Dear NCCN,

On behalf of Centocor Ortho Biotech, I respectfully request the NCCN Guidelines™ - Prostate Cancer Panel to review the enclosed data for inclusion of ZYTIGA™ (abiraterone acetate) Tablets for the treatment of castration recurrent prostate cancer.

**Specific Change:** Recommend ZYTIGA™ as an additional systemic therapy for patients with castration recurrent prostate cancer.

**FDA Clearance:** FDA has approved ZYTIGA™ in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) who have received prior chemotherapy containing docetaxel.

**Rationale:** Approval was based on a Phase 3, international, randomized, double-blind, placebo-controlled, multicenter study in patients with metastatic castration-resistant prostate cancer (mCRPC) whose disease had progressed after receiving docetaxel-based chemotherapy (N = 1195). At the protocol pre-specified interim analysis, treatment with ZYTIGA in combination with prednisone showed a statistically significant improvement in median overall survival compared to the placebo plus prednisone arm and resulted in a 35 percent reduction in the risk of death (14.8 months vs. 10.9 months; hazard ratio [HR] = 0.646; 95 percent confidence interval [CI]: 0.543, 0.768; p < 0.0001). In an updated survival analysis, results were consistent with those from the interim analysis (median 15.8 months vs. 11.2 months; HR = 0.74; 95 % CI: 0.638, 0.859). The most common adverse reactions (≥ 5%) are joint swelling or discomfort, hypokalemia, edema, muscle discomfort, hot flush, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia and upper respiratory tract infection.

The following publications are submitted with the Full Prescribing Information in support of this proposed addition. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of some of these publications.

1. ZYTIGA™ (abiraterone acetate) Tablets PRESCRIBING INFORMATION, Distributed by Centocor Ortho Biotech Inc., Horsham, PA. April 2011.


Sincerely,

Lisa Meadows RPh, PharmD-c, BCOP
Manager, Medical Information