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Medicare Advantage Medical Utilization Review Policy

Policy:	**Oncology (Injectable) – Gonadotropin-Releasing Hormone Analogs Utilization Management Medical Policy** • Camcevi™ (leuprolide subcutaneous injection – Accord BioPharma) • Leuprolide Depot (leuprolide acetate 22.5 mg for depot suspension [formerly Lutrate Depot] – Cipla USA, Inc.) • Firmagon® (degarelix subcutaneous injection – Ferring) • Trelstar® (triptorelin pamoate intramuscular injection – Verity)
Date:	05/09/2023
Applicable Lines of Business:	Medicare Advantage - Medical
Applicable States:	NGS, J6: Wisconsin, Minnesota, Illinois NGS, JK: New York, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

OVERVIEW

Camcevi, Leuprolide Depot (formerly Lutrate Depot), Trelstar, and Firmagon are all indicated for the treatment of advanced **prostate cancer**.[1-4,8] Camcevi, Leuprolide Depot, and Trelstar are gonadotropin-releasing hormone (GnRH) agonists, whereas Firmagon is a GnRH antagonist. Table 1 has the approved doses for the four agents.

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

Drug	Route of Administration	Dose and Frequency
Camcevi	Subcutaneous	• 42 mg every 6 months
Leuprolide Depot (formerly 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

Guidelines

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

- **Head and Neck Cancer:** Guidelines (version 1.2023 – December 20, 2022) recommend androgen receptor therapy (e.g., leuprolide and bicalutamide) for patients with recurrent, unresectable, or metastatic androgen receptor positive salivary gland tumors.[4,5]

  Prostate Cancer: Guidelines (version 1.2023 – September 16, 2022) 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, Firmagon, and Trelstar.[6]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Camcevi, Leuprolide Depot, Trelstar, and Firmagon. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). All approvals are provided for the duration noted below.

This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage.

Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles.

RECOMMENDED AUTHORIZATION CRITERIA

I. Coverage of Camcevi is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Prostate Cancer.

Criteria. Approve for 1 year.

Dosing. Approve one of the following doses (A or B):
A) For Camcevi, approve the following dose (administered as a subcutaneous injection): 42 mg injection not more frequently than once every 6 months.

Other Uses with Supportive Evidence

2. Head and Neck Cancer – Salivary Gland Tumors.

Criteria. Approve for 1 year if the patient meets the following criteria (A and B):
A) The patient has recurrent, unresectable, or metastatic disease; AND
B) The patient has androgen receptor-positive disease.

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

II. Coverage of Firmagon, Leuprolide Depot, or Trelstar is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Prostate Cancer.

Criteria. Approve for 1 year.

Dosing. Approve one of the following doses:

A) 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 (40 mg/mL vial); 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 (20 mg/mL vial).

B) 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.

C) For Leuprolide Depot, approve the following dose (administered as an intramuscular injection): 22.5 mg injection not more frequently than once every 3 months.

Conditions Not Recommended for Approval

Coverage of Camcevi, Leuprolide Depot, Trelstar, 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. Firmagon® subcutaneous injection [prescribing information]. Parsippany, NJ: Ferring; February 2020.
2. Trelstar® intramuscular injection [prescribing information]. Wayne, PA: Verity; May 2020.
3. Camcevi subcutaneous injection [prescribing information]. Durham, NC: Accord BioPharma; May 2021.
4. The NCCN Head and Neck Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – December 20, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.
5. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023. Search terms: leuprolide acetate, degarelix, triptorelin pamoate.
6. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 9, 2023.
7. Lutrate Depot intramuscular injection [prescribing information]. Warren, NJ: Cipla USA, Inc; February 2023.
8. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs – Related to LCD L33394 (A52453) (Original Effective Date 10/1/15, Revision Effective Date 01/01/2023). Accessed May 9, 2023.
9. Centers for Medicare and Medicaid Services, National Government Services, Inc, Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394) [original date 10/01/2015; revision effective date 11/1/2022]. Accessed May 9, 2023.

History

Type of Revision	Summary of Changes*	Date
Policy created	New policy created containing all LHRH products, see archived policy	7/11/18
Policy revision	Reviewed and revised original policy created 07/11/2018 in accordance with Local Coverage Article A52453 and Oncology - Gonadotropin-Releasing Hormone Analogs Injectable Products Utilization Review Policy	08/28/2019
Policy revision	Completion of 2019 monthly monitoring process in accordance with Local Coverage Determination L33394, Local Coverage Article A52453, and Oncology – Gonadotropin-Releasing Hormone Analogs Injectable Products Utilization Review Policy.	11/26/2019
Policy revision	Non-clinical update to policy to add the statement "This policy incorporates Medicare coverage guidance as set forth in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), as well as in companion policy articles and other guidance applicable to the relevant service areas. These documents are cited in the References section of this policy. In some cases, this guidance includes specific lists of HCPCS and ICD-10 codes to help inform the coverage determination process. The Articles that include specific lists for billing and coding purposes will be included in the Reference section of this policy. However, to the extent that this policy cites such lists of HCPCS and ICD-10 codes, they should be used for reference purposes only. The presence of a specific HCPCS or ICD-10 code in a chart or companion article to an LCD is not by itself sufficient to approve coverage. Similarly, the absence of such a code does not necessarily mean that the applicable condition or diagnosis is excluded from coverage."	1/30/2020
Policy revision	*Added the following to the Policy Statement "Note: Conditions for coverage outlined in this Medicare Advantage Medical Policy may be less restrictive than those found in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles. Examples of situations where this clinical policy may be less restrictive include, but are not limited to, coverage of additional indications supported by CMS-approved compendia and the exclusion from this policy of additional coverage criteria requirements outlined in applicable National Coverage Determinations, Local Coverage Determinations and/or Local Coverage Articles." *Updated references *Updated dosing on all indications	08/07/2020
Policy revision	**Prostate Cancer:** Re-formatted the dosing section (no clinical changes). • **Firmagon**: Revised the maintenance dose from: "For maintenance dose (first one is given 28 days after starting dose), approve up to 80 mg administered as one subcutaneous injection every 28 days (20 mg/mL vial)" to "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 (20 mg/mL vial)". • **Trestar:** Revised the dosing section from "Up to 3.75 mg intramuscular injection once every 4 weeks" to " 3.75 mg injection **not more frequently than** once every 4 weeks". Same changes were made to the 11.25 mg, and 22.5 mg dosage strengths. **Head and Neck Cancer – Salivary Gland Tumors:** Criterion "Patient has recurrent disease with distant metastases" was revised to "Patient has distant metastases".	01/04/2022
Policy revision	Camcevi (leuprolide subcutaneous injection) was added the policy. **Prostate Cancer**: Criteria for dosing for Camcevi was added. **Head and Neck Cancer – Salivary Gland Tumors**: Criteria for dosing for Camcevi was added..	04/11/2022
Policy revision	**Head and Neck Cancer – Salivary Gland Tumors:** "Patient has distant metastases" was reworded to "Patient has recurrent, unresectable, or metastatic disease."	02/16/2023
Policy revision	Leuprolide Depot (formerly Lutrate Depot) was added to the policy.	05/09/2023

	Prostate Cancer: Criteria and dosing for Leuprolide Depot was added.	