PHEN

Prostate Health Education Network, Inc.

June 20, 2018

James Mohler, MD Chair, National Comprehensive Cancer Network Prostate Cancer Treatments Guidelines Panel

Dear Dr. Mohler,

I am addressing two issues which are impacting patient access and requesting that the NCCN Prostate Cancer Treatments Guidelines Panel review its guidelines pertaining to each.

Issue I: Access to SpaceOAR perirectal spacer

Nationally there are seven Medicare Administrative Contractors (MAC's). Six of these provide reimbursement coverage for SpaceOAR. However the seventh, National Government Services (NGS), does not. This means that medicare patients in the New England States, New York, Illinois, Minnesota and Wisconsin do not have access to SpaceOAR. Part of NGS's rationale for denying coverage is that the NCCN guidelines under "Principles of Radiation Therapy" (PROS-D, page 1/3) states that "Perirectal spacer materials **may** be employed..." Is it possible that this statement could be strengthened to change "may" to "is recommended to be employed..."?

Issue II: Denosumab vs Zolendronic Acid

Both Denosumab and Zolendronic Acid are designated as category 1 in the guidelines for treatment of bone metastases. However, within PROS-G, page 3/3, the guidelines states: "when compared to Zolendronic Acid Denosumab was shown to be superior in prevention of skeletal-related events." Notwithstanding, United HealthCare is changing its policy to indicate Denosumab as a step-therapy behind Zolendronic Acid and citing the NCCN guidelines in designating both as category 1. This change will deny patients the superior treatment. In addition, Zolendronic Acid relative to Denosumab increases patients risk for kidney failure. African American patients are 3 times more likely to experience kidney failure representing 35% of all patients in the US receiving dialysis. Subjecting prostate cancer patients at high risk for kidney failure to Zolendronic Acid versus Denosumab increases their risk for bone complications and kidney failure. What adjustments to the guidelines can be made to close this loop-hole which is driven by cost and not by patient interests?

Thanks for your consideration of adding these issues to the agenda for our upcoming meeting on June 30.

Sincerely,

Thomas A. Farrington

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