June 10, 2019

Institute for Clinical and Economic Review
Steven D. Pearson, MD, MSc, President
Two Liberty Square
Ninth Floor
Boston, MA 02109

Submitted Electronically:  publiccomments@icer-review.org

RE:  2020 Update to ICER Value Framework

Dear Dr. Pearson,

The National Osteoporosis Foundation (NOF) is pleased to respond to the Institute for Clinical and Economic Review’s (ICER’s) call for stakeholder comments to inform its value framework update. Our comments reflect our interest in engaging ICER in a continuing dialogue to ensure that patients with osteoporosis receive clinically appropriate treatments to manage this chronic disease.

NOF is the nation’s leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention and treatment of osteoporosis. Established in 1984 as America’s only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and related areas.

Our Policy Institute brings together the expertise, resources, and perspective of the full spectrum of bone health stakeholders to advocate for health policy initiatives that promote bone health and reduce both the personal and financial costs of fragility fractures. Included in NOF’s core mission are efforts to stimulate education and research toward advancing appropriate use of existing therapies and development of new treatment options.

NOF leadership and colleagues representing the National Bone Health Alliance (NBHA) provided input and shared our concerns with ICER, both within the comment processes and at the California Technology Assessment Forum (CTAF) public meeting assessing the comparative...
clinical effectiveness and value of anabolic agents (teriparatide and abaloparatide) for the treatment of osteoporosis in postmenopausal women.

We support ICER’s goal of improving the quantity and quality of information available to clinicians, patients, and payers so that treatment and coverage decisions lead to high-value health care for all Americans. ICER has recognized that osteoporosis is an emerging health policy crisis that threatens to further stress our health care financing systems.

Osteoporosis, the weakening of the bones through loss of bone mineral content and a decrease in bone quality, is a common disease of aging that affects approximately 10 million Americans. Approximately half of women and one quarter of men will suffer at least one fracture due to osteoporosis during their lifetimes. Experts estimate that there are approximately two million osteoporotic fractures each year, which results in $19 billion in related costs. By 2025, these figures are predicted to grow to approximately three million fractures and $25 billion in costs annually as the population of older Americans increases.1

Although new diagnostic and treatment options continue to emerge, osteoporosis remains under-diagnosed and under-treated. The care gap in osteoporosis has actually worsened over time. It is, therefore, critical that physicians and patients have access to important new therapies to determine the best course of treatment for each individual. In fact, in a recent NOF survey of 2,200+ patients and caregivers, 98 percent stressed the importance of access to all available osteoporosis treatments. Of this same patient population, 43% had been prescribed two or more osteoporosis medications throughout their treatment, underscoring the unique circumstances for many osteoporosis patients whose fracture risk and type of treatment may change over time.

Our comments reflect our hope that ICER’s framework update will drive recognition of the inherent value in, and cost-effectiveness of, addressing the osteoporosis care gap and reducing the prevalence of preventable fragility fractures.

**ICER should ensure that its assumptions on disease burden, costs of care, and incremental cost of new treatments are up to date.**

Accurate estimates of the base case costs associated with a particular condition are an essential component of a valid health economic review. ICER’s preference for robust data, collected over a long time period may, unfortunately, may have the unintended consequence of skewing cost estimates and reducing assessment reliability. Osteoporosis offers a clear example of ICER’s methodology driving underestimates in care costs associated with fragility fractures. The model most recently used included cost inputs from 30 years ago. While ICER adjusted historic cost estimates for inflation, that adjustment did not account for the changes in care and the use of new technology that has occurred in the last 25 years. The resulting adjusted inputs underestimate the financial burden of osteoporosis by as much as 50% when compared to estimates generated from 2007-14 care data. Similarly, we ask that ICER recognize the long-term consequences of

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1 https://icer-review.org/topic/osteoporosis/
fragility fractures on patients and account for disease burden beyond the acute care and rehabilitation settings to capture longer-term impact on mortality and morbidity.

Underestimating the burden of osteoporosis ultimately reduces ICER’s calculated value for treatments it reviews despite their demonstrated efficacy in preventing fractures. Given that the treatment rates for elderly post-fracture patients at greatest risk of a fragility fracture are as low as 20%, ICER should ensure that its evaluations do not perpetuate under treatment by undervaluing new treatment options.

**ICER should incorporate disease-specific, real world patient experience and preferences into its quantitative value assessments.**

ICER has expressed a commitment to incorporating the patient experience into its reviews and has published final reports on new products that include patient preference information within a discussion of contextual considerations. We urge ICER to incorporate relevant real-world data and patient preference information into the assumptions and other inputs that ultimately drive its efforts to quantify value. This is especially important within the context of osteoporosis treatments and other conditions with high rates of under-treatment and treatment discontinuation.

- ICER assumes 100% persistence for existing treatments in its base case despite peer-reviewed publications suggesting real world discontinuation rates of 30-60%;
- ICER’s osteoporosis model compared therapies of different duration and extrapolated efficacy estimates without adjusting for persistence;
- ICER selected zoledronic acid (ZA) as the comparator against which newer bone-forming agents would be reviewed despite the fact that these agents slow bone loss rather than build new bone, and are generally used in a treatment context that differs from the reviewed bone-forming agents;

We urge ICER to:

- Compare treatments that have similar impacts on the underlying disease process;
- Take into account that higher-risk patients may require more rapid-impact treatments;
- Simulate real world estimates of persistence of each therapy over time; and
- Assume credible ranges for the decline of effect over time.

NOF believes that ICER’s review process may be better-equipped to address existing shortcomings on model inputs and assumptions if ICER provided sufficiently generous comment timeframes to enable stakeholders to prepare meaningful responses. Accuracy, validity, and completeness should take priority over the expedience of established timelines, particularly when patients have their health, and even their lives at stake.

**ICER should increase its patient and caregiver community engagement efforts throughout its process**
ICER’s most recent review of osteoporosis treatments acknowledged the inherent difficulties in ensuring that value is assessed in a patient-centric manner. Those difficulties cannot be overcome, however, unless patient and caregiver engagement are at the center of ICER’s assessments and meaningfully inform its understanding of the outcomes that are relevant to patients.

NOF has recently reached out to the patient and caregiver community to explore the preferences that drive treatment decisions and persistence, including the all-too-frequent decision to decline treatment or diagnostic testing. Patient advocacy organizations across disease states have recognized the importance of the patient voice throughout the product development and approval processes. This important information should also play a pivotal role in any evaluations that, like ICER’s work, are intended to or could have the effect of shaping access. Outcomes specific to patients and their disease state, such as alleviation of symptoms or the ability to be productive in work or home settings, often are not captured through clinical trial data or reflected by global or specific clinical measures that feed into a QALY. Patient advocates, armed with sufficient time to devise proactive and meaningful input, can not only improve the validity of ICER’s assessments, but increase patient acceptance of and agreement on the results of its reviews.

We urge ICER to ensure that patient organizations have sufficient advance notice of an upcoming review to gather data on outcomes most important to patients, disease burden, and factors that might encourage or discourage patients considering a treatment, and that this information is appropriately incorporated into ICER’s reports. We also believe that ICER’s practice of limiting stakeholder input to a 10-page maximum dilutes its message of inclusiveness and collaboration with patients and their advocacy organizations.

**ICER’s analyses should consider the disease-specific patient population.**

NOF has previously expressed our concern that complicated patients with osteoporosis -- patients who are excluded from randomized clinical trials -- are not adequately considered in ICERs reports. While we understand ICER’s strong preference for relying on the highest level of evidence, patients at highest risk for fracture may not be captured in that evidence. For these patients, using and even starting with a newer therapy may sometimes be the best choice. ICER does a serious disservice to these patients if it discounts the validity of the as-yet-unpublished clinical trial data and substantial observational data on this subpopulation into its evaluation.

Similarly, ICER’s use of Net Health Benefit ignores the urgency to treat in some patients. Patients who have had a prior fracture and those with multiple fractures have a substantially increased risk for future fracture, particularly within the 2-year period following the initial fracture. ICER reviews should not ignore the added benefit of faster action in addressing low bone density for individuals at greatest near-term risk of fragility fracture.

**Conclusion**

Once again, NOF appreciates the opportunity to provide feedback as ICER considers updates to its value framework. We look forward to working with you to ensure that patients with bone
fragility receive the treatment they need to avoid preventable fragility fractures and improve their overall health outcomes.

If you have any questions or wish to discuss our concerns in greater detail, please contact me at 703-647-3020 or our Chief Mission Officer, Claire Gill, at 703-647-3025.

Very truly yours,

Elizabeth Thompson
Chief Executive Officer
National Osteoporosis Foundation