Comment to CMS on Provenge National Coverage Determination:

On behalf of Men's Health Network (MHN), we commend CMS for following the science around Provenge as well as providing for broad on-label access in the Proposed Decision Memo. CMS needs to be clear that this decision supports coverage according to the FDA label and that local Medicare contractors should not be adding additional barriers for men who desperately need this therapy. The final National Coverage Determination should make certain that men with metastatic, castrate-resistant prostate cancer have access to Provenge per its FDA-approved label.

Prostate cancer is the most prevalent form of cancer among American males. Nearly 220,000 men were projected to be diagnosed with prostate cancer in 2010, and about 32,000 were projected to die from this disease. Men with advanced prostate cancer face many serious challenges. For these men access to treatment is of utmost importance to extend and improve their lives.

For over a decade there has been an immense need for innovative treatments to improve the plight of men suffering from advanced prostate cancer. As you know, prostate cancer is a complex and problematic disease that affects not only the male patient, but also his wife, daughter, partner, and other family members.

African-American men have one of the highest rates of incidence and death from prostate cancer in the world. They are 1.6 times as likely to be diagnosed with prostate cancer and 2.4 times as likely to die of this disease.

To conclude, Men's Health Network is very happy that CMS let the science direct their decision and that the draft guidance provides for on-label access to Provenge as clearly reasonable and necessary. Access to this therapy is critically important to men and their families. CMS needs to ensure that local Medicare contractors do not add barriers to access for Provenge.

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