TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Degarelix acetate (Firmagon)	**CRITERIA ID:** TX.CC.PHAR.34
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 05/03/2024	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 05/03/2024, 03/20/2025	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for degarelix acetate (Firmagon).

PURPOSE:
To provide clinical criteria standards which align with FDA approved indication(s) and/or established practice guidelines for prior authorization review. Prior authorization is required to determine medical necessity of the requested drug(s), which ensures safety, clinical appropriateness and cost-effectiveness while maintaining optimal therapeutic outcomes.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) that Degarelix Acetate (Firmagon) is medically necessary when the clinical criteria, as listed below, are met.

Description/Mechanism of Action:
Degarelix acetate (Firmagon®) is a gonadotropin-releasing hormone (GnRH) receptor antagonist.

FDA Approved Indication(s):
Firmagon is indicated for treatment of advanced prostate cancer.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of prostate cancer;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a, b, or c):*

a. Starting dose does not exceed 240 mg given as two injections of 120 mg each;
b. Maintenance dose does not exceed 80 mg as a single injection per 28 days;
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications:

1. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III below (Diagnoses/Indications for which coverage is NOT authorized), refer to the off-label use policy CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Firmagon for prostate cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following:*
   a. New dose does not exceed 80 mg as a single injection per 28 days;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications:

1. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III below (Diagnoses/Indications for which coverage is NOT authorized), refer to the off-label use policy CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 or evidence of coverage documents.

B. The following are conditions for which treatment with degarelix acetate is considered not medically necessary:

1. Transsexualism (F64.0);
2. Dual role transvestism (F64.1);
3. Gender identity disorder of childhood (F64.2);
4. Other gender identity disorders (F64.8);
5. Gender identity disorder, unspecified (F64.9);

REFERENCES:

CP.PHAR.170 Degarelix Acetate (Firmagon)
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	Created from Corporate criteria to align with TMHP guidance on Senate Bill 14 – Section III. B. added.	05/03/2024
Annual Review	No Changes	03/20/2025