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(703) 691-1805 | Fax (703) 691-1855

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Society of Interventional Radiology
The vision to heal

September 22, 2025

Mehmet C. Oz, MD, MBA
Administrator
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Abe Sutton, JD
Deputy Administrator and Director
Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201
Via: WISeR@cms.hhs.gov

RE: Opposition to Prior Authorization Requirements in the WISeR Model – Impact on Vertebral Augmentation and Patient Mortality

Dear Dr. Oz and Mr. Sutton:

The Society of Interventional Radiology (SIR) is a professional medical association representing over 8,000 members, including U.S. physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. We write to express our strong concerns about the Centers for Medicare & Medicaid Services' (CMS) implementation of the Wasteful and Inappropriate Service Reduction (WISeR) Model in the Medicare Fee-for-Service (FFS) program.

The WISeR Model is fundamentally at odds with the Administration's stated priority to reduce administrative burden in healthcare delivery. Prior authorization (PA) has consistently been shown to impose excessive and often harmful bureaucratic barriers, particularly in specialty care such as interventional radiology, where timely access to image-guided, minimally invasive procedures is essential. These delays can have severe clinical consequences, especially for elderly patients with vertebral compression fractures (VCFs), a vulnerable population that depends heavily on Medicare coverage.

Clinical Impact of Delaying or Denying Vertebral Augmentation
Robust clinical evidence underscores the survival benefit of vertebral augmentation, including balloon kyphoplasty (BKP) and vertebroplasty (VP), over non-surgical management (NSM) for patients with VCFs. A landmark study by *Hirsch et al. (2019)* analyzed over 2 million Medicare beneficiaries and quantified

this benefit using Number Needed to Treat (NNT) metrics over 5 years. For balloon kyphoplasty, the NNT to prevent one death versus NSM is 14.0 at 1 year and 8.8 at 5 years. For vertebroplasty, the NNT is 22.0 at 1 year and 23.0 at 5 years. These figures demonstrate that vertebral augmentation is not merely a palliative procedure; it is a lifesaving intervention for patients who are appropriately selected.

Quantifying the Mortality Consequences of Prior Authorization

Prior authorization leading to denial or delay of care may involuntarily shift patients to NSM, forfeiting the survival benefit of vertebral augmentation. To estimate the potential human cost of this policy, we modeled a hypothetical cohort of 1,000 Medicare patients who would otherwise receive VP or BKP but are instead unable to do so due to PA-related barriers. Assuming a 50/50 distribution of BKP and VP, the estimated additional deaths resulting from denial of treatment are as follows:

Time Horizon	Estimated Additional Deaths (Midpoint)	Range (Conservative Aggressive)
Year 1	58 deaths	47 – 96 deaths
Year 5	79 deaths	71 – 87 deaths

This analysis is based on peer-reviewed survival data and published NNT values. The range accounts for 95% confidence intervals and variability in the mix of procedures. Even under conservative assumptions, these numbers represent a significant and preventable loss of life attributable solely to administrative delay. Moreover, this estimate reflects only a fraction of the total Medicare population that undergoes vertebral augmentation each year. Scaling the impact across thousands of patients could result in hundreds to thousands of avoidable deaths nationwide.

Policy Implications and Urgent Recommendations

Prior authorization may appear to offer cost-containment advantages on paper, but its real-world implementation in critical procedures such as vertebral augmentation is ethically and clinically indefensible. Administrative obstacles must not outweigh clear evidence of survival benefit, particularly when the cost of delay is measured in lives lost.

SIR strongly urges CMS to remove prior authorization requirements for vertebral augmentation procedures from the WISeR Model and any future demonstrations. We ask that you engage clinical stakeholders, including interventional radiologists, to evaluate the real-world impact of PA policies on patient outcomes and prioritize patient-centered care by aligning regulatory models with the principles of timely, evidence-based, and minimally invasive treatment.

The inclusion of prior authorization in the WISeR Model undermines both the Administration's stated goals and the clinical imperative to provide life-saving care without harmful delays. For Medicare patients with vertebral compression fractures, timely vertebral augmentation is not optional; it is often the difference between recovery and decline, or even life and death. We appreciate the opportunity to provide comments and urge CMS to reconsider this harmful provision.

Given the seriousness of this issue, we respectfully request a meeting with CMS to discuss our concerns further and explore potential alternatives that protect both patient care and program integrity. If you have any questions or would like to coordinate a meeting, please contact Ashley Maleki, SIR's Senior Manager of Health Policy and Economics, at amaleki@sirweb.org or (703) 844-0378.

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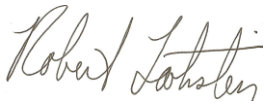
Sincerely,



Robert A. Lookstein, MD, FSIR
President, Society of Interventional Radiology

Cc: Eve Lee, MBA, CAE
Chief Executive Officer, Society of Interventional Radiology