

Submitted by:

Name: Marian Ibrahim, PharmD

Company/Organization: Sanofi

Address: 55 Corporate Drive, Bridgewater, NJ 08807

Phone: (800) 633-1610

Email: Marian.ibrahim@sanofi.com

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NCCN Guidelines Panel: Prostate Cancer

In follow-up to the publication of the *NCCN Prostate Cancer Guidelines, Version 1.2020* and the reference to the results of the CARD study on PROS-16, 16A, and PROS-H 1 of 2, we wish to submit the results of the CARD Study Pain Response and Health-related Quality of Life Analysis.

Specific Changes: Recommend that reference to ‘cabazitaxel’ (as subsequent therapy to docetaxel) in the NCCN Guidelines Version 1.2020 be cited with the results from the CARD Study presentation of the pain response and health-related quality of life analysis presented at the American Society of Clinical Oncology Genitourinary Conference, February 2020. A summary of results is included in the ‘Rationale’ section below.

FDA Clearance: “JEVTANA®(cabazitaxel) injection, is a microtubule inhibitor indicated in combination with prednisone for treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.” Prescribing Information Rev 3/20.

Rationale: In support of this specific request for the guideline update,

- Proportion of patients with a decrease of $\geq 30\%$ from baseline in average BPI-SF pain intensity score at two consecutive evaluations ≥ 3 weeks apart without increase in analgesic usage score; cabazitaxel 45.0% vs abiraterone or enzalutamide 19.3% ($p < 0.0001$)
- Median time to first symptomatic skeletal event (SSE), Cabazitaxel median not reached vs abiraterone or enzalutamide median time to first SSE 16.7 months (HR = 0.59, 95% Confidence Interval 0.35-1.01, $p = 0.05$)

A copy of the presentation of the CARD Pain Response and HRQL Study is submitted with this request: Fizazi K, et al. Pain response and health-related quality of life analysis in patients with metastatic castration-resistant prostate cancer (mCRPC) receiving cabazitaxel vs abiraterone or enzalutamide in the CARD study. Presented – Genitourinary Cancers Symposium, Feb 2020 #GU20

We appreciate the opportunity to provide this information for consideration by the NCCN Prostate Cancer Panel.

Sincerely,

Marian Ibrahim, PharmD