



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Erleada (apalutamide) is indicated for the treatment of patients with prostate cancer. Erleada is an androgen receptor (AR) inhibitor that binds directly to the ligand-binding domain of the AR. Erleada inhibits AR nuclear translocation, inhibits DNA binding, and impedes AR-mediated transcription. Through this process, Erleada administration causes decreased tumor cell proliferation and increased apoptosis leading to a decrease in tumor volume (1).

### **Regulatory Status**

FDA-approved indications: Erleada is an androgen receptor inhibitor indicated for the treatment of patients with: (1)

- Metastatic castration-sensitive prostate cancer (mCSPC)
- Non-metastatic castration-resistant prostate cancer (nmCRPC)

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy (1).

Erleada can cause fetal harm and potential loss of pregnancy. Prescribers should advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Erleada (1).

Falls and fractures occurred in patients receiving Erleada. 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 (1).

Seizure occurred in patients receiving Erleada. Permanently discontinue Erleada in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with Erleada. Advise patients of the risk of developing a seizure while receiving Erleada and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others (1).

Safety and effectiveness of Erleada in pediatric and female patients have not been established (1).



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## **ERLEADA (apalutamide)**

### **Summary**

Erleada (apalutamide) is indicated for the treatment of patients with prostate cancer. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Erleada while maintaining optimal therapeutic outcomes.

### **References**

1. Erleada [package insert]. Thousand Oaks, CA: Janssen Products, LP; September 2024.
2. NCCN Drugs & Biologics Compendium® Apalutamide 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.