Submitted by:

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NCCN Guidelines Panel: Breast Cancer

For consideration for inclusion in the *NCCN Breast Cancer Guidelines, Version 4.2021*, BINV-Q 1 of 8, we wish to submit the results of the "Randomised Multicentre Trial of Three Weekly Cabazitaxel versus Weekly Paclitaxel Chemotherapy in the First Line Treatment of HER2 Negative Metastatic Breast Cancer (MBC)^{1"}, Amit Bahl, et al, ASCO Annual Meeting 2021, Abstract Number 1008.

<u>Specific Changes</u>: Request consideration for inclusion of cabazitaxel as an alternative taxane chemotherapy to paclitaxel for patients requiring a systemic therapy regimen for recurrent unresectable (local or regional) or Stage IV (M1) invasive breast cancer.

<u>FDA Clearance</u>: "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 2/21.

Rationale: The authors' conclusions from the study:

- Cabazitaxel (every 3 weeks) as first line chemotherapy in HER2 negative MBC does not significantly improve progression-free survival (PFS) compared to once weekly paclitaxel
- PFS and Overall Survival (OS) were similar between every 3 weekly cabazitaxel and weekly paclitaxel
- Cabazitaxel was associated with better overall patient reported health outcomes and a lower risk of peripheral neuropathy
- Every 3 week cabazitaxel is safe and well tolerated for MBC and requires fewer hospital visits than weekly paclitaxel

Reference included:

J Clin Oncol 39, 2021 (suppl 15; abstr 1008)

PowerPoint Slide Set: Cabazi 3 weekly v Paclitaxel ASCO2021.pptx

Sincerely,

Marian Ibrahim, PharmD

Clinical Trial Registry Number NCT03048942