DENOSUMAB APPROVED FOR PATIENTS ON ADT (with provisions)

The National Cancer Institute has recommended, and the FDA has approved, the prescribing of Denosumab for patients on Androgen Deprivation Therapy (ADT) when Bone mineral density (BMD) imaging with either Quantitative Computerized Tomography (QCT) or Dual-Energy X-ray Absorptiometry (DEXA) testing indicates loss of bone mineral density. It is NOT approved for bone loss prevention. Read on:

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The committee voted in favor of an approval for denosumab for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer but against its use for bone loss prevention, due to the potential for the small, increased risk of certain infections, including skin and urinary tract infections, seen in some clinical trials involving denosumab.

"Some patients undergoing androgen deprivation therapy may not develop enough loss of BMD to cause an increased risk of bone fracture," explained James L. Gulley, M.D., Ph.D., of the Laboratory of Tumor Immunology and Biology in NCI's Center for Cancer Research, who was a voting member on the FDA advisory committee. "And the general feeling of the committee was, until we get more safety data, let's not recommend an indication for prevention of BMD loss," he said.

http://www.cancer.gov/clinicaltrials/results/denosumab-bmd-prostate1009