

# Reimbursement and Access Guide

## Information to Support the Reimbursement and Access Process for ERLEADA®

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#### 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 (CONT'D)

##### 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.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.

**Johnson & Johnson**

 **Erleada®**  
(apalutamide) 60 mg tablet  
240 mg tablet

# Introduction

This Reimbursement and Access Guide has been created to provide you and your office staff with information to assist with access for ERLEADA® (apalutamide). This guide provides information about how to access ERLEADA®, coding, guidance related to payer-approval processes, and important product information to support your patients.

- This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice
- Laws, regulations, and policies concerning reimbursement are complex and updated frequently
  - While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it
  - Similarly, all codes are supplied for informational purposes only, and this information does not represent any statement, promise, or guarantee by Johnson & Johnson about coverage, levels of reimbursement, payment, or charge
- Please consult with your payer organization(s) for local or actual coverage and reimbursement policies, and with your internal reimbursement specialist for any reimbursement or billing questions

## IMPORTANT SAFETY INFORMATION (CONT'D)

### WARNINGS AND PRECAUTIONS (CONT'D)

**Cerebrovascular and Ischemic Cardiovascular Events (cont'd)** — 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.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.






J&J

**withMe**

Once you have made the clinical decision to prescribe ERLEADA®, Johnson & Johnson has resources to help you support your patients.

## Comprehensive Support Throughout Your Patients' Treatment Journey

J&J withMe is your single source for access, affordability, and treatment support programs from Johnson & Johnson. Your patients will be connected to ERLEADA withMe.

		
<p><b>Access support to help navigate payer processes</b></p> <p>J&amp;J withMe helps verify insurance coverage for your patients taking ERLEADA®, providing benefits investigation support, prior authorization support, information on the exceptions and appeals process, and reimbursement information.</p> <p>With a Provider Portal account, you can view a patient dashboard with real-time status updates on your requests, like benefits investigation results and savings program claims, and initiate prior authorizations</p>	<p><b>Affordability Resources for Your Patients</b></p> <p>Help patients discover ways to afford their J&amp;J medicine – regardless of their insurance type or even if they have no insurance at all</p>	<p><b>Personalized, free 1-on-1 support for your patients throughout their treatment journey – Offered through ERLEADA withMe</b></p> <p>Each patient's treatment journey is unique. We're here to help by providing personalized 1-on-1 support from oncology trained nurses*</p> <p>*Care Navigators do not provide medical advice.</p>

### Get started with J&J withMe

Visit [Portal.JNJwithMe.com](https://Portal.JNJwithMe.com) to investigate insurance coverage for your patients, enroll your patients in savings, or sign them up for Care Navigator support.

Visit [JNJwithMe.com/hcp/](https://JNJwithMe.com/hcp/) for access and affordability information for the J&J medicine you prescribed.

Questions?

Call 833-JNJ-wMe1 (833-565-9631), Monday through Friday, 8:00 AM to 8:00 PM ET

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe ERLEADA®.

### IMPORTANT SAFETY INFORMATION (CONT'D)

#### WARNINGS AND PRECAUTIONS (CONT'D)

**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.

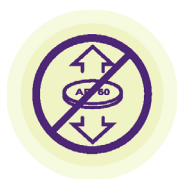
**Seizure** — In 2 randomized studies (SPARTAN and TITAN), 5 patients (0.4%) treated with ERLEADA® and 1 patient treated with placebo (0.1%) experienced a seizure. Permanently discontinue ERLEADA® in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will 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.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.

 **Erleada**<sup>®</sup>  
(apalutamide) 60 mg tablets  
240 mg tablet

# ERLEADA® (apalutamide) Dosing and Administration

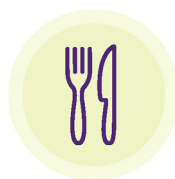
ERLEADA® offers the convenience of alternate methods of administration for patients who have difficulty swallowing tablets whole or who have a feeding tube.<sup>1\*</sup>



No initial dose adjustments needed for renal or hepatic impairment<sup>1†</sup>



No need for concurrent chemotherapy



**Do not crush or split tablet(s).** ERLEADA® can be taken with or without food

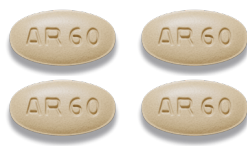


Only ARI with alternate methods of dosing for patients who have difficulty swallowing tablets whole

\*ERLEADA® has not been evaluated in patients with severe renal or hepatic impairment.

ARI, androgen receptor inhibitor.

**60 mg tablet**  
**4 tablets, once daily**



(~17 mm x 9 mm)

**240 mg tablet**  
**1 tablet, once daily**



(~21 mm x 10 mm)

**Comparison of 60 mg and 240 mg tablets**



Tablets shown are not actual size.<sup>4,5</sup>

## IMPORTANT SAFETY INFORMATION (CONT'D)

### WARNINGS AND PRECAUTIONS (CONT'D)

**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®.

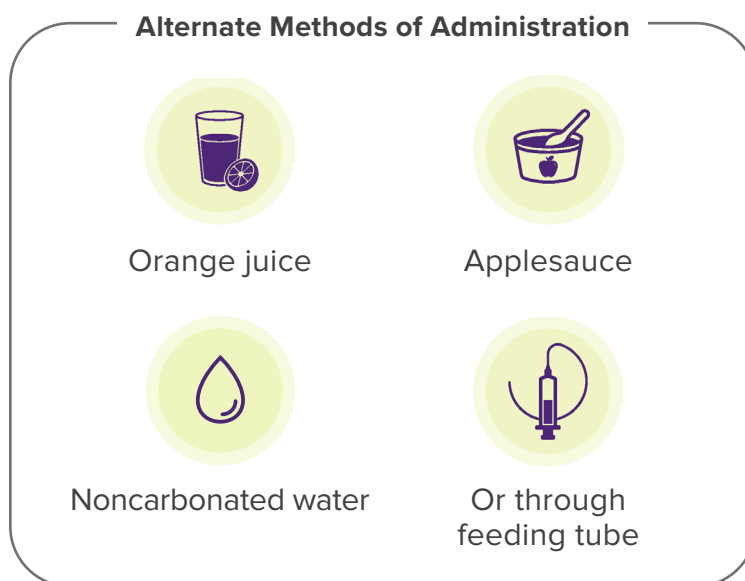
Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. 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)*].

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.

 **Erleada®**  
(apalutamide) 60 mg tablets  
240 mg tablet

# ERLEADA® (apalutamide) Dosing and Administration (cont'd)

ERLEADA® offers the convenience of alternate methods of administration for patients who have difficulty swallowing tablets whole or who have a feeding tube.<sup>1-3\*</sup>



\*For detailed instructions on administration, please see the full ERLEADA® Prescribing Information.

## Dosage Modification

- If Grade 3 or greater adverse reactions, or other intolerable adverse reactions occur, withhold ERLEADA®. Consider permanent discontinuation of ERLEADA® for Grade 3 or 4 cerebrovascular and ischemic cardiovascular events. Permanently discontinue ERLEADA® for severe ILD/pneumonitis or if no other potential causes of ILD/pneumonitis are identified, or confirmed SCARs, or for other Grade 4 skin reactions. For other adverse reactions, when symptoms improve to less than or equal to Grade 1 or original grade, resume ERLEADA® at the same dose or a reduced dose (180 mg or 120 mg), if warranted.<sup>1</sup>

### IMPORTANT SAFETY INFORMATION (CONT'D)

#### WARNINGS AND PRECAUTIONS (CONT'D)

**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)].

ILD, interstitial lung disease; SCARs, severe cutaneous adverse reactions.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Accessing ERLEADA® (apalutamide)



## Specialty Distributors

- If you are an in-office dispensing pharmacy or hospital, you can order ERLEADA® from authorized Specialty Distributors. Please see a list of authorized Specialty Distributors below.
- All other providers and practices can contact a Specialty Pharmacy Provider (SPP). See a list of authorized SPPs on page 6.

Specialty Distributor (SD)*	Phone	Fax
ASD Healthcare	1-800-746-6273	1-800-547-9413
Besse Medical	1-800-543-2111	1-800-543-8695
Cardinal Health SD	1-877-453-3972	1-877-274-9897
Cardinal PR 120	1-800-981-4699	1-787-625-4398
McKesson Specialty Health	1-855-477-9800	N/A
McKesson Plasma and Biologics	1-877-625-2566	1-888-752-7626
Oncology Supply	1-800-633-7555	1-800-248-8205
Priority Healthcare (Curascript)	1-877-599-7748	1-800-862-6208

\*This list is provided for informational purposes only. Johnson & Johnson does not endorse the use of any particular distributor. This information was current at time of publication.

Contact your specialty distributor to confirm product availability.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### WARNINGS AND PRECAUTIONS (CONT'D)

**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)]

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Accessing ERLEADA® (apalutamide) (cont'd)



## Specialty Pharmacy Providers (SPPs)

- If you are a healthcare provider (HCP) or HCP office prescribing ERLEADA®, you can contact an SPP within the ERLEADA® distribution network
- SPPs may offer services to verify insurance coverage, identify potential patient assistance programs, and provide medication adherence support
  - For an example of the SPP process, see page 7
- J&J withMe can assist with identifying specialty pharmacy options that fit each patient’s insurance plan

Independently Owned Specialty Pharmacies*	Phone	Fax
Acaria	1-866-892-1580	1-866-892-2263
AllianceRx (Walgreens)	1-855-244-2555	1-877-231-8302
Amber Pharmacy	1-888-370-1724	1-877-645-7514
BioMatrix Specialty Pharmacy	1-888-662-6779	1-877-800-4790
BioPlus	1-888-292-0744	1-800-269-5493
Hy-Vee Pharmacy Solutions	1-877-794-9833	1-402-861-4941
Kroger Specialty Pharmacy	1-855-802-3230	1-888-315-3270
Onco360	1-877-662-6633	1-877-662-6355
Publix	1-844-797-8254	1-863-413-5723
Special Care Puerto Rico	1-888-727-1727 or 1-877-899-8997	1-855-230-9963 or 1-787-783-2951

Payer or Wholesaler-Owned Specialty Pharmacies*	Phone	Fax
Accredo	1-844-516-3319	1-888-302-1028
Aetna Specialty Pharmacy	1-866-782-2779	1-866-329-2779
Biologics	1-800-850-4306	1-800-823-4506
Magellan Rx Pharmacy	1-866-554-2673	1-866-364-2673
Optum Specialty Oncology	1-877-445-6874	1-877-342-4596
CVS Specialty Customer Care	1-855-539-4712	1-888-435-1256
Humana Specialty Pharmacy	1-800-486-2668	1-877-405-7940

\*This represents a partial list of SPPs supplying ERLEADA®. It is not intended to serve as a comprehensive list. Johnson & Johnson does not endorse the use of any of the listed pharmacies in particular.

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient’s doctor or nurse, provide case management services, or serve as a reason to prescribe ERLEADA®.

## IMPORTANT SAFETY INFORMATION (CONT'D)

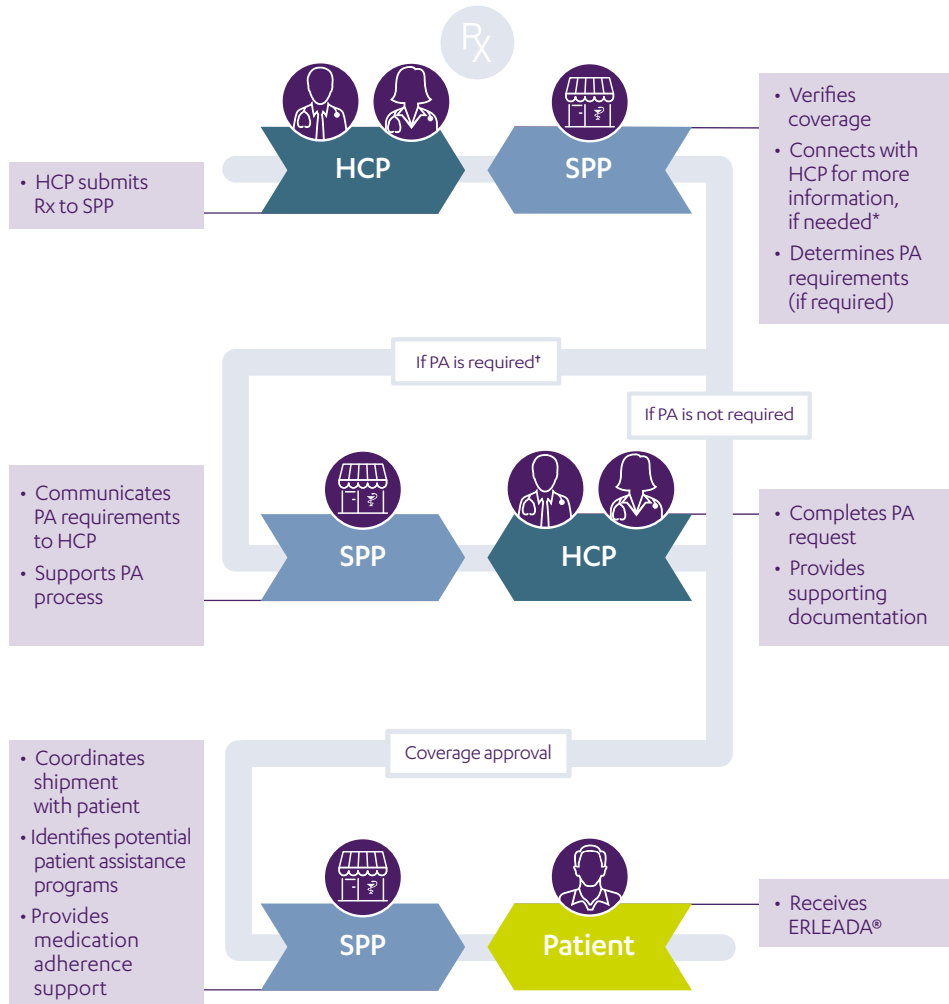
### ADVERSE REACTIONS

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.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Example of the Specialty Pharmacy Provider (SPP) Process



J&J withMe can help verify insurance coverage for patients, provide reimbursement information, and triage prescriptions to specialty pharmacy providers.

PA = prior authorization.

\*In some cases, if a patient's insurance requires that the specialty medication be fulfilled through a specific pharmacy benefit manager-owned pharmacy, the SPP that originally received the prescription will coordinate with your staff and the approved SPP to triage the prescription.

\*Also supports exception request process when applicable. If a PA submission or exception request is denied, an appeal can be filed to request that the payer reconsider the initial decision. Either the provider or the patient can initiate an appeal.

**For more information on the steps outlined above, please see the [Coverage Decisions](#) section of this guide.**

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe ERLEADA®.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### ADVERSE REACTIONS (CONT'D)

#### 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%)

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.





# Coding

## ICD-10-CM

ICD-10-CM codes are used to identify a patient's diagnosis. The diagnosis of non-metastatic CRPC and mCSPC can be reported using a combination of the following codes:

ICD-10 code <sup>4</sup>	Diagnosis
C61	Malignant neoplasm of prostate
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
Z19.2	Hormone resistant malignancy status

CRPC, castration-resistant prostate cancer; FDA, U.S. Food and Drug Administration; ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification; mCSPC, metastatic castration-sensitive prostate cancer; PSA, prostate-specific antigen.

These codes are not intended to be promotional, or to encourage or suggest a use of drug that is inconsistent with FDA-approved use. Please refer to the current policy for the latest codes, since these codes are subject to change. The codes provided are not intended to be exhaustive and may require a higher level of specificity. Please consult your ICD-10 code book for additional information.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### ADVERSE REACTIONS (CONT'D)

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

- Chemistry** — In the TITAN study: hypertriglyceridemia ERLEADA<sup>®</sup> 17% (2.5%), placebo 12% (2.3%). In the SPARTAN study: hypercholesterolemia ERLEADA<sup>®</sup> 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA<sup>®</sup> 70% (2%), placebo 59% (1.0%); hypertriglyceridemia ERLEADA<sup>®</sup> 67% (1.6%), placebo 49% (0.8%); hyperkalemia ERLEADA<sup>®</sup> 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<sup>®</sup> vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA<sup>®</sup> treatment (6%) vs placebo (0.5%).

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.

# Coverage Decisions

Third-party payers, including both public (eg, Medicare and Medicaid) and commercial (eg, private, employer-sponsored) plans, may require more information than a prescription alone to cover a medication. There are 3 primary categories of requests for additional information:

- Prior authorization
- Exception request
- Appeals

Although there is no standardized process that applies across all payers, the goal is the same: to ensure that a prescribed medication is medically necessary and being used correctly.

## Prior Authorization (PA)

Prior authorization (also called pre-authorization or pre-auth) is a common payer-required approval process that requires providers to submit medical necessity documentation in a specific way before coverage is approved for a requested therapy or service.

PA requirements – and the list of drugs subject to PA – will vary among payers. It is not unusual for there to be different coverage rules for the same therapy among payers within the same geographic area.

Often, a payer will provide a specific form or process for PA. Providers may want to supplement this with documentation providing enough detail to support the request, such as medical chart notes, laboratory results, and prescription records.

### Tips for Filing a PA

#### Forms and documents you may want to accompany a PA submission include:

- Letter of medical necessity
- Patient Authorization form
- Copy of the patient's health plan or prescription card (front and back)
- Supporting documentation:
  - Summary of patient diagnosis
    - Date of diagnosis
    - Laboratory results and date
    - Current condition
  - Patient history and physical findings
    - Previous therapies/procedures and response to those interventions
    - Description of patient's recent symptoms/condition

## IMPORTANT SAFETY INFORMATION (CONT'D)

### ADVERSE REACTIONS (CONT'D)

**Rash (cont'd)** — 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®.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Coverage Decisions (cont'd)

## Exception Request



Exception requests may be required when a product has been recently approved and a plan has not yet reviewed the product or made a coverage decision on it. In these cases, an exception, or nonformulary request, can be made.

An exception request is a specific type of coverage determination that asks a payer to reconsider a tiering or formulary decision. There are 2 categories of exception requests:

- **Formulary exception:** used to obtain a prescription drug that is not included on a plan's formulary or to change step therapy or quantity/dosage limits
- **Tiering exception:** used to obtain a nonpreferred drug at the cost-sharing terms applicable to drugs in the preferred tier

Enrollees, their appointed representative, or the healthcare provider may request a formulary or tiering exception. A statement from the healthcare provider supporting medical necessity will be necessary. This evidence may be submitted verbally or in writing, depending on the payer's requirements. Medicare publishes requirements for Part D plans; however, most plans will seek similar information. Exception requests are granted when a plan determines that a requested drug is medically necessary for that patient.

## IMPORTANT SAFETY INFORMATION (CONT'D)

### ADVERSE REACTIONS (CONT'D)

**Hypothyroidism** — In 2 randomized studies (SPARTAN and TITAN), hypothyroidism was 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.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Coverage Decisions (cont'd)

## Appeals

An appeal refers to any of the procedures used to challenge a payer's adverse coverage determination regarding benefits that a beneficiary believes he or she is entitled to receive. If a payer does not grant an exception request, that decision may be appealed.

If a PA submission or exception request is denied, an appeal can be filed to request that the payer reconsider the initial decision. Either the provider or the patient can initiate an appeal.

- Most plans allow multiple levels of appeal, which typically start with a written explanation of why the patient is clinically appropriate for the prescribed medication
- Some plans offer verbal or peer-to-peer review requests between the treating physician and the medical director at the health plan
- A non-Medicare payer may have an appeals process that is unique to that payer

### Tips for Filing an Appeal



- Review the denial notice to understand the reason for denial and to identify the appeal process requirements (documentation, time frame, etc)
- Review accuracy and completeness of the original PA request (patient information, documentation, etc)
- Create a comprehensive letter of appeal (demographic, diagnostic, and treatment information)
- Include any supporting documentation as required by the payer (the denial letter, letter of medical necessity, patient records/Electronic Medical Records, etc)

## IMPORTANT SAFETY INFORMATION (CONT'D)

### 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)].

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Resources to Support Your Patients

Resources are available through J&J withMe to help assist patients to access ERLEADA® (apalutamide). Please consult with your Johnson & Johnson representative for more information on the tools and resources available for your patients.

## Sample Letters

Some payers and other formulary decision makers may require that treating physicians complete a Letter of Medical Necessity or request a formulary exception before patients can receive a specific therapy. We have provided a sample Letter of Medical Necessity and a sample Letter of Formulary Exception Request below.\* Editable sample letter templates are available for download on [JNJwithMe.com/hcp/](http://JNJwithMe.com/hcp/).

### Sample Letter of Medical Necessity

[Insert Physician Letterhead]

[Insert Name of Medical Director]      Re:    Member Name: [Insert Member Name]  
[Insert Payer Name]                      Member Number: [Insert Member Number]  
[Insert Address]                            Group Number: [Insert Group Number]  
[Insert City, State ZIP]

**REQUEST:** Authorization for treatment with ERLEADA® (apalutamide)  
**DIAGNOSIS:** [Insert Diagnosis] [Insert ICD]  
**DOSAGE FORM AND STRENGTH:** [Insert Dosage Form & Strength]  
**REQUEST TYPE:**  Standard  EXPEDITED

Dear [Insert Name of Medical Director or name of individual responsible for prior authorization]:

I am writing to support my request for an **authorization** for the above-mentioned patient to receive treatment with ERLEADA® for [Insert indication]. My request is supported by the following:

**Summary of Patient's Diagnosis**  
[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

**Summary of Patient's History**  
[Insert:]

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type (eg, inpatient, hospital outpatient, outpatient clinic, private practice, or other) and rationale (eg, compliance or closely monitoring patients)
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with ERLEADA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

**Rationale for Treatment**  
[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of ERLEADA®, I believe treatment with ERLEADA® at this time is medically necessary, and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for ERLEADA® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request.] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,  
[Insert Healthcare Provider's Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

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### Sample Letter of Formulary Exception Request

[Insert Physician Letterhead]

[Insert Name of Medical Director]      RE:    Member Name: [Insert Member Name]  
[Insert Payer Name]                      Member Number: [Insert Member Number]  
[Insert Address]                            Group Number: [Insert Group Number]  
[Insert City, State Zip]

**REQUEST:** Authorization for treatment with ERLEADA® (apalutamide)  
**DIAGNOSIS:** [Insert Diagnosis] [Insert ICD]  
**DOSAGE FORM AND STRENGTH:** [Insert Dosage Form & Strength]  
**REQUEST TYPE:**  Standard  EXPEDITED

Dear [Insert Name of Medical Director]:

I am writing to request a **formulary exception** for the above-mentioned patient to receive treatment with ERLEADA® for [Insert indication]. My request is supported by the following:

**Summary of Patient's Diagnosis**  
[Insert patient's diagnosis, date of diagnosis, lab results and date, current condition]

**Summary of Patient's History**  
[Insert:]

- Previous therapies/procedures, including dose and duration, response to those interventions
- Description of patient's recent symptoms/condition
- Site of medical service—include site type: Inpatient, hospital outpatient, outpatient clinic, private practice, or other
- Rationale for not using drugs that are on the plan's formulary
- Summary of your professional opinion of the patient's likely prognosis or disease progression without treatment with ERLEADA®

Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition.]

**Rationale for Treatment**  
[Insert summary statement for rationale for treatment such as: Considering the patient's history, condition, and the full Prescribing Information supporting uses of ERLEADA®, I believe treatment with ERLEADA® at this time is medically necessary and should be a covered and reimbursed service.]

[You may consider including documents that provide additional clinical information to support the recommendation for ERLEADA® for this patient, such as the full Prescribing Information, peer-reviewed journal articles, or clinical guidelines.]

[Given the urgent nature of this request.] please provide a timely authorization. Contact my office at [Insert Phone Number] if I can provide you with any additional information.

Sincerely,  
[Insert Physician Name and Participating Provider Number]

Enclosures [Include full Prescribing Information and the additional support noted above]

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\*PLEASE NOTE: These are sample letters. Use of these letters does not guarantee reimbursement.

**Questions? Call 833-JNJ-wMe1 (833-565-9631),  
Monday through Friday, 8:00 AM to 8:00 PM ET**

The patient support and resources provided by J&J withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe ERLEADA®.

Please see Important Safety Information throughout and [click here](#) for full Prescribing Information.



# Important Safety Information (cont'd)

## DRUG INTERACTIONS (CONT'D)

### 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 for ERLEADA®](#).

cp-50507v7

**References:** **1.** ERLEADA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Nubeqa® (darolutamide) [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc. **3.** Xtandi® (enzalutamide) [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc. **4.** American Medical Association. ICD-10-CM 2018; The Complete Official Code Book. Chicago, IL: Optum 360 LLC; 2017. **5.** Data on File. Janssen Biotech Inc.