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 TRELSTAR

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

TRELSTAR (triptorelin pamoate)

POLICY

I. INDICATIONS

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

A. FDA-Approved Indication
Trelstar is indicted for the palliative treatment of advanced prostate cancer

B. Compendial Uses
1. Prostate cancer
2. Gender dysphoria[3]
3. Endometrial hyperplasia
4. Endometriosis[3]
5. Fibrocystic breast changes
6. Uterine leiomyoma

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. CRITERIA FOR INITIAL APPROVAL

A. Prostate cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

B. Gender dysphoria
Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

1. The member has a diagnosis of gender dysphoria.
2. The member has reached Tanner stage 2 of puberty or greater.

C. Endometrial hyperplasia
Authorization of 12 months may be granted for treatment of non-atypical endometrial hyperplasia

D. Endometriosis
Authorization of up to 6 months total therapy may be granted for treatment of endometriosis.

E. Fibrocystic breast changes
Authorization of 3 months may be granted for treatment of benign fibrocystic mastopathy when one of the following criteria is met:

1. The requested drug will be used as a single agent
2. The requested drug will be used in combination with tamoxifen or cyproterone.

F. Uterine Leiomyoma
Authorization of up to 6 months total therapy may be granted for treatment of uterine fibroids.

III. CONTINUATION OF THERAPY

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 #
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All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

A. Prostate cancer, gender dysphoria, endometrial hyperplasia, fibrocystic breast changes
Authorization for 12 months may be granted when all of the following criteria are met:

1. The member is currently receiving therapy with Trelstar.
2. The member is receiving benefit from therapy.

B. All other indications
All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

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.

SECTION 2

1. Trelstar [package insert]. Madison, NJ: Allergan Inc.; May 2020.
2. The NCCN Drugs & Biologics Compendium® © 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 8, 2020. Trelstar. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed September 8, 2020.