MEDICAL MUTUAL®

Drug Policy

Policy:	**Gonadotropin Releasing Hormone (GnRH) Antagonists**	**Annual Review Date:** **07/18/2024**
Impacted Drugs:	• Generic ganirelix acetate subcutaneous injection • Fyremadel® (ganirelix acetate subcutaneous injection – Ferring; generic only)	**Last Revised Date:** **07/18/2024**

OVERVIEW

Cetrotide and Ganirelix are synthetic decapeptides that are analogs of native gonadotropin releasing hormone (GnRH) with GnRH antagonist activity. GnRH induces the production and release of LH and follicle stimulating hormone (FSH) from the anterior pituitary. Both agents compete with natural GnRH for binding to membrane receptors on pituitary cells and control the release of LH and FSH in a reversible manner.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one preferred product within the 130-day look-back period is excluded from this program.

Preferred Medication

- Cetrotide (cetrorelix acetate)

Non-Preferred Medication

- Generic Fyremadel
- Generic ganirelix acetate subcutaneous injection

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria

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Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period; OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent); OR
    3. There are no generic alternatives to the requested non-preferred agent

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cetrotide [prescribing information]. Rockland, MA: EMD Serono, Inc.; May 2018.
2. Ganirelix acetate injection [prescribing information]. Whitehouse Station, NJ: Merck & Co.; March 2019.

3. Cetrorelix acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 14 June 2021. Accessed on 12 July 2021.
4. Ganirelix acetate. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 14 June 2021. Accesssed on 12 July 2021.