

Janssen Scientific Affairs, LLC

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May 23, 2018

Joan McClure
275 Commerce Drive
Fort Washington, PA 19034
USA

Dear Ms. McClure,

Please consider the following information.

Response(s):

- ERLEADA - Compendia Communication - NCCN Guidelines - May 2018

I look forward to working with you as you consider the enclosed information. The information provided is not intended as an endorsement of any usage not contained in the Prescribing Information. For complete information, please refer to the full Prescribing Information, including the following sections: INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

If you require further information, please feel free to contact me via the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Sincerely,


Lisa Meadows, RPh
Therapeutic Manager
Medical Information

Inquiry #:01157058

Enclosure(s)/Electronic Link(s):

- ERLEADA™ (apalutamide) Prescribing Information at https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-50722e17-d630-456e-befb-8a37a3e3e99d

Need Help? If you have any additional questions, please contact us via:

 1-800-JANSSEN Monday - Friday, 9 am - 8 pm EST	 24x7 Access to Medical Information www.janssenmd.com
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To report a possible adverse event or product quality complaint, please call the Medical Information Center immediately, at 1-800-JANSSEN (1-800-526-7736).

ERLEADA™ (apalutamide)
Compendia Communication – NCCN Guidelines – May 2018

May 23, 2018

Name: Lisa Meadows Ambrose, RPh, BCOP
Company/Organization: Janssen Biotech, Inc.
Address: 850 Ridgeview Drive Horsham, PA 19044
Phone: 804.539.7417
E-mail: LMeadows@its.jnj.com
Date of request: May 23, 2018
NCCN Guidelines® Panel: Prostate Cancer

Dear NCCN,

On behalf of Janssen Biotech, Inc., I respectfully request the NCCN Guidelines® Prostate Cancer Panel review the suggested changes to the NCCN Guidelines® for Prostate Cancer that correspond to the most current ERLEADA™ Prescribing Information and current literature.

SPECIFIC CHANGES AND RATIONALE:

- **PROS-F, page 3 of 4: Principles of Androgen Deprivation Therapy**
 - Suggest revising: “No significant difference was seen in overall survival.” to “Overall survival data were not mature at the time of the final analysis for metastasis-free survival (24% of the required number of events).”
 - At the time of the first interim analysis of overall survival (24% of events reported), median overall survival was not reached in the apalutamide group versus 39.0 months in the placebo group (HR=0.70; 95% CI, 0.47 to 1.04; $P=0.07$). The final overall survival analysis will be conducted after approximately 427 events have been reported.¹⁻³
- **PROS-14: Systemic Therapy for M0 Castration-Resistant Prostate Cancer (CRPC) algorithm:** “PSA increasing → Yes → Imaging → No metastases (M0) → Change or maintain current treatment and continue monitoring”
 - Please consider adding a footnote in this section and contextual information within the Discussion section:
 - Currently, there are no specific recommendations in the ERLEADA Prescribing Information regarding treatment discontinuation based on disease progression. In SPARTAN, the phase 3, randomized, double-blind, placebo-controlled, multicenter study evaluating the efficacy and safety of apalutamide compared to placebo in patients with high-risk NM-CRPC receiving continuous ADT, **treatment with apalutamide was continued until radiographic disease progression confirmed** by blinded central imaging review, locoregional-only progression, initiation of new

treatment, unacceptable toxicity, or withdrawal. **PSA results were blinded and were not used for treatment discontinuation.**^{1,2}

FDA CLEARANCE: The FDA has approved ERLEADA™ for the treatment of patients with NM-CRPC.¹

Sincerely,
Lisa Meadows Ambrose RPh, PharmD-c, BCOP
Therapeutic Manager, Oncology Medical Information
Janssen Scientific Affairs, LLC

REFERENCES

1. ERLEADA (apalutamide) [Prescribing Information]. Horsham, PA: Janssen Products, LP; https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-50722e17-d630-456e-befb-8a37a3e3e99d.
2. Smith MR, Saad F, Chowdhury S, et al. Apalutamide treatment and metastasis-free survival in prostate cancer. *N Engl J Med*. 2018;378(15):1408-1418.
3. Small EJ, Saad F, Chowdhury S, et al. SPARTAN, a phase 3 double-blind, randomized study of apalutamide vs placebo in patients with nonmetastatic castration-resistant prostate cancer. Oral presentation presented at: the American Society of Clinical Oncology Genitourinary (ASCO-GU) Cancers Symposium; February 8-10, 2018; San Francisco, CA.