release of gonadotropins. Subcutaneous degarelix administration causes a decrease in plasma concentrations of luteinizing hormone and follicle stimulating hormone with subsequent lower testosterone levels. Testosterone suppression levels after treatment with degarelix are comparable to levels seen after surgical castration.

An example of a preparation of degarelix acetate is Firmagon®.

REFER TO DECISION SUPPORT TREE

POLICY

- Degarelix for the treatment of prostate cancer is considered **medically necessary** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
- Degarelix for the treatment of other conditions/diseases is considered **investigational**.

MEDICAL APPROPRIATENESS

- Degarelix for the treatment of prostate cancer is considered **medically appropriate** if the disease is advanced.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

Tennessee State law requires coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is relative to life-threatening illnesses, such as cancer, AIDS, and coronary heart disease and recognized in one of the standard reference compendia (As defined in the statute: The United States Pharmacopoeia Drug Information, The American Medical Association Drug Evaluations, & The American Hospital Formulary Service Drug Information) or in the medical literature. This law is applicable to all fully insured members. The law is not applicable to self-funded accounts, but coverage for off-label uses may be provided based on the contractual agreement.

ADDITIONAL INFORMATION

For appropriate dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., The American Hospital Formulary Service Drug Information).

Evaluation of advanced prostate cancer is determined by various means and combinations of tests, including, but not limited to, the TNM staging system documenting the extent of the tumor, lymph node involvement and metastasis; the Gleason scoring system; radiological testing for bone metastasis; and transrectal ultrasound.

No controlled studies were found in the published literature that validate the use of degarelix in the treatment of other conditions/diseases.

SOURCES



BlueCross BlueShield
of Tennessee

Policy

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MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2009). *Degarelix*. Retrieved June 23, 2009 from MICROMEDEX Healthcare Series.

U. S. Food and Drug Administration. (2008, December). Center for Drug Evaluation and Research. *Tradenam[®] (degarelix for injection) for subcutaneous administration*. Retrieved June 23, 2009 from <http://www.fda.gov/cder/foi/label/2008/022201lbl.pdf>.

EFFECTIVE DATE 12/12/2009

ID_BT



**BlueCross BlueShield
of Tennessee**

Pharmaceutical Decision Support Tree

Degarelix Acetate

1. Does the individual have a diagnosis of prostate cancer?

If yes, go to question # 2

If no, this does not meet medical necessity and/or medical appropriateness criteria

2. Is the disease advanced?

If yes, this satisfies medical necessity and medical appropriateness criteria

If no, this does not meet medical necessity and/or medical appropriateness criteria