MetroPlus Health

Policy and Procedure

Title: Zoladex	Division: Medical Management Department: Utilization Management
Approval Date: 5/31/2022	LOB: Medicaid, HIV SNP, HARP
Effective Date: 5/31/2022	Policy Number: UM-MP336
Review Date: 5/31/2023	Cross Reference Number:
Retired Date:	Page 1 of 5

1. **POLICY DESCRIPTION:**
   Antineoplastic Agent- Gonadotropin-Releasing Hormone Agonist, Zoladex (goserelin acetate)

2. **RESPONSIBLE PARTIES:**
   Medical Management Administration, Utilization Management, Integrated Care Management, Pharmacy, Claim Department, Providers Contracting.

3. **DEFINITIONS:**
   Zoladex is a synthetic decapeptide luteinizing hormone-releasing hormone (LHRH) agonist analogue. It inhibits and suppresses the pituitary gonadotropin secretion.

4. **POLICY:**

Initial Request:

A. Member cannot obtain the medication through the patient assistance program (see Appendix A on enrollment) **AND**
B. Use for an FDA-approved indication for which there are no alternative options: (see Appendix B)

   a. Breast cancer, For palliation of advanced disease in pre- and peri-menopausal women
   Approved x 12 months

   b. Abnormal uterine bleeding, Endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding
   Approved x 2 doses

Note: If TerSera denies a patient enrollment in the patient assistance program the request for plan coverage should follow the medical exception review process and be approved only if there is no alternate therapy available. Plans should document why the drug is not covered by the patient assistance program as well as justification for coverage by the plan including strong clinical support and reason an alternate therapy cannot be used.

Renewal Request:

A. Member cannot obtain the medication through the patient assistance program (see Appendix A on enrollment) **AND**
B. Another gonadotropin-releasing hormone (GnRH) product (i.e: leuprolide, histrelin, triptorelin) has been tried and failed **OR** if transition to another GnRH is medically contraindicated **AND**

C. Use for an FDA-approved indication for which there are no alternative options: (see Appendix B)

a. Breast cancer, For palliation of advanced disease in pre- and peri-menopausal women
Approved x 12 months

b. Abnormal uterine bleeding, Endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding
Approved x 2 doses

Note: If TerSera denies a patient enrollment in the patient assistance program the request for plan coverage should follow the medical exception review process and be approved only if there is no alternate therapy available. Plans should document why the drug is not covered by the patient assistance program as well as justification for coverage by the plan including strong clinical support and reason an alternate therapy cannot be used.

5. LIMITATIONS/ EXCLUSIONS:

N.A

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J9202	Goserelin acetate implant, per 3.6 mg

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C61	Prostate cancer
N80	Endometriosis
C50	Breast Cancer
N89.7	Dysfunctional Uterine Bleeding
N92.5	Dysfunctional Uterine Bleeding
N93.8	Dysfunctional Uterine Bleeding
C61	Prostate Cancer

8. REFERENCES:

1. Zoladex 3.6mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; February 2019.
2. Zoladex 10.8mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; February 2019.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed (March 2022).
4. New York State Department of Health Coverage for Zoladex; March 2022

Appendix A

For program applications for the patient assistance program and additional information please visit https://www.zoladexhcp.com/access-support/ or contact TerSera Support Source at 855-686-8725.

Appendix B

FDA-approved and Compendia-supported indications for Zoladex (goserelin)		Lupron (leuprolide acetate)	Eligard (leuprolide acetate)	Fensolvi (leuprolide acetate)	Vantas (histrelin acetate implants)	Supprelin LA (histrelin acetate implants)	Trelstar (triptorelin pamoate)	Triptodur (triptorelin pamoate)
FDA Approved	*Breast cancer, For palliation of advanced disease in pre- and peri-menopausal women*							
	Endometriosis	X (FDA Approved)					X (Compendia)	X (Compendia)
	Hypoplasia of endometrium						X (Compendia)	X (Compendia)
	Prostate cancer, Advanced (palliative treatment)	X (FDA Approved)	X (FDA Approved)		X (FDA Approved)		X (FDA Approved)	
	Abnormal uterine bleeding, Endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding							
	Prostate cancer, In combination with flutamide for locally confined stage B2-C disease	X (Compendia)		X (Compendia)				
Compendia Supported	Abnormal uterine bleeding (chronic anovulatory uterine bleeding and severe anemia)							

	Breast cancer, Adjuvant treatment of hormone receptor-positive, axillary lymph node-positive disease in premenopausal women	X (Compendia)		X (Compendia)				
	Gender dysphoria - Male-to-female transsexual; Adjunct	X (Compendia)		X (Compendia)			X (Compendia)	X (Compendia)
	In vitro fertilization	X (Compendia)		X (Compendia)			X (Compendia)	X (Compendia)
	Precocious puberty	X (FDA Approved)		X (FDA Approved		X (FDA Approved)		X (FDA Approved)
	Prostate cancer	X (Compendia)		X (Compendia)				

REVISION LOG:

REVISIONS	DATE
Creation date	5/31/2022
Annual Review	5/31/2023

Approved:	Date:	Approved:	Date:
Glendon Henry — Digitally signed by Glendon Henry Date: 2022.06.02 08:27:34 -04'00'		Sanjiv Shah MD — Digitally signed by Sanjiv Shah MD Date: 2022.06.03 13:40:13 -04'00'	
Glendon Henry, MD **Senior Medical Director**		**Sanjiv Shah, MD** **Chief Medical Officer**	

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Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.