September 12, 2016

Steven Pearson, MD, MSc, FRCP
President
Institute for Clinical and Economic Review
Boston, MA 02109

Via electronic mail: publiccomment@icer-review.org

Dear Dr. Pearson,

The National Multiple Sclerosis Society (Society) appreciates the opportunity to respond to the Institute for Clinical and Economic Review’s (ICER) national call for input for proposed improvements to its value assessment framework. The Society works to provide solutions to the challenges of MS so that everyone affected by this disease can live their best lives. To fulfill this mission, we fund cutting-edge research, drive change through advocacy, facilitate professional education, collaborate with MS organizations around the world, and provide services designed to help people affected by MS move their lives forward.

**ICER should ensure that its value assessment framework adequately emphasizes the patient’s perspective**

We recognize that the concept of value is a fundamental component to the healthcare and health delivery system. We believe that considerations of value must include the perspectives of all stakeholders, especially those of people who live with MS and other diseases. Determining and incorporating the patient perspective on value is critical to strengthening ICER’s value assessment framework. In our previous engagement with ICER, we have noted that patient preferences vary greatly through disease states and have cautioned against the use of a one-size fits all model.

We recommend that ICER incorporate the National Health Council’s value rubric into the next iteration of its value assessment framework to help evaluate the patient-centeredness of its value model and aide in the development of a formal process for patient engagement throughout ICER’s review process. The rubric, available in full [here](#), outlines the domains that must exist for a value framework to be considered patient-centered:

- Patient Partnership, involving patients in every step of the value model development and dissemination process;
- Transparency to Patients, disclosing assumptions and inputs to patients in an understandable way and in a timely fashion;
- Inclusiveness of Patient, reflecting perspectives drawn from a broad range of stakeholders, including the patient community;
- Diversity of Patients/Populations, accounting for differences across patient subpopulations, trajectory of disease, and stage of a patient’s life;
- Outcomes Patients Care About, including outcomes that patients have identified as important and consistent with their goals, aspirations, and experiences; and
• Patient-Centered Data Sources, including data sources that reflect the outcomes most important to patients and capture their experiences to the extent possible

Incorporating the patient perspective in value discussions is a relatively new effort. Patient perspectives towards value tend to differ greatly from those of payers; therefore, there is a paucity of data regarding patient perspectives on value and how best to incorporate those attitudes into value frameworks.

Many organizations are working on methods and best practices to help facilitate the patient perspectives into value discussions. The Society is currently funding studies to better understand how people who live with MS view value and will share the findings of these studies with ICER when they are available. Additionally, we are participating in FasterCures and Avalere’s Patient-Perspective Value Framework (PPVF) Initiative, which seeks to develop a value framework for assessing therapies, diagnostics, and other healthcare services, which is in line with patients’ concepts of value. We recommend ICER develop a formal process to routinely solicit feedback from all relevant stakeholders, as new information and data is generated that will help incorporate the patient’s perspective on value into frameworks that assess the value of new innovative treatments and therapies as they are utilized by the health care system.

ICER Should Actively and Transparently Engage Patient Community and Stakeholders

We believe that ICER should expand its engagement with patients, patient and caregiver organizations, and clinical experts throughout its review of the specific diseases areas. The Society would like to thank ICER for implementing its survey to gain insight directly from people living with MS during its Review of Drugs for Relapsing-Remitting and Primary Progressive MS and believe that this type of engagement with patients should be part of a formal process for engaging with patients, patient organizations, and stakeholders. Ideally, this engagement should begin well in advance of ICER’s review process to ensure that background, scoping documents and review reflect the consensus of these communities within the particular disease area.

Additionally, ICER could improve its current process by being more transparent regarding its consideration of the feedback it obtains from stakeholders during its outreach. We appreciated the engagement and incorporation of feedback from the MS community as a part of ICER’s MS review, but believe this engagement could be strengthened by providing a formal transparent process that identified what feedback was or was not incorporated into the final ICER review and stating the reasoning behind these decisions.

ICER should utilize alternatives to the Quality Adjusted Life Year

The Society has previously recommended that ICER should clarify its calculation of the quality adjusted life year (QALY), particularly as there are concerns that a cost-per-QALY cannot adequately account for the value of substantially improving the life of a person with a disability or serious medical condition. ICER should examine both alternative approaches and health utilities such as disability adjusted life years, which may enable payers to develop policies that better reflect individual patient values.
ICER should examine health care utilization outcomes by gauging direct and indirect costs
We believe that any model used should examine both direct and indirect costs of the disease area under review: including long-term care, lost wages, the cost of drugs, the cost of outpatient care, the cost of rehabilitation, and the cost of assistive technology. These are all critical economic impacts that are not reflected by traditional health care utilization outcomes such as emergency room visits or inpatient stays. Additionally, ICER should allow public comment on the economic model that is used to allow for feedback on new or innovative models that would better reflect the economic costs of different disease areas.

ICER should incorporate additional sources and types of data for evidence reports
The Society believes that ICER should look beyond randomized clinical trials (RCTs) within its evidence reports. In our previous correspondence to ICER, we noted that RCTs are not designed, controlled, conducted, or powered to establish the cost effectiveness of a therapy or the impact of a therapy on the evolution of disability in the course of MS over a clinically-relevant time period. RCTs provide limited data, real-world treatment impacts, or information on patient reported outcomes and therefore alternative data should be utilized. Additionally, information on the range of studies that ICER uses should be discussed amongst stakeholders before scoping and background documents are released for public comment, so that stakeholders can understand and help assess the usefulness of those studies for decision-making.

ICER should broaden its cost perspectives beyond 5 years
ICER’s current practice of using a five-year timeframe for calculating budget impact may not fully capture the benefits of the current disease modifying therapies, especially for chronic diseases like MS. ICER should utilize feedback from stakeholders and clinical experts to determine an appropriate timeframe to accurately assess the full impacts based on available data.

Specifically in MS, the five year timeframe is problematic as it is unlikely to fully capture the economic benefits of delaying disease progression, particularly lower health care utilization costs, thought to result from the use of disease modifying treatments. There is growing evidence that suggests early and consistent treatment will have benefits for people living with MS that extend for a decade or longer; therefore we believe that at least 10 years will be needed to determine the impacts for a review of MS therapies.

Thank you for the opportunity to comment on this iteration of ICER’s value assessment framework. If you have any questions, please contact Leslie Ritter, Senior Director, Federal Government Relations at leslie.ritter@nmss.org or 202-408-1500. We look forward to continued discussions.

Sincerely,

Bari Talente, Esq.
Executive Vice President, Advocacy