Erleada™ (apalutamide)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2021
Revision Date: January 01, 2021
Review Date: August 19, 2020
Line of Business: Commercial
Policy Type: Prior Authorization

Disclaimer

Description

Erleada (apalutamide) is an androgen receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. Erleada (apalutamide) inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription.

Erleada (apalutamide) is indicated for the treatment of patients with (1) non-metastatic castration-resistant prostate cancer and (2) metastatic castration-sensitive prostate cancer (mCSPC).

Apalutamide is available as Erleada in 60 mg tablets.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of

the Act. These compendia guide review of off-label and off-evidence prescribing and are subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Erleada (apalutamide) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Prostate Cancer (non-metastatic castration-resistant)

- The member has a diagnosis of non-metastatic castration-resistant prostate cancer **AND**
- The member has an intolerance or contraindication to both Xtandi (enzalutamide) and Nubeqa (darolutamide) **AND**
- The member will use Erleada (apalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog)

Prostate Cancer (metastatic castration-sensitive)

- The member has a diagnosis of metastatic castration-sensitive prostate cancer **AND**
- The member has an intolerance or contraindication to Xtandi (enzalutamide) **AND**
- The member will use Erleada (apalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog)

Recommended dose: 240 mg administered orally once daily. Erleada (apalutamide) can be taken with or without food.

Erleada (apalutamide) will be approved in 6 month durations or as determined through clinical review.

The quantity limit for all strengths of Erleada (apalutamide) is 120 tablets per 30 days.

Coverage Limitations

Erleada (apalutamide) therapy is not considered medically necessary for members with the following concomitant conditions:

- Members that have experienced disease progression while on Erleada (apalutamide).
- Concomitant use with an androgen receptor inhibitor or androgen synthesis inhibitor (e.g. enzalutamide, abiraterone, nilutamide, flutamide, bicalutamide) due to lack of evidence supporting efficacy and safety.

- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Erleada (apalutamide).

The SPARTAN trial supported approval of Erleada (apalutamide). In this trial, patients were included if they were 18 years of age or older, had confirmed adenocarcinoma of the prostate that was castration-resistant, and were at high risk for the development of metastasis (defined as a PSA doubling time of 10 months or less during continuous androgen deprivation therapy). Patients were excluded from the trial if distant metastasis was detected at screening. Additionally, patients were required to have no local or regional nodal disease (N0) or to have malignant pelvic lymph nodes that measured less than 2 cm in the short axis (N1) and were allowed below the aortic

bifurcation. Erleada (apalutamide) was administered concurrently with androgen-deprivation therapy throughout the trial.

Warnings and Precautions
Falls and Fractures
Falls and fractures occurred in patients receiving Erleada (apalutamide). Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone targeted agents.

Seizure
Seizure occurred in patients receiving Erleada (apalutamide). Permanently discontinue Erleada (apalutamide) in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with Erleada (apalutamide). Advise patients of the risk of developing a seizure while receiving Erleada (apalutamide) and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

Erleada (apalutamide) should not be used in pregnant members, because the drug can cause fetal harm and potential loss of pregnancy.

For specific recommendations on warnings and precautions, patient monitoring and on dose adjustments, omissions, and discontinuation, please refer to the current prescribing information.

Provider Claims Codes

There are no provider claim codes associated with this policy.

Medical Terms

Erleada; apalutamide; prostate cancer; castration resistant; CRPC; castration sensitive; CSPC; pharmacy

References

Clinical Pharmacology Copyright © 2020. Gold Standard Inc.

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Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO (2020).

National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

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Smith M, Saad F, Chowdhury S, et al. Apalutamide Treatment and Metastasis-free Survival in Prostate Cancer. NEJM 2018; published online at NEJM.org on February 8, 2018.