CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Utilization Management Medical Policy

- Camcevi™ (leuprolide subcutaneous injection – Accord BioPharma)
- Camcevi™ ETM (leuprolide subcutaneous injection – Foresee Pharmaceuticals)
- Eligard® (leuprolide acetate subcutaneous injection – Tolmar)
- Firmagon® (degarelix subcutaneous injection – Ferring)
- Lutrate Depot® (leuprolide acetate 22.5 mg for depot suspension – Avyxa Pharma)
- Trelstar® (triptorelin pamoate intramuscular injection – Verity)
- Vabrinty (leuprolide acetate subcutaneous injection – Tolmar)

REVIEW DATE: 01/22/2025; selected revision 08/13/2025, 09/10/2025

OVERVIEW

Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Trelstar, Vabrinty, and Firmagon are all indicated for the treatment of advanced **prostate cancer**.[1-4,8-10] Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Vabrinty, and Trelstar are gonadotropin-releasing hormone (GnRH) agonists, whereas Firmagon is a GnRH receptor antagonist. Vabrinty is an authorized generic of Eligard.[10] Table 1 has the approved doses for the agents.

Table 1. Recommended FDA-Approved Dosages.[1-4, 8-10]

Drug	Route of Administration	Dose and Frequency
Camcevi	Subcutaneous	• 42 mg every 6 months
Camcevi ETM	Subcutaneous	• 21 mg every 3 months
Eligard	Subcutaneous	• 7.5 mg every month • 22.5 mg every 3 months • 30 mg every 4 months • 45 mg every 6 months
Lutrate Depot	Intramuscular	• 22.5 mg every 3 months
Firmagon	Subcutaneous	• Starting dose of 240 mg given as two injections of 120 mg • Maintenance dose of 80 mg as one injection given every 28 days (first maintenance dose is given 28 days after the starting dose)
Trelstar	Intramuscular	• 3.75 mg every 4 weeks • 11.25 mg every 12 weeks • 22.5 mg every 24 weeks
Vabrinty (Eligard authorized generic)	Subcutaneous	• 7.5 mg – once monthly • 22.5 mg – once every 3 months • 30 mg – once every 4 months • 45 mg – once every 6 months

Guidelines

The GnRH analogs have been addressed in National Comprehensive Cancer Network guidelines:

- **Head and Neck Cancers:** Guidelines (version 2.2025 – January 17, 2025) recommend androgen receptor therapy (e.g., leuprolide and bicalutamide) for patients with recurrent, unresectable, or metastatic androgen receptor positive salivary gland tumors under "Useful in Certain Circumstances" (category 2A).[5,6] Abiraterone in combination with prednisone and GnRH agonist (Trelstar, leuprolide, or Zoladex [goserelin subcutaneous implant]) is also noted under "Useful in Certain Circumstances" (category 2A).

- **Prostate Cancer:** Guidelines (version 1.2025 – December 4, 2024) note androgen deprivation therapy as primary systemic therapy for regional or advanced disease and as neoadjuvant/concomitant/adjuvant therapy in combination with radiation in localized or locally advanced prostate cancers. Many drugs can be used as androgen deprivation therapy, including Camcevi, Eligard, Firmagon, and Trelstar.[7]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Trelstar, Vabrinty, and Firmagon. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Trelstar, Vabrinty, and Firmagon as well as the monitoring required for adverse events and long-term efficacy, approval requires Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Trelstar, Vabrinty, and Firmagon to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Firmagon, Vabrinty, or Trelstar is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. Prostate Cancer. Approve Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Firmagon, Vabrinty, or Trelstar for 1 year if prescribed by or in consultation with an oncologist or urologist.

Dosing. Approve ONE of the following doses (A, B, C, D, E, F, or G):

A) For Camcevi, approve the following dose (administered as a subcutaneous injection): 42 mg injection not more frequently than once every 6 months; OR

B) For Camcevi ETM, approve the following dose (administered as a subcutaneous injection): 21 mg injection not more frequently than once every 3 months; OR

C) For Eligard, approve ONE of the following doses (administered as a subcutaneous injection) [i, ii, iii, or iv]:
- **i.** 7.5 mg injection not more frequently than once every month; OR
- **ii.** 22.5 mg injection not more frequently than once every 3 months; OR
- **iii.** 30 mg injection not more frequently than once every 4 months; OR
- **iv.** 45 mg injection not more frequently than once every 6 months; OR

D) For Firmagon, approve ONE of the following doses (i or ii):
- **i.** For starting dose, approve 240 mg administered as two subcutaneous injections of 120 mg; OR
- **ii.** For maintenance dose (first one is given 28 days after starting dose), approve up to 80 mg administered as one subcutaneous injection not more frequently than once every 28 days; OR

E) For Trelstar, approve ONE of the following doses (administered as an intramuscular injection) [i, ii, or iii]:
- **i.** 3.75 mg injection not more frequently than once every 4 weeks; OR

ii. 11.25 mg injection not more frequently than once every 12 weeks; OR
iii. 22.5 mg injection not more frequently than once every 24 weeks; OR

F) For Lutrate Depot, approve the following dose (administered as an intramuscular injection): 22.5 mg injection not more frequently than once every 3 months; OR

G) For Vabrinty, approve ONE of the following doses (administered as a subcutaneous injection) [i, ii, iii, or iv]:
i. 7.5 mg injection not more frequently than once every month; OR
ii. 22.5 mg injection not more frequently than once every 3 months; OR
iii. 30 mg injection not more frequently than once every 4 months; OR
iv. 45 mg injection not more frequently than once every 6 months.

Other Uses with Supportive Evidence

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2. Head and Neck Cancer – Salivary Gland Tumors. Approve Camcevi, Camcevi ETM, Eligard, Vabrinty, or Trelstar for 1 year if the patient meets ALL of the following (A, B, and C):
A) Patient has recurrent, unresectable, or metastatic disease; AND
B) Patient has androgen receptor-positive disease; AND
C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following doses (A, B, C, D, or E):
A) For Camcevi, approve the following dose (administered as a subcutaneous injection): 42 mg injection not more frequently than once every 6 months; OR
B) For Camcevi ETM, approve the following dose (administered as a subcutaneous injection): 21 mg injection not more frequently than once every 3 months; OR
C) For Eligard, approve ONE of the following doses (administered as a subcutaneous injection) [i, ii, iii, or iv]:
i. 7.5 mg injection not more frequently than once every month; OR
ii. 22.5 mg injection not more frequently than once every 3 months; OR
iii. 30 mg injection not more frequently than once every 4 months; OR
iv. 45 mg injection not more frequently than once every 6 months; OR
D) For Trelstar, approve ONE of the following doses (administered as an intramuscular injection) [i, ii, or iii]:
i. 3.75 mg injection not more frequently than once every 4 weeks; OR
ii. 11.25 mg injection not more frequently than once every 12 weeks; OR
iii. 22.5 mg injection not more frequently than once every 24 weeks; OR
E) For Vabrinty, approve ONE of the following doses (administered as a subcutaneous injection) [i, ii, iii, or iv]:
i. 7.5 mg injection not more frequently than once every month; OR
ii. 22.5 mg injection not more frequently than once every 3 months; OR
iii. 30 mg injection not more frequently than once every 4 months; OR
iv. 45 mg injection not more frequently than once every 6 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Camcevi, Camcevi ETM, Eligard, Lutrate Depot, Trelstar, Vabrinty, and Firmagon is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Eligard® subcutaneous injection [prescribing information]. Fort Collins, CO: Tolmar; May 2024.
2. Firmagon® subcutaneous injection [prescribing information]. Parsippany, NJ: Ferring; February 2020.
3. Trelstar® intramuscular injection [prescribing information]. Wayne, PA: Verity; April 2024.
4. Camcevi subcutaneous injection [prescribing information]. Durham, NC: Accord BioPharma; March 2024.
5. The NCCN Head and Neck Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 17, 2025.
6. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 17, 2025. Search terms: leuprolide acetate, degarelix, triptorelin pamoate, leuprolide mesylate.
7. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 17, 2025.
8. Lutrate Depot intramuscular injection [prescribing information]. Parsippany, NJ: Avyxa Pharma; November 2024.
9. Camcevi™ ETM subcutaneous injection emulsion [prescribing information]. Taipei City, Taiwan: Foresee Pharmaceuticals; August 2025.
10. Vabrinty subcutaneous injection [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals; June 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/17/2024
Annual Revision	**Head and Neck Cancer – Salivary Gland Tumors:** Added Trelstar to approval criteria and dosing.	01/22/2025
Selected Revision	**Prostate Cancer:** Changed "Leuprolide Depot" to "Lutrate Depot" in approval criteria and dosing. Name change to Lutrate Depot was also done throughout the policy.	08/13/2025
Selected Revision	Two agents, Camcevi ETM and Vabrinty, were added to the policy. **Prostate Cancer:** Added Camcevi ETM and Vabrinty amongst the agents that may be approved. **Head and Neck Cancer – Salivary Gland Tumors:** Added Camcevi ETM and Vabrinty amongst the agents that may be approved.	09/10/2025