

THE UNIVERSITY OF TEXAS
MD Anderson
~~Cancer~~ Center

Department of Urology -1373
713-792-3250
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December 10, 2013

The Honorable Max Baucus
Chairman, Senate Finance Committee
511 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Orrin Hatch
Ranking Member, Senate Finance Committee
104 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Dave Camp
Chairman, Ways & Means Committee
341 Cannon House Office Building
Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member, Ways & Means Committee
1236 Longworth House Office Building
Washington, D.C. 20515

Re: Need to Ensure Access to Vital Cancer Treatment

Dear Senators and Representatives:

I am a Urologist at the University of Texas MD Anderson Cancer Center and have been treating bladder cancer patients for 36 years. I am writing to express my deep concerns that bladder cancer patients are at risk of losing access to new, clinically-effective and cost-efficient cancer treatments. Access to these treatments has been put in jeopardy because of a recent decision by the Centers for Medicare & Medicaid Services (CMS) to "package" hospital outpatient payments for bladder cancer treatment. I am writing to urge you to take action to ensure that Medicare beneficiaries are able to access the treatments for the detection of cancer.

As you may know, more than 72,000 Americans are estimated to be diagnosed with bladder cancer in the United States this year. For more than 15,000 people that diagnosis will prove fatal. The average age of someone receiving a bladder cancer diagnosis is 73 years old and roughly 90 percent are 55 years or older. As such, the population affected by this disease is overwhelmingly reliant on Medicare to provide treatments for their diseases.

In a major step to help improve treatment of bladder cancer, three years ago the FDA approved a drug-device combination called "blue light cystoscopy with Cysview." This new technology is widely regarded as a major breakthrough in the early detection and treatment of "non-muscle invasive" bladder cancer. Since receiving FDA approval, several peer-reviewed scientific articles have shown that blue light cystoscopy is more effective (both in health outcomes *and* cost) in treating bladder cancer while also significantly reducing recurrence rates.

Unfortunately, in the recent 2014 Hospital Outpatient Prospective Payment System final rule, CMS moved to “package” payment for the drug used to perform blue light cystoscopy into the procedure payment. This packaging has the effect of eliminating all payment for the drug, which in turn severely limits the ability of providers to treat patients with blue light cystoscopy. In fact, because the resulting reimbursement rate is substantially below the cost of providing this treatment, hospitals are unable to maintain the devices necessary to perform the procedure.

I am deeply concerned that CMS’s regulatory action will have a serious and detrimental impact on the treatment of bladder cancer in the United States. Blue light cystoscopy not only improves patient outcomes but also provides substantial savings to Medicare through a reduction in future treatments. My concern is that CMS’s recent action will ultimately prohibit access to this more effective treatment altogether.

Congress, when faced with a similar situation in 2000 when CMS packaged “contrast agents,” quickly took action to pass legislation ensuring contrast agents were adequately reimbursed and Medicare beneficiaries maintained access to services using those drugs. I again urge Congress to take the same steps now and similarly require CMS to establish separate payment classifications of cystoscopy “with” and “without” drugs, just as it did for contrast agents. Such a classification system would ensure that providers are fairly reimbursed for the cost of the drugs and are, therefore, able to continue offering these lifesaving services. Most importantly, through the clarification, Congress can ensure that Medicare beneficiaries and all Americans are able to benefit from this breakthrough bladder cancer treatment.

I urge you to take action to help ensure Medicare beneficiaries, and all Americans, diagnosed with non-muscle invasive bladder cancer have access to the best treatments available.

Sincerely,



H. Barton Grossman, M.D.
Clinical Professor, Department of Urology

cc: Karen Fisher (Karen_Fisher@finance.senate.gov)
Dan Todd (dan_todd@finance.senate.gov)
Brett Baker (brett.baker@mail.house.gov)
Cybele Bjorklund (cybele.bjorklund@mail.house.gov)



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M E D I C I N E

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E-mail: mschoenberg@jhmi.edu

Mark P. Schoenberg, M.D.
*Bernard L. Schwartz Distinguished Professor
of Urologic Oncology
Director of Urologic Oncology*

December 6, 2013

The Honorable Max Baucus
Chairman, Senate Finance Committee
511 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Dave Camp
Chairman, Ways & Means Committee
341 Cannon House Office Building
Washington, D.C. 20515

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The Honorable Sander Levin
Ranking Member, Ways & Means Committee
1236 Longworth House Office Building
Washington, D.C. 20515

Re: Need to Ensure Access to Vital Cancer Treatment

Dear Senators and Representatives:

I am a Urologist and have been treating bladder cancer patients for twenty years. I am writing to express my deep concerns that bladder cancer patients are at risk of losing access to new, clinically-effective and cost-efficient cancer treatments. Access to these treatments has been put in jeopardy because of a recent decision by the Centers for Medicare & Medicaid Services (CMS) to "package" hospital outpatient payments for bladder cancer treatment. I am writing to urge you to take action to ensure that Medicare beneficiaries are able to access the treatments for the detection of cancer.

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Unfortunately, in the recent 2014 Hospital Outpatient Prospective Payment System final rule, CMS moved to "package" payment for the drug used to perform blue light cystoscopy into the procedure payment. This packaging has the effect of eliminating all payment for the drug, which in turn severely limits the ability of providers to treat patients with blue light cystoscopy. In fact, because the resulting reimbursement rate is substantially below the cost of providing this treatment, hospitals are unable to maintain the devices necessary to perform the procedure.

I am deeply concerned that CMS's regulatory action will have a serious and detrimental impact on the treatment of bladder cancer in the United States. Blue light cystoscopy not only improves patient outcomes but also provides substantial savings to Medicare through a reduction in future treatments. My concern is that CMS's recent action will ultimately prohibit access to this more effective treatment altogether.

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I urge you to take action to help ensure Medicare beneficiaries, and all Americans, diagnosed with non-muscle invasive bladder cancer have access to the best treatments available.

Sincerely,

A handwritten signature in black ink, appearing to be the name 'Mark', followed by a long horizontal line extending to the right.

cc: Karen Fisher (Karen_Fisher@finance.senate.gov)
Dan Todd (dan_todd@finance.senate.gov)
Brett Baker (brett.baker@mail.house.gov)
Cybele Bjorklund (cybele.bjorklund@mail.house.gov)



Tracy M. Downs, MD FACS
Associate Professor of Urology
Director Bladder Cancer and
Intravesical Therapy Programs

The Honorable Max Baucus
Chairman, Senate Finance Committee
511 Hart Senate Office Building
Washington, D.C. 20510

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The Honorable Sander Levin
Ranking Member, Ways & Means Committee
1236 Longworth House Office Building
Washington, D.C. 20515

Re: Need to Ensure Access to Vital Cancer Treatment

Dear Senators and Representatives:

I am a Urologist at The University of Wisconsin Hospital and have been treating bladder cancer patients for 10 years. I am writing to express my deep concerns that bladder cancer patients are at risk of losing access to new, clinically-effective and cost-efficient cancer treatments. Access to these treatments has been put in jeopardy because of a recent decision by the Centers for Medicare & Medicaid Services (CMS) to "package" hospital outpatient payments for bladder cancer treatment. I am writing to urge you to take action to ensure that Medicare beneficiaries are able to access the treatments for the detection of cancer.

As you may know, more than 72,000 Americans are, estimated to be diagnosed with bladder cancer in the United States this year. For more than 15,000 people that diagnosis will prove fatal. The average age of someone receiving a bladder cancer diagnosis is 73 years old and roughly 90 percent are 55 years or older. As such, the population affected by this disease is overwhelmingly reliant on Medicare to provide treatments for their diseases.

In a major step to help improve treatment of bladder cancer, three years ago the FDA approved a drug-device combination called "blue light cystoscopy with Cysview." This new technology is widely regarded as a major breakthrough in the early detection and treatment of "non-muscle invasive" bladder cancer. Since receiving FDA approval, several peer-reviewed scientific articles have shown that blue light cystoscopy is more effective (both in health outcomes *and* cost) in treating bladder cancer while also significantly reducing recurrence rates.

Unfortunately, in the recent 2014 Hospital Outpatient Prospective Payment System final rule, CMS moved to "package" payment for the drug used to perform blue light cystoscopy into the procedure payment. This packaging has the effect of eliminating all payment for the drug, which in turn severely limits the ability of providers to treat patients with blue light cystoscopy. In fact, because the resulting reimbursement rate is substantially below the cost of providing this treatment, hospitals are unable to maintain the devices necessary to perform the procedure.



I am deeply concerned that CMS's regulatory action will have a serious and detrimental impact on the treatment of bladder cancer in the United States. Blue light cystoscopy not only improves patient outcomes but also provides substantial savings to Medicare through a reduction in future treatments. My concern is that CMS's recent action will ultimately prohibit access to this more effective treatment altogether.

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I urge you to take action to help ensure Medicare beneficiaries, and all Americans, diagnosed with non-muscle invasive bladder cancer have access to the best treatments available.

Sincerely,

Tracy M. Downs, MD FACS

cc: Karen Fisher (Karen_Fisher@finance.senate.gov)
Dan Todd (dan_todd@finance.senate.gov)
Brett Baker (brett.baker@mail.house.gov)
Cybele Bjorklund (cybele.bjorklund@mail.house.gov)



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GARY D. STEINBERG, M.D., F.A.C.S.
*Bruce and Beth White Family Professor
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December 9, 2013

The Honorable Max Baucus
Chairman, Senate Finance Committee
511 Hart Senate Office Building
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The Honorable Orrin Hatch
Ranking Member, Senate Finance Committee
104 Hart Senate Office Building
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Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member, Ways & Means Committee
1236 Longworth House Office Building
Washington, D.C. 20515

Re: Need to Ensure Access to Vital Cancer Treatment

Dear Senators and Representatives:

I am a Urologist at The University of Chicago Medical Center and have been treating bladder cancer patients for over 20 years. I am writing to express my deep concerns that bladder cancer patients are at risk of losing access to new, clinically-effective and cost-efficient cancer treatments. Access to these treatments has been put in jeopardy because of a recent decision by the Centers for Medicare & Medicaid Services (CMS) to "package" hospital outpatient payments for bladder cancer treatment. I am writing to urge you to take action to ensure that Medicare beneficiaries are able to access the treatments for the detection of cancer.

As you may know, more than 72,000 Americans are estimated to be diagnosed with bladder cancer in the United States this year. For more than 15,000 people that diagnosis will prove fatal. The average age of someone receiving a bladder cancer diagnosis is 73 years old and roughly 90 percent are 55 years or older. As such, the population affected by this disease is overwhelmingly reliant on Medicare to provide treatments for their diseases.

In a major step to help improve treatment of bladder cancer, three years ago the FDA approved a drug-device combination called "blue light cystoscopy with Cysview." This new technology is widely regarded as a major breakthrough in the early detection and treatment of "non-muscle

invasive" bladder cancer. Since receiving FDA approval, several peer-reviewed scientific articles have shown that blue light cystoscopy is more effective (both in health outcomes *and* cost) in treating bladder cancer while also significantly reducing recurrence rates.

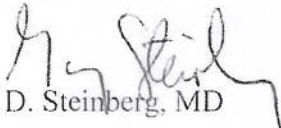
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I urge you to take action to help ensure Medicare beneficiaries, and all Americans, diagnosed with non-muscle invasive bladder cancer have access to the best treatments available.

Sincerely,


Gary D. Steinberg, MD

cc: Karen Fisher (Karen_Fisher@finance.senate.gov)
Dan Todd (dan_todd@finance.senate.gov)
Brett Baker (brett.baker@mail.house.gov)
Cybele Bjorklund (cybele.bjorklund@mail.house.gov)

Bladder
Cancer
Advocacy
Network



Leading the way to awareness and a cure

December 5, 2013

The Honorable Max Baucus
Chairman, Senate Finance Committee
511 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Orrin Hatch
Ranking Member, Senate Finance Committee
104 Hart Senate Office Building
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The Honorable Dave Camp
Chairman, Ways & Means Committee
341 Cannon House Office Building
Washington, D.C. 20515

The Honorable Sander Levin
Ranking Member, Ways & Means Committee
1236 Longworth House Office Building
Washington, D.C. 20515

Re: Need to Ensure Access to Vital Cancer Treatment

I am writing on behalf of the Bladder Cancer Advocacy Network (BCAN) to express my deep concerns about Medicare beneficiaries at risk of losing access to a new, clinically-effective and cost-efficient cancer treatment. Access to this FDA-approved treatment has been put in jeopardy because of a recent decision by the Centers for Medicare & Medicaid Services (CMS) to “package” hospital outpatient payments for bladder cancer treatment. I am writing to urge you to take action to ensure beneficiaries are able to access this treatment for the detection of bladder cancer.

BCAN is the only national organization devoted to advancing bladder cancer research and supporting those impacted by the disease. Through a comprehensive program of research, education and advocacy, we provide a community of hope for the hundreds of thousands of people in the United States who have bladder cancer.

As you may know, more than 72,000 Americans are estimated to be diagnosed with bladder cancer in the United States this year. For more than 15,000 people that diagnosis will prove fatal. The average age of someone receiving a bladder cancer diagnosis is 73 years old and roughly 90 percent are 55 years or older. As such, the population affected by this disease is overwhelmingly reliant on Medicare to provide treatments for their diseases.

In a major step to help improve treatment of bladder cancer, three years ago the FDA approved a drug-device combination called “blue light cystoscopy with Cysview.” This new technology is an important advancement the early detection and treatment of “non-muscle invasive” bladder cancer.

Unfortunately, in the recent finalized 2014 Hospital Outpatient Prospective Payment rule, CMS moved to “package” payment for the drug used to perform blue light cystoscopy into the procedure payment. This packaging has the effect of eliminating all payment for the drug, which in turn severely limits

physician's ability to treat their patients with blue light cystoscopy, and limits the opportunity for patients to receive this potentially life-saving technology.

On behalf of bladder cancer patients and their families, BCAN is deeply concerned that CMS's regulatory action will have a serious and detrimental impact on the treatment of bladder cancer in the United States. Congress, when faced with a similar situation in 2000 when CMS packaged "contrast agents," quickly took action to pass legislation ensuring contrast agents were adequately reimbursed and Medicare beneficiaries maintained access to services using those drugs. I again urge Congress to take the same steps now and similarly require CMS to establish separate payments classifications of cystoscopy "with" and "without" drugs, just as it did for contrast agents. Such a classification system would ensure that providers are fairly reimbursed for the cost of the drugs and are, therefore, able to continue offering these lifesaving services. Most importantly, through the clarification, Congress can ensure that Medicare beneficiaries and all Americans are able to benefit from this important new bladder cancer treatment.

I urge you to take action to help ensure Medicare beneficiaries, and all Americans, diagnosed with non-muscle invasive bladder cancer have access to the best treatments available.

Sincerely,



Diane Zipursky Quale
Co-Founder and President



Monica Smith
Executive Director

cc: Karen Fisher (Karen_Fisher@finance.senate.gov)
Dan Todd (dan_todd@finance.senate.gov)
Brett Baker (brett.baker@mail.house.gov)
Cybele Bjorklund (cybele.bjorklund@mail.house.gov)



UNC
SCHOOL OF MEDICINE

Department of Urology

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Urologic Oncology, Robotic Surgery

Gregory Bianchi, MD
General Urology

Kristy Borawski, MD
*Neurourology, Female Urology
Reconstructive Surgery, Urodynamics*

Timothy P. Bukowski, MD
Pediatric Urology

Culley C. Carson III, MD
*Prostate Diseases, Stone Disease
Sexual Dysfunction*

Floyd A. Fried, MD
Professor Emeritus

Matthew E. Nielsen, MD
Urologic Oncology, Robotic Surgery

Mathew Raynor, MD
*Robotic Surgery
Minimally Invasive Surgery*

Angela Smith, MD
Urologic Oncology, Robotic Surgery

Richard W. Sutherland, MD
Pediatric Urology

Davis P. Viprakasit, MD
*Endourology
Laparoscopy/Robotic Surgery
Benign Prostatic Hyperplasia*

Eric M. Wallen, MD
Urologic Oncology, Robotic Surgery

Michael E. Woods, MD
Urologic Oncology, Robotic Surgery

Mary W. Dunn, RN, MSN, OCN, NP-C
Nurse Practitioner

Colleen E. Prince, RD, PA-C
Physician Assistant

Sarah R. Holland, PA-C
Physician Assistant

Heather M. Schultz, MSN, RN, FNP-C
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The Honorable Max Baucus
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511 Hart Senate Office Building
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Ranking Member, Ways & Means Committee
1236 Longworth House Office Building
Washington, D.C. 20515

Re: Need to Ensure Access to Vital Cancer Treatment

Dear Senators and Representatives:

I am a Urologist at University of North Carolina (UNC) Hospital and have been treating bladder cancer patients for 20 years. I am writing to express my deep concerns that bladder cancer patients are at risk of losing access to new, clinically-effective and cost-efficient cancer treatments. Access to these treatments has been put in jeopardy because of a recent decision by the Centers for Medicare & Medicaid Services (CMS) to "package" hospital outpatient payments for bladder cancer treatment. I am writing to urge you to take action to ensure that Medicare beneficiaries are able to access the treatments for the detection of cancer.

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I am deeply concerned that CMS's regulatory action will have a serious and detrimental impact on the treatment of bladder cancer in the United States. Blue light cystoscopy not only improves patient outcomes but also provides substantial savings to Medicare through a reduction in future treatments. My concern is that CMS's recent action will ultimately prohibit access to this more effective treatment altogether. Congress, when faced with a similar situation in 2000 when CMS packaged "contrast agents," quickly took action to pass legislation ensuring contrast agents were adequately reimbursed and Medicare beneficiaries maintained access to services using those drugs. I again urge Congress to take the same steps now and similarly require CMS to establish separate payment classifications of cystoscopy "with" and "without" drugs, just as it did for contrast agents. Such a classification system would ensure that providers are fairly reimbursed for the cost of the drugs and are, therefore, able to continue offering these lifesaving services. Most importantly, through the clarification, Congress can ensure that Medicare beneficiaries and all Americans are able to benefit from this breakthrough bladder cancer treatment.

I urge you to take action to help ensure Medicare beneficiaries, and all Americans, diagnosed with non-muscle invasive bladder cancer have access to the best treatments available.

Sincerely,



Raj S Pruthi, MD, FACS
Professor and Chair
Department of Urology
UNC School of Medicine-Chapel Hill

cc: Karen Fisher (Karen_Fisher@finance.senate.gov)
Dan Todd (dan_todd@finance.senate.gov)
Brett Baker (brett.baker@mail.house.gov)
Cybele Bjorklund (cybele.bjorklund@mail.house.gov)



J. Stephen Jones, M.D., F.A.C.S., M.B.A.
Chief of Surgical Operations, Regional Hospitals
Professor, Cleveland Clinic Lerner College of Medicine

September 6, 2013

VIA ELECTRONIC SUBMISSION

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1601-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: **Comments to Proposal for Reimbursement of Cysview[®] in CY 2014 Hospital
Outpatient and Ambulatory Surgical Center Prospective Payment System
Proposed Rule**

Dear Administrator Tavenner:

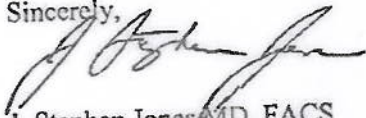
I am a practicing urologist from Cleveland, Ohio with extensive experience in the management of Non-muscle-invasive bladder cancer. I am writing today regarding the proposal for reimbursement of the bladder cancer drug Cysview[®] in the CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule. For the following reasons, I urge you to provide separate payment for Cysview[®], a breakthrough drug for bladder cancer patients.

Bladder cancer is a particularly aggressive form of cancer with a high recurrence rate (50-70% of all patients) and a mortality rate of over 50% in advanced cases. Cysview[®] used with blue light cystoscopy has revolutionized the way that urologists treat this life-threatening disease. Prior to the availability of Cysview[®], cystoscopy procedures only enabled urologists to resect cancerous lesions of the bladder that were readily visible under white light, sometimes leaving a portion of lesions undetected, which allowed them to continue to grow. Cysview[®] with blue light cystoscopy, however, allows urologists to more accurately stage and treat more cancerous lesions, thereby reducing the probability of recurrence of bladder cancer in those patients who have the opportunity to benefit from the treatment. Studies show that this reduces recurrence of cancer in these patients.

I understand that Medicare proposes in 2014 to "package" payment for this breakthrough cancer drug within the payment for the procedure—effectively eliminating payment for the cost of the drug—because, in the Agency's view, Cysview is "used in a diagnostic procedure." Cysview[®] is used as part of first line treatment of non-muscle invasive papillary cancer of the bladder through resection of bladder cancer tumors both at initial treatment and for treatment of bladder cancer recurrences. Cysview[®] is not used to diagnose bladder cancer; it is used to treat bladder cancer *after* the disease has been diagnosed through a previous cystoscopy. It is important to understand that this allows complete removal of tumor that would have been left in the patient using traditional procedures.

In order for Medicare beneficiaries to benefit from the advances in bladder cancer treatment that Cysview[®] has to offer, hospitals must be appropriately reimbursed for Cysview[®]. If Medicare adopts its current proposal, hospitals will be disincentivized to offer Cysview[®] to their patients, and my ability to treat bladder cancer patients with this breakthrough technology will be threatened. I urge CMS to reconsider its proposal so that bladder cancer patients can fully benefit from Cysview[®]. I appreciate your consideration of this important matter.

Sincerely,



J. Stephen Jones MD, FACS
Chief of Surgical Operations
Cleveland Clinic Regional Hospitals
Professor & Horvitz/Miller Distinguished Chair

UNIVERSITY OF MINNESOTA

Twin Cities Campus

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Medical School*

*Mayo Memorial Building
MMC 394
420 Delaware St. SE
Minneapolis, MN 55455
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Fax: 612-624-4430*

September 6, 2013

VIA ELECTRONIC SUBMISSION

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1601-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Comments to Proposal for Reimbursement of Cysview[®] in CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule

Dear Administrator Tavenner:

I am a practicing urologist from Minneapolis, MN that sees 15-25 bladder cancer patients per month. I am writing today regarding the proposal for reimbursement of the bladder cancer drug Cysview[®] in the CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule. For the following reasons, I urge you to provide separate payment for Cysview[®], a breakthrough drug for bladder cancer patients.

Bladder cancer is a particularly aggressive form of cancer with a high recurrence rate (50-70% of all patients) and a mortality rate of over 50% in advanced cases. Cysview[®] used with blue light cystoscopy has revolutionized the way that urologists treat this life-threatening disease. Prior to the availability of Cysview[®], cystoscopy procedures only enabled urologists to resect cancerous lesions of the bladder that were readily visible under white light, sometimes leaving a portion of lesions undetected, which allowed them to continue to grow. Cysview[®] with blue light cystoscopy, however, allows urologists to more accurately stage and treat more cancerous lesions, thereby reducing the probability of recurrence of bladder cancer in those patients who have the opportunity to benefit from the treatment.

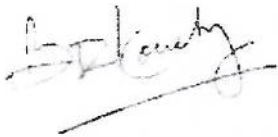
I understand that Medicare proposes in 2014 to “package” payment for this breakthrough cancer drug within the payment for the procedure—effectively eliminating payment for the cost of the drug—because, in the Agency’s view, Cysview is “used in a diagnostic procedure.”

Driven to DiscoverSM

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Sincerely,



Badrinath R. Konety, MD, MBA
Professor and Chair, Department of Urology
Dougherty Family Chair in Uro-Oncology
Director, Institute for Prostate and Urologic Cancers
Associate Director for Clinical Affairs, Masonic Cancer Center



Wexner
Medical
Center

September 5, 2013

VIA ELECTRONIC SUBMISSION

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1601-P
P.O. Box 8010
Baltimore, MD 21244-8010

**Re: Comments to Proposal for Reimbursement of Cysview® in CY 2014
Hospital Outpatient and Ambulatory Surgical Center Prospective Payment
System Proposed Rule**

Dear Administrator Tavenner:

I am a practicing urologist from Columbus, Ohio that sees on average 135 bladder cancer patients per month. I am writing today regarding the proposal for reimbursement of the bladder cancer drug Cysview® in the CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule. For the following reasons, I urge you to provide separate payment for Cysview®, a breakthrough drug for bladder cancer patients.

Bladder cancer is a particularly aggressive form of cancer with a high recurrence rate (50-70% of all patients) and a mortality rate of over 50% in advanced cases. Cysview® used with blue light cystoscopy has revolutionized the way that urologists treat this life-threatening disease. Prior to the availability of Cysview®, cystoscopy procedures only enabled urologists to resect cancerous lesions of the bladder that were readily visible under white light, sometimes leaving a portion of lesions undetected, which allowed them to continue to grow. Cysview® with blue light cystoscopy, however, allows urologists to more accurately stage and treat more cancerous lesions, thereby reducing the probability of recurrence of bladder cancer in those patients who have the opportunity to benefit from the treatment.

I understand that Medicare proposes in 2014 to “package” payment for this breakthrough cancer drug within the payment for the procedure—effectively eliminating

Office of Dr. Kamal Pohar
Department of Urology
The Ohio State University Wexner Medical Center
The James Cancer Hospital and Solove Research Institute

915 Olentangy River Rd
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Wexner
Medical
Center

payment for the cost of the drug—because, in the Agency's view, Cysview is "used in a diagnostic procedure." Cysview[®] is used as part of first line treatment of non-muscle invasive papillary cancer of the bladder through resection of bladder cancer tumors both at initial treatment and for treatment of bladder cancer recurrences. Cysview[®] is not used to diagnose bladder cancer; it is used to treat bladder cancer *after* the disease has been diagnosed through a previous cystoscopy.

In order for Medicare beneficiaries to benefit from the advances in bladder cancer treatment that Cysview[®] has to offer, hospitals must be appropriately reimbursed for Cysview[®]. If Medicare adopts its current proposal, hospitals will be disincentivized to offer Cysview[®] to their patients, and my ability to treat bladder cancer patients with this breakthrough technology will be threatened. I urge CMS to reconsider its proposal so that bladder cancer patients can fully benefit from Cysview[®]. I appreciate your consideration of this important matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kamal Pohar'.

Kamal Pohar, MD, FRCSC
Associate Professor

Office of Dr. Kamal Pohar
Department of Urology
The Ohio State University Wexner Medical Center
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Seth P. Lerner, M.D., F.A.C.S.
Professor of Urology

September 6, 2013

VIA ELECTRONIC SUBMISSION

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1601-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: **Comments to Proposal for Reimbursement of Cysview® in CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule**

Dear Administrator Tavenner:

I am a practicing urologist from Houston, Texas that sees 50 bladder cancer patients per month. I am writing today regarding the proposal for reimbursement of the bladder cancer drug Cysview® in the CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule. For the following reasons, I urge you to provide separate payment for Cysview®, a breakthrough drug for bladder cancer patients.

Bladder cancer is a particularly aggressive form of cancer with a high recurrence rate (50-70% of all patients) and a mortality rate of over 50% in advanced cases. Cysview® used with blue light cystoscopy has revolutionized the way that urologists treat this life-threatening disease. Prior to the availability of Cysview®, cystoscopy procedures only enabled urologists to resect cancerous lesions of the bladder that were readily visible under white light, sometimes leaving a portion of lesions undetected, which allowed them to continue to grow. Cysview® with blue light cystoscopy, however, allows urologists to more accurately stage and treat more cancerous lesions, thereby reducing the probability of recurrence of bladder cancer in those patients who have the opportunity to benefit from the treatment.

I understand that Medicare proposes in 2014 to “package” payment for this breakthrough cancer drug within the payment for the procedure—effectively eliminating payment for the cost of the drug—because, in the Agency’s view, Cysview is “used in a diagnostic procedure.” Cysview® is used as part of first line treatment of non-muscle invasive papillary cancer of the bladder through resection of bladder cancer tumors both at initial treatment and for treatment of bladder cancer recurrences. Cysview® is not used to diagnose bladder cancer; it is used to treat bladder cancer *after* the disease has been diagnosed through a previous cystoscopy.

In order for Medicare beneficiaries to benefit from the advances in bladder cancer treatment that Cysview[®] has to offer, hospitals must be appropriately reimbursed for Cysview[®]. If Medicare adopts its current proposal, hospitals will be disincentivized to offer Cysview[®] to their patients, and my ability to treat bladder cancer patients with this breakthrough technology will be threatened. I urge CMS to reconsider its proposal so that bladder cancer patients can fully benefit from Cysview[®]. I appreciate your consideration of this important matter.

Sincerely,



Seth P. Lerner, MD, FACS
Professor, Scott Department of Urology
Beth and Dave Swalm Chair in Urologic Oncology
Director of Urologic Oncology
Director of the Multidisciplinary Bladder Cancer Program
Faculty Group Practice Medical Director

Keck Medical Center of USC

USC INSTITUTE OF UROLOGY
The Catherine and Joseph Aresty
Department of Urology

Keck Hospital of USC
USC Norris Cancer Hospital

September 6, 2013

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Centers for Medicare & Medicaid Services
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Attention: CMS-1601-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Comments to Proposal for Reimbursement of Cysview® in CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule

Dear Administrator Tavenner:

I am a practicing urologist from Los Angeles, CA that sees 20 of bladder cancer patients per month. I am writing today regarding the proposal for reimbursement of the bladder cancer drug Cysview® in the CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule. For the following reasons, I urge you to provide separate payment for Cysview®, a breakthrough drug for bladder cancer patients.

Bladder cancer is a particularly aggressive form of cancer with a high recurrence rate (50-70% of all patients) and a mortality rate of over 50% in advanced cases. Cysview® used with blue light cystoscopy has revolutionized the way that urologists treat this life-threatening disease. Prior to the availability of Cysview®, cystoscopy procedures only enabled urologists to resect cancerous lesions of the bladder that were readily visible under white light, sometimes leaving a portion of lesions undetected, which allowed them to continue to grow. Cysview® with blue light cystoscopy, however, allows urologists to more accurately stage and treat more cancerous lesions, thereby reducing the probability of recurrence of bladder cancer in those patients who have the opportunity to benefit from the treatment.

I understand that Medicare proposes in 2014 to "package" payment for this breakthrough cancer drug within the payment for the procedure—effectively eliminating payment for the cost of the drug—because, in the Agency's view, Cysview is "used in a diagnostic procedure." Cysview® is used as part of first line treatment of non-muscle invasive papillary cancer of the bladder through resection of bladder cancer tumors both at initial treatment and for treatment of bladder cancer recurrences. Cysview® is not used to diagnose bladder cancer; it is used to treat bladder cancer after the disease has been diagnosed through a previous cystoscopy.

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*The Catherine and Joseph Aresty
Department of Urology*

*Keck Hospital of USC
USC Norris Cancer Hospital*

In order for Medicare beneficiaries to benefit from the advances in bladder cancer treatment that Cysview® has to offer, hospitals must be appropriately reimbursed for Cysview®. If Medicare adopts its current proposal, hospitals will be disincentivized to offer Cysview® to their patients, and my ability to treat bladder cancer patients with this breakthrough technology will be threatened. I urge CMS to reconsider its proposal so that bladder cancer patients can fully benefit from Cysview®. I appreciate your consideration of this important matter.

Sincerely,



Sia Daneshmand, M.D.
Associate Professor of Urology (Clinical Scholar)
Director of Urologic Oncology
Director of Clinical Research
Urologic Oncology Fellowship Director



VANDERBILT UNIVERSITY



MEDICAL CENTER

Department of Urologic Surgery

September 6, 2013

VIA ELECTRONIC SUBMISSION

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
United States Department of Health and Human Services
Attention: CMS-1601-P
P.O. Box 8010
Baltimore, MD 21244-8010

**Re: Comments to Proposal for Reimbursement of Cysview® in CY 2014 Hospital
Outpatient and Ambulatory Surgical Center Prospective Payment System
Proposed Rule**

Dear Administrator Tavenner:

I am a practicing urologist from Nashville, TN that performs 25 procedures on bladder cancer patients per month. I am writing today regarding the proposal for reimbursement of the bladder cancer drug Cysview® in the CY 2014 Hospital Outpatient and Ambulatory Surgical Center Prospective Payment System Proposed Rule. For the following reasons, I urge you to provide separate payment for Cysview®, a breakthrough drug for bladder cancer patients.

Bladder cancer is a particularly aggressive form of cancer with a high recurrence rate (50-70% of all patients) and a mortality rate of over 50% in advanced cases. Cysview® used with blue light cystoscopy has revolutionized the way that urologists treat this life-threatening disease. Prior to the availability of Cysview®, cystoscopy procedures only enabled urologists to resect cancerous lesions of the bladder that were readily visible under white light, sometimes leaving a portion of lesions undetected, which allowed them to continue to grow. Cysview® with blue light cystoscopy, however, allows urologists to more accurately stage and treat more cancerous lesions, thereby reducing the probability of recurrence of bladder cancer in those patients who have the opportunity to benefit from the treatment.

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Cysview[®] is used as part of first line treatment of non-muscle invasive papillary cancer of the bladder through resection of bladder cancer tumors both at initial treatment and for treatment of bladder cancer recurrences. Cysview[®] is not used to diagnose bladder cancer; it is used to treat bladder cancer *after* the disease has been diagnosed through a previous cystoscopy.

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Sincerely,

A handwritten signature in black ink, appearing to read 'Sam S. Chang'.

Sam S. Chang, MD, FACS
Professor of Urologic Surgery
Department of Urologic Surgery
Vanderbilt University Medical Center
Nashville, TN 37232

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October 25, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Tavenner:

On behalf of the Alliance for Aging Research, we write to express our concern over the Centers for Medicare & Medicaid Services' (CMS) proposed revisions to the Hospital Outpatient Prospective Payment System (OPPS) affecting "packaged payment" standards for drugs and biologics. The Alliance urges you to stop implementation of changes to your current policies until further analysis can be done. We feel that sweeping changes to CMS' currently policy should not be pursued unless quality standards and a mechanism to report patient outcomes are put in place to ensure optimal care for Medicare beneficiaries.

For more than a decade, CMS has allowed for drugs and biologics to be included in packaged payments if their per-day costs are under a specific dollar amount and/or if they are used 100% of the time in conjunction with a procedure. The changes proposed this year require packaging of payments for drugs and biologics that are above \$90 per day and are used less than 100% of the time with a procedure. We understand that packaging policies play a role in promoting cost efficiency, but widely broadening the scale and scope of what will be packaged will provide a financial disincentive for hospitals to provide best practices.

According to the U.S. Census Bureau, the number of people aged 65 and older will more than double between 2010 and 2050 to 88.5 million, and those 85 and older will increase three-fold, to 19 million. With this demographic shift will come an increase in the prevalence of diseases disproportionately affecting seniors such as cardiovascular disease, cancer and neurological diseases. The Alliance for Aging Research, www.agingresearch.org, is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application to improve the experience of aging and health. As such, we are concerned that the redefinition of "packaging" under consideration by CMS would establish a new precedent that could severely limit patient access to needed therapies for these conditions now and in the future. Of immediate concern to us is the impact the new packaging proposal will have on the diagnosis and treatment of coronary heart disease (CHD).

CHD is a leading cause of death in the United States, particularly among older adults. To diagnose CHD, many people require myocardial perfusion imaging (MPI) in combination with a stress test. In order to have an accurate image of a blocked coronary artery, patients must reach a target heart rate either through exercise or through pharmacological stress. Approximately half of patients cannot reach their target heart rate through exercise, particularly the elderly, because of

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disability or other existing medical conditions such as diabetes. For people who cannot reach their target rate through exercise and who exhibit other identified risks, the American College of Cardiology recommends that they be pharmacologically stressed, which costs providers considerably more than exercise. The drug used to stress a patient is currently billed separately, however with the proposed changes CMS would package both tests and provide only one payment to a hospital regardless of whether or not a drug or exercise is used. This change creates an incentive for hospitals to exercise stress their patients rather than to pharmacologically stress them because they will be paid more. In cases where a patient should otherwise be stressed using a drug because of medical necessity this will increase the likelihood of an inaccurate diagnosis and place undue fatigue on the patient.

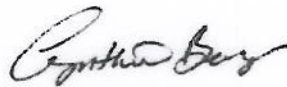
CHD is just one age-related disease that will be impacted by this change. We are also aware that if these new criteria are implemented, hexaminolevulinic acid hydrochloride, which is used as an imaging agent to perform cystoscopy to more effectively detect bladder cancer lesions and prevent recurrence, will also be included in packaging payment. The median age at diagnosis of bladder cancer is 69 years for men and 71 years for women. With advancing age, the risk of developing bladder cancer increases, and patients' outcomes worsen making accurate and timely diagnosis critical.

We ask CMS to delay the proposed changes to OPPS packaging payments until further review and analysis can be done on their effects on patient care. Thank you for considering our views. If you have any questions or would like additional information, please do not hesitate to contact us at (202) 293-2856 or via email (speschin@agingresearch.org and cbens@agingresearch.org).

Sincerely,



Susan Peschin, MHS
Chief Executive Officer



Cynthia Bens
Vice President, Public Policy

cc: Hon. Max Baucus, Chairman, Senate Committee on Finance
Hon. Orrin Hatch, Ranking Member, Senate Committee on Finance
Hon. Tom Harkin, Chairman, Senate Committee on Health, Education, Labor and Pensions
Hon. Lamar Alexander, Ranking Member, Senate Committee on Health, Education, Labor and Pensions
Hon. Fred Upton, Chairman, House Committee on Energy and Commerce
Hon. Henry Waxman, Ranking Member, House Committee on Energy and Commerce
Hon. Dave Camp, Chairman, House Committee on Ways and Means
Hon. Sander Levin, Ranking Member, House Committee on Ways and Means