[Physician Letterhead]

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| --- | --- |
| [Prescription Insurance Plan Name] ATTN: [Department][Medical/Pharmacy Director Name] [Prescription Insurance Plan Address][City, State, ZIP code] | RE: [Member Name] Date of Birth: [Date of Birth]Policy Number: [Policy ID]Group Number: [Group #] |

**REQUEST:** Authorization for treatment with ERLEADA® (apalutamide)

**DIAGNOSIS:** [Insert diagnosis] [Insert ICD]

**RECOMMENDED DOSE AND FREQUENCY:** [Insert dosage and frequency]

**REQUEST TYPE:** ☐ Standard ☐ EXPEDITED

Dear [Medical/Pharmacy Director Name],

A prior authorization was recently submitted for my patient, [Patient Name], to receive treatment with ERLEADA®. However, the [Prescription Insurance Plan Name] denied coverage, and stated the following reason(s) why: [insert reason(s) for the denial as stated on the explanation of benefits].

I am writing to request that you reconsider this decision as there is a well-established and compelling clinical rationale for prescribing ERLEADA® to patients with [metastatic castration-sensitive prostate cancer (mCSPC) or non-metastatic castration-resistant prostate cancer (nmCRPC)]. Please see the patient’s medical history and clinical rationale below, which support why ERLEADA® is medically necessary and should be a covered treatment.

# **Patient Diagnosis and Medical History**

[Patient Name] is [a/an] [age]-year-old [male] who was diagnosed with [mCSPC or nmCRPC] on [date] and who has been in my care since [date].

[Using your medical judgement and discretion, include details pertaining to the patient’s diagnosis and characterization of their medical condition. Consider including:

* Previous and current treatment/procedures and response to those interventions
* A description of the patient’s current symptoms and condition
* A list of the patient’s comorbidities (eg, diabetes, hypertension, obesity, mild cognitive impairment, chronic kidney disease, pill dysphagia, suboptimal social support)
* The patient’s prostate-specific antigen (PSA) levels and Gleason scores and their clinical relevance, as applicable
* Prognosis or risk of disease progression without treatment with ERLEADA®
* The number of metastatic lesions and location of sites]

# **Clinical Rationale**

Based on my medical opinion and expertise in treating patients with [mCSPC or nmCRPC], the most appropriate treatment is ERLEADA®. ERLEADA® is an FDA-approved treatment for these patients, recommended by clinical guidelines and supported by clinical data for its overall survival benefit and established safety profile.

[Consider including the following NCCN Guidelines® and AUA/SUO support if apalutamide (ERLEADA®) is being prescribed for patients with mCSPC.]

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend apalutamide (ERLEADA®) with ADT as an NCCN Category 1 preferred treatment option for patients with mCSPC.1 To view the most recent version of the guidelines, visit [**www.nccn.org**](https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1459).

Similarly, the American Urological Association/Society of Urologic Oncology (AUA®/SUO®) Guideline for Advanced Prostate Cancer strongly recommends that clinicians should offer ADT in combination with apalutamide (ERLEADA®) as a treatment option for patients with metastatic hormone-sensitive prostate cancer (Evidence level: Grade A).2 To view the most recent version of the guideline, visit [**www.auanet.org**](https://www.auanet.org/guidelines-and-quality/guidelines/oncology-guidelines/prostate-cancer).

[Consider including the following clinical data if ERLEADA® is being prescribed for patients with mCSPC.]

The TITAN trial was a multicenter, randomized, double-blind, placebo-controlled trial of ERLEADA® 240 mg orally once daily + ADT or placebo orally once daily + ADT in patients with newly diagnosed mCSPC or relapsed metastatic disease after an initial diagnosis of localized disease (N=1052)3

* ERLEADA® + ADT demonstrated a 52% reduction in the risk of radiographic progression or death vs ADT alone (rPFS; HR=0.48; 95% CI: 0.39-0.60; *P*<0.0001). Median follow-up time was 22.7 months. Median rPFS was NE vs 22.1 months3
* ERLEADA® + ADT demonstrated statistically significant, superior OS vs ADT alone in men with mCSPC3:
	+ 35% reduction in the risk of death; HR=0.65; 95% CI: 0.53-0.79; median OS was NR vs 52.2 months. Median follow-up time was 44.0 months4
	+ **Primary analysis** median OS was NE vs NE; HR=0.67; 95% CI: 0.51-0.89; P=0.0053. Median follow-up was 22.7 months3,4
* ERLEADA® + ADT demonstrated improvement in OS regardless of disease volume vs ADT alone4:
	+ 30% reduction in the risk of death in patients with high-volume disease (HR=0.70; 95% CI: 0.56-0.88)5
	+ 48% reduction in the risk of death in patients with low-volume disease (HR=0.52; 95% CI: 0.35-0.79)5

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trial (TITAN) were rash, hot flush, hypertension, arthralgia, and pruritus. ERLEADA® was discontinued due to adverse reactions in 8% of patients, most commonly from rash (2.3%). Adverse reactions leading to dose interruption or reduction of ERLEADA® occurred in 23% of patients; the most frequent (>1%) were rash, fatigue, and hypertension. Serious adverse reactions occurred in 20% of ERLEADA®-treated patients and 20% in patients receiving placebo.3

To view the relevant publication, please see the *Journal of Clinical Oncology* at [**www.ascopubs.org/doi/pdf/10.1200/JCO.20.03488**](http://www.ascopubs.org/doi/pdf/10.1200/JCO.20.03488).

[Consider including the following real-world evidence data if ERLEADA® is being prescribed for patients with mCSPC]

In a real-world, head-to-head analysis of apalutamide (ERLEADA®) vs enzalutamide treatment initiation in patients with mCSPC:ERLEADA® demonstrated a 23% reduction in the risk of death at 24 months vs enzalutamide (HR=0.77; 95% CI: 0.62-0.96; *P*=0.019)6

In a real-world, head-to-head analysis of apalutamide (ERLEADA®) vs abiraterone acetate treatment initiation in patients with mCSPC: ERLEADA® demonstrated a 26% reduction in the risk of death at 24 months vs abiraterone acetate (HR=0.74; 95% CI: 0.59-0.93; *P*=0.010)7

**Data Source and Study Design**

* Clinical data from Precision Point Specialty (PPS) Analytics from community urology practices were linked with administrative claims data from the Komodo Research Database6,7
* Primary endpoints: Overall survival of patients with mCSPC at 24 months6,7
* Retrospective, longitudinal, head-to-head analyses that applied causal inference based upon a prespecified power calculation6,7
* Inverse probability of treatment weighting (IPTW) was used to account for differences in baseline characteristics between cohorts6,7
* Patients with mCSPC were grouped into treatment cohorts based on their first dispensed or paid pharmacy claim (index date):
	+ For ERLEADA® or enzalutamide on or after 12/16/2019 (enzalutamide FDA approval in mCSPC)6
	+ For ERLEADA® or abiraterone acetate on or after 09/17/2019 (ERLEADA® FDA approval in mCSPC)7
* Concurrent use of ADT was not required6,7
* Concomitant ADT use was observed in 79.2% of patients in the ERLEADA® cohort and 77.8% in the enzalutamide cohort6
* Concomitant ADT use was observed in 76.8% of patients in the ERLEADA® cohort and 74.0% in the abiraterone acetate cohort7
* These studies were designed taking into account the various guidance the FDA has issued on RWE6,7

**Limitations6,7**

* These studies were not designed to assess differences in safety between cohorts
* Miscoding or misclassification in clinical records or administrative claims can lead to selection and limitation biases despite efforts to balance the study populations
* While the Komodo Research Database captured >90% of oncology-related deaths, as validated against CDC estimates, some deaths may still be missed
* Abiraterone acetate is only indicated for high-risk mCSPC, which may result in residual differences relative to the ERLEADA® treatment cohort after IPTW adjustments
* Regression analyses could only adjust for documented covariates, and unknown confounders may be present
* Unlike Phase 3 trials assessing overall survival at specific events, these studies evaluated survival at 24 months. Longer follow-up studies may be needed to fully assess the therapeutic effects

Visit the link below to view relevant publications presented at the European Conference of Oncology Pharmacy:

[**www.janssenscience.com/therapeutic-areas/oncology/congress/ecop-2024**](http://www.janssenscience.com/therapeutic-areas/oncology/congress/ecop-2024)

[Consider including the following NCCN Guidelines® and AUA/SUO Guidelines if apalutamide (ERLEADA®) is being prescribed for patients with nmCRPC.]

The NCCN Guidelines recommend apalutamide (ERLEADA®) with ADT as an NCCN Category 1 preferred treatment option for patients with nmCRPC and a PSA doubling time ≤10 months.1 To view the most recent version of the guidelines, visit [**www.nccn.org**](https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1459).

Similarly, the American Urological Association/Society of Urologic Oncology (AUA®/SUO®) Guideline for Advanced Prostate Cancer strongly recommends that clinicians should offer apalutamide (ERLEADA®) with continued ADT as a treatment option for patients with nmCRPC at high risk for developing metastatic disease (PSA doubling time ≤10 months; Evidence Level: Grade A).2 To view the most recent version of the guideline, visit [**www.auanet.org**](https://www.auanet.org/guidelines-and-quality/guidelines/oncology-guidelines/prostate-cancer).

[Consider including the following clinical data if ERLEADA® is being prescribed for patients with nmCRPC.]

The SPARTAN trial was a multicenter, randomized, double-blind, placebo-controlled trial of ERLEADA® 240 mg orally once daily + ADT or placebo orally once daily + ADT in patients with nmCRPC (N=1207). ERLEADA® + ADT demonstrated a 2-year improvement in median metastases-free survival (MFS) vs ADT alone3

* 72% reduction in the risk of distant metastasis or death; HR=0.28; 95% CI: 0.23-0.35; *P*<0.001. Median follow-up was 20.3 months4
* Median MFS was 40.5 months with ERLEADA® + ADT vs 16.2 months with
placebo + ADT4
* Secondary endpoint: >1-year median OS improvement (HR=0.78; 95% CI: 0.64-0.96; *P*=0.0161). Median OS was 73.9 with ERLEADA® + ADT vs 59.9 months with placebo + ADT. Median follow-up was 52 months3

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trial (SPARTAN) were fatigue, hypertension, rash, diarrhea, nausea, weight decreased, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema. ERLEADA® was discontinued due to adverse reactions in 11% of patients, most commonly from rash (3.2%). Adverse reactions leading to dose interruption or reduction of ERLEADA® occurred in 33% of patients; the most frequent (>1%) were rash, diarrhea, fatigue, nausea, vomiting, hypertension, and hematuria. Serious adverse reactions occurred in 25% of ERLEADA®-treated patients and 23% in patients receiving placebo.3

To view the relevant publication, visit the *New England Journal of Medicine* at [**https://www.nejm.org/doi/full/10.1056/nejmoa1715546**](https://www.nejm.org/doi/full/10.1056/nejmoa1715546).

[Using your medical judgement and discretion, consider including the following dosing and administration information as it pertains to your patient:

Furthermore, the different dosing and administration options of ERLEADA® allow for the most suitable route of administration and manageable dosing regimen for my patient. ERLEADA® can be administered as one 240 mg tablet or four 60 mg tablets, and for patients who cannot swallow tablets, it may be administered through a feeding tube or syringe, or dispersed in orange juice, applesauce, or noncarbonated water. These options ensure that my patient can receive their treatment in the most appropriate way to meet their needs.]

# **Summary**

Based on the information provided, I believe ERLEADA® (apalutamide) is an appropriate and medically necessary treatment for my patient, [Patient Name], I greatly appreciate you taking the time to review this information and reconsider the initial coverage decision.

If you have any further questions about this matter, please contact me at [phone number of your office/clinic] or via email at [your email].

**Sincerely,**

[Your Signature]

[Your Name]

[NPI Number]

# **Enclosures**

For your background, Important Safety Information and data references are listed below.

[List and attach medical records, laboratory work, imaging results, and full Prescribing Information]

**INDICATIONS**

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with:

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

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

**Cerebrovascular and Ischemic Cardiovascular Events** **—** In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 3.7% of patients treated with ERLEADA® and 2% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4.4% of patients treated with ERLEADA® and 1.5% of patients treated with placebo. Across the SPARTAN and TITAN studies, 4 patients (0.3%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with history of unstable angina, myocardial infarction, congestive heart failure, stroke, or transient ischemic attack within 6 months of randomization were excluded from the SPARTAN and TITAN studies.

In the SPARTAN study, cerebrovascular events occurred in 2.5% of patients treated with ERLEADA® and 1% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA® and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, 3 patients (0.2%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from a cerebrovascular event.

Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

**Fractures** **—** In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

**Falls —** In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared with 9% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

**Seizure —** In 2 randomized studies (SPARTAN and TITAN), 5 patients (0.4%) treated with ERLEADA® and 1 patient treated with placebo (0.1%) experienced a seizure. 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.

**Severe Cutaneous Adverse Reactions** **—** Fatal and life-threatening cases of severe cutaneous adverse reactions (SCARs), including Stevens‑Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) occurred in patients receiving ERLEADA®.

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other Grade 4 skin reactions, permanently discontinue ERLEADA® [see Dosage and Administration (2.2)].

**Interstitial Lung Disease (ILD)/Pneumonitis —** Fatal and life-threatening interstitial lung disease (ILD) or pneumonitis can occur in patients treated with ERLEADA®.

Post-marketing cases of ILD/pneumonitis, including fatal cases, occurred in patients treated with ERLEADA®. Across clinical trials (TITAN and SPARTAN, n=1327), 0.8% of patients treated with ERLEADA® experienced ILD/pneumonitis, including 0.2% who experienced Grade 3 events *[see Adverse Reactions (6.1, 6.2)]*.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (eg, dyspnea, cough, fever). Immediately withhold ERLEADA® if ILD/pneumonitis is suspected. Permanently discontinue ERLEADA® in patients with severe ILD/pneumonitis or if no other potential causes of ILD/pneumonitis are identified *[see Dosage and Administration (2.2)]*.

**Embryo-Fetal Toxicity** **—** The safety and efficacy of ERLEADA® have not been established in females. Based on findings from animals and its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® [see Use in Specific Populations (8.1, 8.3)].

**ADVERSE REACTIONS**

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

**Laboratory Abnormalities — All Grades (Grade 3-4)**

* **Hematology** **—** In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA® 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA® 41% (1.8%), placebo 21% (1.6%)
* **Chemistry** **—** In the TITAN study: hypertriglyceridemia ERLEADA® 17% (2.5%), placebo 12% (2.3%). In the SPARTAN study: hypercholesterolemia ERLEADA® 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1.0%); hypertriglyceridemia ERLEADA® 67% (1.6%), placebo 49% (0.8%); hyperkalemia ERLEADA® 32% (1.9%), placebo 22% (0.5%)

**Rash —** In 2 randomized studies (SPARTAN and TITAN), rash was most commonly described as macular or maculopapular. Adverse reactions of rash were 26% with ERLEADA® vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) vs placebo (0.5%).

The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines and topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 28% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

**Hypothyroidism —** In 2 randomized studies (SPARTAN and TITAN), hypothyroidismwas reported for 8% of patients treated with ERLEADA® and 1.5% of patients treated with placebo based on assessments of thyroid-stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA® and 7% of patients treated with placebo. The median onset was at the first scheduled assessment. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose adjusted.

**DRUG INTERACTIONS**

**Effect of Other Drugs on ERLEADA® —** Co-administration of a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA® dose based on tolerability [see Dosage and Administration (2.2)].

**Effect of ERLEADA® on Other Drugs**

CYP3A4, CYP2C9, CYP2C19, and UGT Substrates — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

P-gp, BCRP, or OATP1B1 Substrates— Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

**Please see full** [**Prescribing Information**](https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/ERLEADA-pi.pdf) **for ERLEADA®.**

cp-50507v7

[The following references are for content associated with clinical data and guidelines for ERLEADA® prescribed for patients with mCSPC.]

**References**: **1.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Prostate Cancer V.4.2024. National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed October 9, 2024. To view the most recent and complete version of the guideline, go to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** Lowrance W, Dreicer R, Jarrard DF, et al. Updates to advanced prostate cancer: AUA/SUO guideline (2023). *J Urol.* 2023;209(6):1082-1090; Unabridged version available at https://www.auanet.org/guidelines-and-quality/guidelines/advanced-prostate-cancer **3.** ERLEADA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **4.** Chi KN, Chowdhury S, Bjartell A, et al. Apalutamide in patients with metastatic castration-sensitive prostate cancer: final survival analysis of the randomized, double-blind, phase III TITAN study. *J Clin Oncol*. 2021;39(20):2294-2303. **5.** Chowdhury S, Bjartell A, Merseburger AS, et al. P0845: Apalutamide for metastatic castration-sensitive prostate cancer: Outcomes in high-volume and low-volume disease from the TITAN final analysis. Presented at: European Association of Urology; July 8-12, 2021; Milan, Italy. **6.** Bilen MA, Lowentritt B, Khilfeh I, et al. Real-world head-to-head analysis of overall survival in patients with metastatic castration-sensitive prostate cancer initiated on apalutamide versus enzalutamide in the United States. Poster presented at: European Congress of OncologyPharmacy; October 2-4, 2024; Lisbon, Portugal. **7.** Lowentritt BH, Bilen MA, Khilfeh I, et al. Overall survival in patients with metastatic castration-sensitive prostate cancer treated with apalutamide versus abiraterone acetate—a head-to-head analysis of real-world patients in the United States. Poster presented at: European Congress of Oncology Pharmacy; October 2-4, 2024; Lisbon, Portugal.

[The following references are for content associated with clinical data and guidelines for ERLEADA® prescribed for patients with nmCRPC.]

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