



PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology (Oral – Androgen Receptor Inhibitor) – Erleada Prior Authorization Policy
- Erleada® (apalutamide tablets – Janssen)

REVIEW DATE: 03/25/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Erleada, an androgen receptor inhibitor, is indicated for the treatment of patients with **non-metastatic, castration-resistant prostate cancer (nmCRPC)** and **metastatic castration-sensitive prostate cancer (mCSPC)**.¹ Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or the patient should have had a bilateral orchiectomy.

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (version 5.2026 – January 23, 2026)²:

- For nmCRPC, Erleada, Xtandi® (enzalutamide capsules or tablets), and Nubeqa® (darolutamide tablets) are all preferred category 1 recommended options, if the prostate-specific antigen doubling time (PSADT) is ≤ 10 months.

- Erleada is recommended in combination with androgen deprivation therapy (ADT) for high-risk second biochemical recurrence in non-metastatic CSPC (category 2B). High-risk criteria are PSADT \leq 9 months; prostate-specific antigen (PSA) \geq 0.5 ng/mL; and prior adjuvant or secondary radiation therapy or not considered a candidate for radiation therapy. For mCSPC, androgen deprivation therapy in combination with abiraterone + steroid, Erleada, docetaxel, and Xtandi are all preferred category 1 recommended options. Yonsa[®] (abiraterone acetate tablets) with methylprednisolone is a category 2B recommendation. Erleada in combination with GnRH agonist or antagonist is recommended (category 2B) as “Useful in Certain Circumstances” in patients with metastatic (M0, no distant metastases) CSPC after maximal pelvic therapy.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Erleada. All approvals are provided for the duration noted below.

- **Erleada[®] (apalutamide tablets - Janssen)** is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. Prostate Cancer – Non-Metastatic, Castration-Resistant. Approve for 1 year if the patient meets the following (A and B):

A) Patient is \geq 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. The medication is used in combination with a gonadotropin-releasing hormone (GnRH) analog; OR

Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).

ii. Patient has had a bilateral orchiectomy.

2. Prostate Cancer –Castration-Sensitive. Approve for 1 year if the patient meets the following (A, B, and C):

A) Patient is \geq 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. The medication is used in combination with a gonadotropin-releasing hormone (GnRH) analog; OR

Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas

- (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
- ii. Patient has had a bilateral orchiectomy; AND
- C) Patient meets ONE of the following (i or ii):**
- i. Patient has high-risk second biochemical recurrence; OR
Note: High risk is defined as prostate-specific antigen doubling time (PSADT) \leq 9 months; prostate-specific antigen (PSA) \geq 0.5 ng/mL; prior adjuvant or secondary radiation therapy or patient is not a candidate for radiation therapy.
 - ii. Patient has metastatic castration-sensitive disease.

CONDITIONS NOT COVERED

- **Erleada® (apalutamide tablets - Janssen) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.**

REFERENCES

1. Erleada® tablets [prescribing information]. Horsham, PA: Janssen; March 2026.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 5.2026 – January 23, 2026). © 2026 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed March 23, 2026.

HISTORY

| Type of Revision | Summary of Changes | Review Date |
|------------------|---|-------------|
| Annual Revision | <p>Prostate Cancer – Non-Metastatic, Castration-Resistant: The criterion requiring the trial of gonadotropin-releasing hormone “agonist” was changed to “analog,” which allows use of both agonists and antagonists. Firmagon and Orgovyx were added as examples in the Note. The separate criterion previously asking for concurrent use of medication with Firmagon was deleted since it is no longer needed.</p> <p>Prostate Cancer – Metastatic, Castration-Sensitive: The criterion requiring the trial of gonadotropin-releasing hormone “agonist” was changed to “analog,” which allows use of both agonists and antagonists. Firmagon and Orgovyx were added as examples in the Note. The separate criterion previously asking for concurrent use of medication with Firmagon was deleted since it is no longer needed.</p> | 04/10/2024 |
| Annual Revision | No criteria changes. | 03/26/2025 |
| Update | 04/17/2025: The policy name was changed from “Oncology – Erleada PA Policy” to “Oncology (Oral – Androgen Receptor Inhibitor) – Erleada PA Policy”. | N/A |
| Annual Revision | Prostate Cancer – Castration-Sensitive: Approval indication changed to as noted. Previously it was “Metastatic” Castration-Sensitive was specified. Added approval option for patients with high-risk second biochemical recurrence along | 03/25/2026 |

| | | |
|--|--|--|
| | with a Note specifying high-risk attributes. Also addressed option for approval in metastatic setting. | |
|--|--|--|

N/A – Not applicable.

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2026 The Cigna Group.