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), Orgovyx (relugolix)] 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. NOTE 1: Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg) are the preferred LHRH analogs in members with prostate cancer for all curative and palliative settings.

2. NOTE 2: For ADT- Androgen Deprivation Therapy- in prostate cancer, the oral LH-RH analog Orgovyx (relugolix) is not recommended per NCH Pathway and NCH Policy. Preferred alternatives are described above in Note #1. The recommendation is based on a lack of Overall Survival benefit with Orgovyx (relugolix) over Lupron Depot/Eligard (leuprolide).

C. Breast Cancer

1. NOTE: Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg) are the preferred LHRH analogs in members with breast cancer for all curative and palliative settings.

2. Eligard/Lupron Depot (J9217 leuprolide 7.5 mg or 22.5 mg) may be used in combination with endocrine therapy (Tamoxifen or an aromatase inhibitor), with or without additional anti-cancer therapy, in perimenopausal/premenopausal women with ER/PR+ breast cancer whenever ovarian suppression/ovarian ablation is clinically indicated.

D. Fertility Preservation in Women Undergoing Cytotoxic Chemotherapy

1. NOTE: Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg) are the preferred LHRH analogs and may be used in female members who are receiving chemotherapy and desire fertility preservation.

III. EXCLUSION CRITERIA

A. Use of the non-preferred LHRH analogs Trelstar (triptorelin), Firmagon (degarelix), J1950 leuprolide (e.g. 3.75 mg or 11.25 mg), or Orgovyx (relugolix) product instead of the preferred Lupron Depot/Eligard (J9217 leuprolide 7.5 mg or 22.5 mg).

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, except when being used for fertility preservation or for other non-cancer indications.

D. Dosing exceeds single dose limit of Leuprolide 65 mg every 12 months, Goserelin 10.8 mg every 3 months, Triptorelin 22.5 mg every 3 months, Histrelin 50 mg every 12 months, Degarelix 240
mg (for loading dose) or 80 mg every month (continuation dose), and Orgovyx 360 mg (for loading dose) or 120 mg (continuation dose).

E. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

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

VIII. ADDENDUM

A. For Fidelis Care members: when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to the use of LHRH analogs for fertility preservation in woman undergoing cytotoxic chemotherapy.