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September 12, 2013

Dr. John McInnes
Director, Division of Outpatient Care
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: CMS Classification of New Bladder Cancer Treatment (HCPCS Code C9275)

Dear Dr. McInnes:

I am writing to share my concerns about how the Centers for Medicare & Medicaid Services (CMS) has classified a bladder cancer drug for reimbursement under the proposed Medicare hospital outpatient prospective payment system (OPPS) rule for calendar year 2014 (the "proposed rule"). I believe that CMS's proposed rule will have a serious impact on access to care for Medicare beneficiaries with bladder cancer.

According to the National Cancer Institute, bladder cancer is the fifth most common cancer diagnosis, with estimates of more than 72,500 new cases in the United States in 2013, resulting in more than 15,000 deaths. Additionally, since the median age for a bladder cancer diagnosis is 73, Medicare policy has a disproportionate impact on the availability of bladder cancer treatment for patients of all ages. Despite bladder cancer's prevalence, there has not been a significant advancement in treatment options for 20 years. In 2010, however, the Food and Drug Administration (FDA) approved a new bladder cancer treatment called Cysview, developed by the New Jersey-based company Photocure. This innovative new technology allows physicians to utilize blue light cystoscopy (versus the traditional white light) to more effectively and efficiently treat bladder cancer. Studies have shown use of blue light technology has been shown to result in substantial improvements in reducing the long-term recurrence of bladder cancer, while also resulting in less damage to patients' bladders. Additionally, this new technology has been shown to be more cost effective than other existing bladder cancer treatments.

Despite the demonstrated benefits of Cysview and blue light cystoscopy, CMS's categorization of the drug for reimbursement purposes appears to be causing

providers to stop offering the treatment and is severely limiting beneficiaries' access to this course of treatment. In 2013, the first year after the expiration of the drug's pass-through status, CMS classified Cysview as a contrast agent. Now, in the proposed rule for calendar year 2014, CMS has reversed that determination and is now proposing it be classified as a "drug that functions as a supply," a previously nonexistent reimbursement category.

I have serious concerns about how these determinations will impact beneficiaries' access to this treatment. I would also like to request more information about how CMS made the payment determinations. Based on the characteristics of the drug, and CMS's proposed rule, my understanding is that Cysview is not a contrast agent and therefore should not have been categorized as one for reimbursements in 2013. In addition, I understand that in order for a drug to be part of an OPSS packaged payment, the cost cannot exceed a threshold determined by both statute and regulation. The current threshold of \$80 is below the cost of Cysview, making the drug ineligible for a package payment. Unfortunately, this decision has already resulted in fewer providers offering the service and created a lasting barrier to care for beneficiaries.

In order to ensure beneficiaries have access to the most effective, and cost-efficient, services available, I ask that you please consider reevaluating the policies proposed in the calendar year 2014 OPSS rule for Cysview to ensure that we are not jeopardizing patient access to effective treatments. I appreciate your consideration of this issue. Should you have any questions please do not hesitate to contact my office.

Sincerely,


ROBERT MENENDEZ
United States Senator

cc: Jonathan Blum, Deputy Director