CVS/caremark

POLICY Document for LUTRATE DEPOT

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, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

Specialty Guideline Management leuprolide depot products

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lupron Depot 1-Month 7.5 mg	leuprolide acetate depot 1-Month 7.5 mg
Lupron Depot 3-Month 22.5 mg	leuprolide acetate depot 3-Month 22.5 mg
Lupron Depot 4-Month 30 mg	leuprolide acetate depot 4-Month 30 mg
Lupron Depot 6-Month 45 mg	leuprolide acetate depot 6-Month 45 mg
Lutrate Depot 3-Month 22.5 mg	leuprolide acetate 3-Month 22.5 mg

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.

FDA-Approved Indications[1-3]

Lupron Depot 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, leuprolide acetate depot 3-month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg, and Lutrate Depot 3-Month 22.5 mg are indicated for the treatment of advanced prostate cancer.

Compendial Uses

- Prostate cancer[4]
- Ovarian cancer - Malignant sex cord-stromal tumors (7.5 mg and 22.5 mg)[4]
- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)[5-7]
- Breast cancer (7.5 mg and 22.5 mg)[4,10]

All other indications are considered experimental/investigational and not medically necessary.

Prescriber Specialties[9]

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

Coverage Criteria

Prostate Cancer[1-4]

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

Gender Dysphoria[5-7]

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

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Ovarian Cancer (7.5 mg and 22.5 mg only)[4]

Authorization of 12 months may be granted for treatment of malignant sex cord-stromal tumors (granulosa cell tumors) as a single agent.

Breast Cancer (7.5 mg and 22.5 mg only)[4]

Authorization of 12 months may be granted for ovarian suppression in premenopausal members with hormone-receptor positive breast cancer at higher risk for recurrence (e.g., young age, high-grade tumor, lymph-node involvement) when used in combination with endocrine therapy.

Continuation of Therapy

Ovarian Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Prostate Cancer

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who are experiencing clinical benefit to therapy (e.g., serum testosterone less than 50 ng/dL) and who have not experienced an unacceptable toxicity.

Breast Cancer[10]

Authorization of 12 months may be granted (up to 5 years total) for continued treatment in members requesting reauthorization who were premenopausal at diagnosis and are still undergoing treatment with endocrine therapy.

Gender Dysphoria[9]

Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.

- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Other

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

Section 2: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

Program Description

The National Comprehensive Care Network® (NCCN®) is a not-for profit alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives. It is comprised of oncology experts who convene regularly to establish the best treatments for patients.[1]

NCCN develops resources to support stakeholders in the health care delivery system including the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

The Guidelines offer broad, high-level, evidence-based recommendations for cancer management. The Compendium extracts the drug and biologic recommendations from the Guidelines detailing their use and level of evidence category. The Templates convert the drug regimens detailed in the Guidelines and Compendium into practical, standardized order sets for safe, clinical use. [2,3]

NCCN Categories of Evidence and Consensus[4]

- **Category 1:** Based upon high-level evidence, there is uniform (defined as ≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2A:** Based upon lower-level evidence, there is uniform (≥85% panel support) NCCN consensus that the intervention is appropriate.
- **Category 2B:** Based upon lower-level evidence, there is NCCN consensus (50% to <85% panel support) that the intervention is appropriate.

- **Category 3:** Based upon any level of evidence, there is major NCCN disagreement (less than 50% panel support, or at least three institutions opposing the recommendation) that the intervention is appropriate.

Policy for Regimen Prior Authorization

Regimen prior authorization allows providers to submit a single request for all oncology drugs or biologics within an NCCN Template that require prior authorization. Regimen requests must be initiated through the provider portal. If submitted via phone or fax, each drug or biologic must be requested individually using drug-specific criteria.

Coverage is provided for a regimen request when all the following criteria are met. If all are not met, further review may be required:

1. The request is initiated through the provider portal.
2. The member is eligible for regimen review.
3. The request is for an oncology drug or biologic.
4. The requested regimen and indication align with an NCCN recommendation with a level of evidence category 1 or 2A.
5. The NCCN template is accepted by the provider without modification.
6. The indication is for a cancer type currently eligible for regimen review.
6. The indication is for a cancer type currently eligible for regimen review.
    1. Ampullary Adenocarcinoma
    2. Anal Carcinoma
    3. Appendiceal Neoplasms and Cancers
    4. Basal Cell Skin Cancer
    5. B-Cell Lymphomas
    6. Biliary Tract Cancers
    7. Bladder Cancer
    8. Bone Cancer
    9. Breast Cancer
    10. Castleman Disease
    11. Central Nervous System Cancers
    12. Cervical Cancer
    13. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
    14. Chronic Myeloid leukemia
    15. Colon Cancer
    16. Cutaneous Lymphomas
    17. Dermatofibrosarcoma Protuberans
    18. Esophageal Cancer
    19. Gastric Cancer
    20. Gastrointestinal Stromal Tumors
    21. Gestational Trophoblastic Neoplasms
    22. Hairy Cell Leukemia
    23. Head and Neck Cancers
    24. Hepatocellular Carcinoma
    25. Histiocytic Neoplasms

26. Hodgkin Lymphoma
27. Kaposi Sarcoma
28. Kidney Cancer
29. Melanoma: Cutaneous
30. Melanoma: Uveal
31. Merkel Cell Carcinoma
32. Mesothelioma: Peritoneal
33. Mesothelioma: Pleural
34. Multiple Myeloma
35. Myelodysplastic Syndromes
36. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
37. Myeloproliferative Neoplasms
38. Neuroendocrine and Adrenal Tumors
39. Non-Small Cell Lung Cancer
40. Occult Primary
41. Ovarian Cancer
42. Pancreatic Cancer
43. Penile Cancer
44. Prostate Cancer
45. Rectal Cancer
46. Small Bowl Adenocarcinoma
47. Small Cell Lung Cancer
48. Soft Tissue Sarcoma
49. Squamous Cell Skin Cancer
50. Systemic Light Chain Amyloidosis
51. Systemic Mastocytosis
52. T-Cell Lymphomas
53. Testicular Cancer
54. Thymomas and Thymic Carcinomas
55. Thyroid Carcinoma
56. Uterine Neoplasms
57. Vaginal Cancer
58. Vulvar Cancer
59. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
60. Wilms Tumor (Nephroblastoma)

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors (G-CSFs) are recommended for primary prophylaxis based on the febrile neutropenia (FN) risk of the chemotherapy regimen. The level of FN risk varies by NCCN Template and is indicated at the top of each template. Regimens classified as high or intermediate risk of FN may include a G-CSF as part of the prior authorization

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and evidence-based practice guidelines.

Duration of Approval

Authorizations may be granted for 12 months or as medically necessary, based on the member's condition and provider's clinical assessment.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. If no specific template exists for the intended maintenance therapy, the selected template can be modified to include only the appropriate maintenance agents. The modified regimen request will be submitted for further review.

REFERENCES:

SECTION 1

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SECTION 2

1. National Comprehensive Cancer Network. *About NCCN*. Available at: https://www.nccn.org/home/about. Accessed September 10, 2025.
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4. National Comprehensive Cancer Network. *NCCN Categories of Evidence and Consensus*. Available at: https://www.nccn.org/guidelines/guidelines-process/development-and-update-of-guidelines. Accessed September 10, 2025.