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April 09, 2019

Kristina Gregory RN, MSN, OCN
3025 Chemical Road
Plymouth Meeting, PA 19462
USA

Dear Ms. Gregory,

Please consider the following information.

Response(s):

- ZYTIGA - NCCN Compendium Communication - APRIL 2019

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 #:01370946

Enclosure(s)/Electronic Link(s):

- ZYTIGA® (abiraterone acetate) Prescribing Information at
https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-ecaf8e16-61b7-48c6-a6ad-2594b810a4af

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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**ZYTIGA® (abiraterone acetate)
NCCN® Communication – April 2019**

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: April 3, 2019
NCCN Guidelines® Panel: Prostate Cancer

Re: Chemotherapy Order Template, Prostate Cancer, Abiraterone/PredniSONE

Dear NCCN,

On behalf of Janssen Biotech, Inc., I respectfully request review of the following dosing information included in the ZYTIGA® (abiraterone acetate) Prescribing Information as related to the current dosing of abiraterone (conventional formulation) and prednisone included in the NCCN® Abiraterone/PredniSONE Chemotherapy Order Template.¹

Specific Changes: We request revision of the dosing information included in page 1 of the NCCN® Chemotherapy Order Template, Prostate Cancer, Abiraterone/PredniSONE Acetate. Specifically, please remove mentions of “28 day cycle” and “on Days 1-28”; and change the prednisone dosing frequency from “twice daily” to “once daily” for regional and castration-naïve metastatic (M1) disease as is the FDA-approved prednisone dosing for metastatic high-risk castration-sensitive prostate cancer and the dose studied in the LATITUDE^{2,3} and STAMPEDE⁴ trials.

FDA Clearance: The FDA has approved ZYTIGA® (abiraterone acetate) in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) and metastatic high-risk castration-sensitive prostate cancer (CSPC).¹ The FDA approved dosing included in the ZYTIGA Prescribing Information is:

Metastatic castration-resistant prostate cancer:

- ZYTIGA 1,000 mg orally once daily with prednisone 5 mg orally **twice** daily.

Metastatic castration-sensitive prostate cancer:

- ZYTIGA 1,000 mg orally once daily with prednisone 5 mg orally **once** daily.

Patients receiving ZYTIGA should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy. ZYTIGA must be taken on an empty stomach with water at least 1 hour before or 2 hours after a meal. Do not crush or chew tablets.¹ Please see the ZYTIGA full Prescribing Information for Dose Modification Guidelines.

Rationale:

The dosing recommendation included in the ZYTIGA® (abiraterone acetate) Prescribing Information for men with metastatic high-risk CSPC is based on dosing in the large phase 3, randomized, double-blind, placebo-controlled, multicenter study of abiraterone acetate plus daily prednisone with androgen deprivation therapy (ADT) compared to placebos with ADT in this patient population (LATITUDE Study; N=1199); and therapy was continued until radiographic or clinical disease progression (defined as the need for cytotoxic chemotherapy, radiation or surgical treatment for cancer, pain requiring chronic opioids, or ECOG performance status decline ≥ 3), unacceptable toxicity, withdrawal or death.^{2,3}

Please note the dosing regimen of ZYTIGA 1,000 mg daily *plus prednisone 5 mg daily* for patients with metastatic high-risk CSPC was detailed in our prior communications to the panel on June 8, 2017 and March 12, 2019.

Sincerely,

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

REFERENCES

1. ZYTIGA (abiraterone acetate) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-ecaf8e16-61b7-48c6-a6ad-2594b810a4af.
2. Fizazi K, Tran NP, Fein L, et al. Abiraterone plus prednisone in metastatic castration-sensitive prostate cancer. *N Engl J Med*. 2017;377(4):352-360.
3. Fizazi K, Tran N, Fein L, et al. Final analysis of phase 3 LATITUDE study in patients (pts) with newly diagnosed high-risk metastatic castration naïve prostate cancer (NDx-HR mCNPC) treated with abiraterone acetate + prednisone (AA+P) added to androgen deprivation therapy (ADT). Poster presented at: American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium; February 14-16; San Francisco, CA. 2019.
4. James ND, de Bono JS, MR Spears, et al. Abiraterone for prostate cancer not previously treated with hormone therapy. *N Engl J Med*. 2017;377:338-351.