



The American Society for
Bone and Mineral Research

California Technology Assessment Forum

Anabolic Therapies for Osteoporosis in Postmenopausal Women:

Effectiveness and Value

Testimony by

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Introduction

Good morning. My name is Benjamin Leder. I am chair of the Professional Practice Committee for the American Society for Bone and Mineral Research (ASBMR), an Associate Professor at Harvard Medical School and a practicing endocrinologist at Massachusetts General Hospital. I thank you for the opportunity to speak to you today.

As a physician scientist who treats patients with osteoporosis, I speak on behalf of ASBMR's members – 4,000 preeminent physicians and biomedical scientists – of the world's largest, most respected society on bone, mineral and musculoskeletal research.

Crisis in Treatment

We are in the midst of a crisis in the treatment of osteoporosis, a devastating disease that is responsible for more than 1.5 million fractures in the U.S. each year, including 300,000 hip fractures. Of those who experience a hip fracture, 25% will be dead within 6 months and another 50% will never regain their former level of independence. And while there are effective osteoporosis therapies, patients have become increasingly reluctant to take them due to fears of real but extremely rare side effects. In this setting, the steady decline

in hip fracture incidence that began with the introduction of bisphosphonates in the 1990s has leveled off. We are concerned that this ICER report and the timing of its publication may increase the barriers between patients and effective treatments, even for those whom anabolic therapies are the only remaining treatment option.

Timing of Report is Premature

First and foremost, given the scant data presently available for analysis, we feel that the ICER report is premature. The current analysis relies on only a handful of placebo-controlled trials and no comparative efficacy studies. By comparison, ICER's recent analysis of therapies for rheumatoid arthritis included 67 randomized controlled trials, including 19 comparative efficacy studies. Moreover, 2 large comparative efficacy trials comparing the anti-fracture benefit of anabolic therapies to bisphosphonates are complete and likely to be published within the coming months. This report would be much stronger were it to include this data. Given this, we strongly recommend that ICER postpone the publication of this report until the results of these trials are reported. If ICER proceeds with publication of the report at this time, we recommend that the results be updated with pending trials as soon as they become available.

Ignoring Comparative Efficacy Trials with Surrogate Endpoints

We are also concerned that ICER neglects a wealth of evidence from numerous studies, including comparative efficacy studies that utilize surrogate markers such as bone mineral density. The relationship between therapy-induced changes in bone density and hip fracture reduction is strong across all classes of agents as was recently summarized in an FNIH-funded meta-analysis presented publically to the FDA in November 2015. We believe that these should have been considered.

Importance of Medication Sequence

Finally, the report does not recognize the growing body of evidence demonstrating that the sequence in which these anabolic and antiresorptive therapies are administered has a profound effect on efficacy. Findings from a recent randomized controlled trial show that 2 years of teriparatide followed by 2 years of the antiresorptive, denosumab, was uniquely effective, increasing femoral neck BMD by over 8% whereas the same medications, if given in the opposite sequence for the same period of time results in much more modest BMD gains.

Conclusion

The ASBMR shares ICER's and the public's concern with the high cost of anabolic osteoporosis therapies. We enthusiastically support all efforts to make them more affordable to our patients. And while we recognize that anabolic therapy should not be the first choice intervention for most patients with osteoporosis, anabolic therapy can be of critical value for those most severely affected and for those who remain at high risk despite long-term treatment with other osteoporosis medications. Like the many ASBMR members I represent, I have witnessed the devastation of osteoporotic fractures – pain, disability, loss of independence, diminished quality of life and premature death. Our patients with osteoporosis deserve unimpeded access to screening, evaluation, and the full array of treatment options. Thank you again for the opportunity to participate in this discussion.

The American Society for Bone and Mineral Research (ASBMR) is the leading professional, scientific and medical society established to bring together clinical and experimental scientists involved in the study of bone, mineral and musculoskeletal research. ASBMR encourages and promotes the study of this expanding field through annual scientific meetings, an official journal (Journal of Bone and Mineral Research®), the Primer on Metabolic Bone Diseases and Disorders of Mineral Metabolism, advocacy and interaction with government agencies and related societies. To learn more about upcoming meetings and publications, please visit www.asbmr.org.