Drug Policy:

LHRH (agonists and antagonist)

POLICY NUMBER UM ONC_1041	SUBJECT Luteinizing Hormone Releasing Hormone (LHRH) Agonists and Antagonist [Lupron Depot (leuprolide), Trelstar (triptorelin), Zoladex (goserelin), Vantas (histrelin), Firmagon (degarelix)]		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 01/12/11, 03/13/13, 02/12/14, 06/10/15, 10/12/15, 12/09/15, 08/25/16, 10/20/16, 11/08/16, 08/10/17, 08/08/18, 07/10/19, 08/14/19, 12/11/19, 08/12/20	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 01/12/11, 03/13/13, 02/12/14, 06/10/15, 10/12/15, 12/09/15, 08/25/16, 10/20/16, 11/08/16, 08/10/17, 08/08/18, 07/10/19, 08/14/19, 12/11/19, 08/12/20	
PRIMARY BUSINESS OWNER: UM **APPROVED BY:** Dr. Andrew Hertler		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM 1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** All	

I. PURPOSE

To define and describe the accepted indications for LHRH agonists or antagonist [Lupron Depot (leuprolide), Trelstar (triptorelin), Zoladex (goserelin), Firmagon (degarelix), Vantas (histrelin)] usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When available, generic alternatives are preferred over brand-name drugs.

B. Prostate Cancer

1. Trelstar (triptorelin) or Lupron Depot/Eligard (leuprolide) are the preferred LHRH analogs in members with prostate cancer for all curative and palliative settings.

C. Breast Cancer

1. Trelstar (triptorelin) or Lupron Depot/Eligard (leuprolide) are the preferred LHRH analogs in members with breast cancer for all curative and palliative settings.
2. Trelstar (triptorelin) or Eligard/Lupron Depot (leuprolide) is being used in combination with endocrine therapy (i.e. Tamoxifen or an aromatase inhibitor), with or without additional anti-cancer therapy AND
3. The member is a pre-menopausal or perimenopausal women with ER/PR + early or late stage breast cancer.

III. EXCLUSION CRITERIA

A. Vantas (histrelin) or Firmagon (degarelix) is being used for prostate cancer or breast cancer.

B. Zoladex (goserelin), Trelstar (triptorelin), or Lupron Depot (leuprolide) is being used in postmenopausal female member.

C. Zoladex (goserelin), Trelstar (triptorelin), or Lupron (Leuprolide) is being used in member with hormone receptor negative (ER and/or PR negative) breast cancer.

D. Dosing exceeds single dose limit of Leuprolide 65 mg, Goserelin 10.8 mg, Triptorelin 22.5 mg, Histrelin 50 mg and Degarelix 240 mg (for loading dose) and 80 mg (continuation dose).

E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Lupron prescribing information.. AbbVie Inc. North Chicago, IL 2020.

B. Trelstar prescribing information. Verity Pharmaceuticals, Inc. Wayne, PA 2020.

C. Zoladex prescribing information. TerSera Therapeutics LLC Lake Forest, IL 2019.

D. Vantas prescribing information. Endo Pharmaceuticals Solutions Inc. Chadds Ford, PA. 2019.

E. Firmagon prescribing information. Ferring Pharmaceuticals Inc. Parsippany, NJ. 2020.

F. Clinical Pharmacology Elsevier Gold Standard. 2020.

G. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

H. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.