May 23, 2014

The Honorable Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201  

Dear Administrator Tavenner:

We are writing in response to the Centers for Medicare & Medicaid Services (CMS) determination of non-coverage of oxygen for cluster headache (CAG-00296R). Our constituents recently shared with us their heartbreaking experiences with cluster headache (CH), which is often identified as one of the most painful conditions known to medical science. Given the excruciating pain associated with CH and the proven effectiveness of oxygen in treating this disorder, we urge you to promptly review your decision.

Approximately 500,000 Americans suffer from CH. Many of the constituents we have heard from experienced debilitating pain for hours at a time over the course of months until they were properly diagnosed and began receiving oxygen treatment. This therapy enables them to live fuller, more productive lives with the assurance that a treatment is available to end CH pain when it strikes. We find the need for accessible CH treatment compelling, especially considering the suicide rate for CH patients has been estimated to be up to 20 times the national average.

Not only do our constituents attest to the effectiveness of this treatment, but medical experts indicate that the majority of published guidelines on the treatment of CH identify oxygen as a well proven and established treatment. According to their research, it is cited as a safe treatment in essentially every textbook that addresses CH management, and there is no published expression that oxygen therapy is an unsafe treatment. In fact, oxygen has been accepted as the standard of care for the treatment of CH since 1952.

Several federal entities, including the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ), list oxygen as an appropriate acute therapy for CH. We find this notable, in particular, because the mission of the National Quality Measures Clearinghouse within AHRQ is to provide evidence-based health care quality measures and information for health care providers, health plans, and delivery systems. Furthermore, the Veterans Administration provides coverage of oxygen for CH. We find it contradictory that a number of federal entities specify that oxygen is an evidenced-based treatment option and even disseminate this information in medical guidelines across the country, yet CMS has determined that this effective and low-cost therapy option should not be covered under Medicare. We ask that you work to rectify these inconsistencies and engage in a dialogue with the appropriate medical experts at these federal agencies as you review your decision.
We also urge you to consider that aside from oxygen therapy, no safe or effective therapy is available for many individuals with CH, particularly those who are Medicare-eligible. For example, sumatriptan is an FDA-approved treatment to terminate cluster headaches. However, this therapy is not proven to be safe for use more than twice a day, and cluster headaches, by definition, are a grouping or “cluster” of reoccurring headache attacks that may last up to three hours and occur up to eight times a day. Furthermore, medical guidelines indicate sumatriptan, and other CH therapies, are not advised for individuals at risk for cardiovascular disease or stroke, which could preclude much of the Medicare-eligible population from using these therapies.

Alternatively, without oxygen treatment or other therapies, a CH sufferer could be rushed to the emergency room by ambulance only to have the condition treated by oxygen at the hospital. Therefore, denying CH sufferers coverage for home oxygen could unnecessarily drive up health care costs at a time Congress and the Administration should be finding new ways to contain them. We are deeply concerned that because Medicare does not cover oxygen therapy, CH patients are pursuing potentially harmful therapies, seeking costly and unnecessary care in the emergency room, or enduring this disabiling pain.

While we appreciate that CMS did not completely dismiss future coverage of oxygen therapy and acknowledged that it is a “promising” treatment option, we are also concerned about CMS’s proposal to further study the therapy in a controlled trial. Several obstacles will make it difficult logistically and ethically for CMS to study oxygen treatment in elderly CH patients. The sporadic onset and end of CH cycles could make it difficult to study an appropriate number of Medicare-eligible patients. Additionally, most of these patients would not be eligible for a clinical trial because they have already tried oxygen to treat CH. Treatment with a placebo may also be difficult to justify because the efficacy of oxygen is considered a settled issue by the expert community and because CH is extremely painful. Therefore, we question whether further study of oxygen therapy is feasible.

In our opinion, the proven effectiveness of oxygen treatment of CH, shortcomings of other treatment options, and incredible pain associated with CH warrant further review of your coverage determination. We appreciate your careful consideration of this request and look forward to your response. Thank you for your attention to our concerns.

Sincerely,

Mike Johanns
United States Senator

Christopher A. Coons
United States Senator