MetroPlus Health

Policy and Procedure

Title: Zoladex (goserelin acetate)	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 11

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

   c. Prostate cancer, For palliation of advanced carcinoma of the prostate
   Approved x 12 months

   d. Prostate cancer, in combination with flutamide for locally confined carcinoma of the prostate *Approved x 12 months*

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

c. Prostate cancer, For palliation of advanced carcinoma of the prostate
Approved x 12 months

d. Prostate cancer, in combination with flutamide for locally confined carcinoma of the prostate *Approved x 12 months*

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:

The use of Zoladex is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA or are compendial supported.

6. APPLICABLE PROCEDURE CODES:

CPT	Description
J9202	Goserelin acetate implant, per 3.6 mg

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast

C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast

C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C61	Malignant neoplasm of prostate
C79.81	Secondary malignant neoplasm of breast
D05.00	Lobular carcinoma in situ of unspecified breast
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.10	Intraductal carcinoma in situ of unspecified breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.80	Other specified type of carcinoma in situ of unspecified breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D05.90	Unspecified type of carcinoma in situ of unspecified breast
D05.91	Unspecified type of carcinoma in situ of right breast
D05.92	Unspecified type of carcinoma in situ of left breast
N80.0	Endometriosis of uterus
N80.00	Endometriosis of the uterus, unspecified
N80.01	Superficial endometriosis of the uterus
N80.02	Deep endometriosis of the uterus
N80.03	Adenomyosis of the uterus

N80.3	Endometriosis of pelvic peritoneum
N80.30	Endometriosis of pelvic peritoneum, unspecified
N80.311	Superficial endometriosis of the anterior cul-de-sac
N80.312	Deep endometriosis of the anterior cul-de-sac
N80.319	Endometriosis of the anterior cul-de-sac, unspecified depth
N80.321	Superficial endometriosis of the posterior cul-de-sac
N80.322	Deep endometriosis of the posterior cul-de-sac
N80.329	Endometriosis of the posterior cul-de-sac, unspecified depth
N80.331	Superficial endometriosis of the right pelvic sidewall
N80.332	Superficial endometriosis of the left pelvic sidewall
N80.333	Superficial endometriosis of bilateral pelvic sidewall
N80.339	Superficial endometriosis of pelvic sidewall, unspecified side
N80.341	Deep endometriosis of the right pelvic sidewall
N80.342	Deep endometriosis of the left pelvic sidewall
N80.343	Deep endometriosis of the bilateral pelvic sidewall
N80.349	Deep endometriosis of the pelvic sidewall, unspecified side
N80.351	Endometriosis of the right pelvic sidewall, unspecified depth
N80.352	Endometriosis of the left pelvic sidewall, unspecified depth
N80.353	Endometriosis of bilateral pelvic sidewall, unspecified depth
N80.359	Endometriosis of pelvic sidewall, unspecified side, unspecified depth
N80.361	Superficial endometriosis of the right pelvic brim
N80.362	Superficial endometriosis of the left pelvic brim
N80.363	Superficial endometriosis of bilateral pelvic brim
N80.369	Superficial endometriosis of the pelvic brim, unspecified side
N80.371	Deep endometriosis of the right pelvic brim

N80.372	Deep endometriosis of the left pelvic brim
N80.373	Deep endometriosis of bilateral pelvic brim
N80.379	Deep endometriosis of the pelvic brim, unspecified side
N80.381	Endometriosis of the right pelvic brim, unspecified depth
N80.382	Endometriosis of the left pelvic brim, unspecified depth
N80.383	Endometriosis of bilateral pelvic brim, unspecified depth
N80.389	Endometriosis of the pelvic brim, unspecified side, unspecified depth
N80.391	Superficial endometriosis of the pelvic peritoneum, other specified sites
N80.392	Deep endometriosis of the pelvic peritoneum, other specified sites
N80.399	Endometriosis of the pelvic peritoneum, other specified sites, unspecified depth
N80.3A1	Superficial endometriosis of the right uterosacral ligament
N80.3A2	Superficial endometriosis of the left uterosacral ligament
N80.3A3	Superficial endometriosis of the bilateral uterosacral ligament(s)
N80.3A9	Superficial endometriosis of the uterosacral ligament(s), unspecified side
N80.3B1	Deep endometriosis of the right uterosacral ligament
N80.3B2	Deep endometriosis of the left uterosacral ligament
N80.3B3	Deep endometriosis of bilateral uterosacral ligament(s)
N80.3B9	Deep endometriosis of the uterosacral ligament(s), unspecified side
N80.3C1	Endometriosis of the right uterosacral ligament, unspecified depth
N80.3C2	Endometriosis of the left uterosacral ligament, unspecified depth
N80.3C3	Endometriosis of bilateral uterosacral ligament(s), unspecified depth
N80.3C9	Endometriosis of the uterosacral ligament(s), unspecified side, unspecified depth
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified

8. REFERENCES:

1. Zoladex 3.6mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; May 2023.
2. Zoladex 10.8mg [package insert]. Lake Forest, IL: TerSera Therapeutics LLC; May 2023.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed (May 2023).
4. New York State Department of Health Coverage for Zoladex; March 2022
5. IPD analytics [database online]. Aventura, FL: IPD analytics LLC; May 2023

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	5/30/2023

Approved:	Date:	Approved:	Date:
Glendon Henry Digitally signed by Glendon Henry Date: 2023.06.02 07:38:36 -04'00'		Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2023.06.05 16:01:49 -04'00'	
Glendon Henry, MD **Sr. Medical Director**		**Sanjiv Shah, MD** **Chief Medical Officer**	

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.