This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4257-D

POLICY Document for ELIGARD

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA

GONADOTROPIN RELEASING HORMONE AGONISTS

PREFERRED PRODUCTS: ELIGARD, FIRMAGON

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the gonadotropin releasing hormone agonist products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Gonadotropin releasing hormone agonists

	Product(s)
Preferred	• **Eligard** (leuprolide acetate) • **Firmagon** (degarelix)
Targeted	• **Lupron Depot** (leuprolide acetate for depot suspension) • **Trelstar** (triptorelin) • **Zoladex** (goserelin acetate)

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B
	Standard Opt-out		ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First
	VF		Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on

Reference #
4257-D

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for prostate cancer.

Coverage for a targeted product is provided when either of the following criteria is met:

A. Member has received treatment with a targeted product in the past 365 days.
B. Member has a documented hypersensitivity to all of the preferred products.

Section 2: Clinical Criteria

JURISDICTION SPECIFIC MEDICARE PART B

ELIGARD (leuprolide acetate)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications are listed below:

Prostate cancer

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
4257-D

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. Relevant medical history
B. Physical examination
C. Results of pertinent diagnostic tests
D. Any relevant procedures

III. CRITERIA FOR APPROVAL

Prostate Cancer

Authorization of 12 months may be granted for treatment of advanced prostate cancer when orchiectomy and/or estrogen administration is either not indicated or is unacceptable to the member.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

REFERENCES:

SECTION 1

1. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; September 2019.
2. Firmagon [package insert]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; February 2020.
3. Lupron Depot [package insert]. North Chicago, IL: AbbVie; March 2019.
4. Trelstar [package insert]. Madison, NJ: Allergan USA, Inc.; May 2020.
5. Zoladex [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; February 2019.

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
4257-D

SECTION 2

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L34822) Version R6. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed July 1, 2020.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed July 1, 2020.
3. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; April 2019.