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Re: Home Oxygen Therapy for Cluster Headache
Comments on Proposed Decision Memo
CAG-00296R

The American Headache Society strongly opposes CMS's proposed decision of October 8, 2010 which would limit Medicare coverage for home oxygen to cluster headache patients enrolled in future clinical trials. We urge CMS to reconsider this decision, and we reassert our unequivocal position that oxygen therapy is both indicated and necessary for many cluster headache sufferers. Indeed it is the only available therapy appropriate for most Medicare patients suffering from this dreaded condition.

The proposed decision turns the concept of "evidence-based medicine" on its head, producing a result that denies relief to patients in the most compelling circumstances:

• It discounts the unequivocal findings of prior studies on the grounds of methodological

imperfections, making hopes for “better” evidence the clear enemy of “good” and sufficient evidence.

• It discounts more than 40 years of successful use in clinical practice. To characterize that experience as merely “promising” totally ignores the enormous benefit this therapy has afforded to innumerable patients. And it ignores the fact that the evidence supporting most other items and services routinely covered by CMS is also based on successful clinical practice, not randomized trials.

• It ignores the fact that oxygen is the standard of care for these patients and is taught as such in every medical textbook and peer-reviewed publication on the subject of cluster headache treatment. For physicians to withhold this therapy, absent contraindications in a particular patient, would likely be construed by many as unethical, and perhaps by others as actionable.

• It introduces a classic “red herring” by suggesting that there are safety issues with oxygen requiring further research in the elderly population. Of course oxygen will be contra-indicated for some elderly patients. That goes without saying and is equally true of countless pharmacological and other therapies for which Medicare provides undisputed national coverage, while relying on the clinical judgment of practitioners to withhold those services where they are medically contraindicated. An appropriate penicillin antibiotic may not be given to a patient with a penicillin allergy, and beta blockers are not appropriate for severely hypotensive, bradycardic, or asthmatic patients. Similarly, oxygen therapy would not be appropriate

for a patient with severe obstructive pulmonary disease or related pulmonary ailments but is nonetheless effective and necessary in the larger group of elderly patients with cluster headache those without contraindication to oxygen. These clinical judgments are made by headache specialists every day with respect to a wide range of therapies used in both elderly and non-elderly populations.

- Contrary to CMS's assertion that it has used the earlier public comments to "inform" its decision, it appears that the Agency has totally ignored those comments which were uniformly supportive of broad coverage.
- Contrary to the assertion that CMS has not received any "expert opinions" (other than the public comments, which it has ignored), and with all due modesty, the American Headache Society represents the established experts in this field of care. That expertise informed our initial request for a national coverage policy, and that expertise has been made readily available to the Agency. We urge CMS to reconsider its proposed decision in light of what we believe is virtually unanimous expert opinion in favor of broad coverage.

At least as troubling as the factors noted above, if not more so, is the fact that the path forward suggested in the proposed decision memo is a veritable blind alley. CMS proposes further research comparing NBOT with a "clinically appropriate comparator." Such research in the elderly population is unacceptable for both practical and ethical reasons.

• To perform a study with greater, or exclusive, involvement of the elderly population that uses an active comparator against oxygen requires the use of a constricting drug, such as a triptan or an ergot derivative, as the only possibly effective comparator. These drugs are generally contraindicated in the elderly. Indeed, package inserts on leading brands indicate that these drugs are not recommended for the elderly. See for example this statement with respect to Imitrex by injection, taken from the manufacturer's Prescribing Information:

"Geriatric Use: The use of sumatriptan in elderly patients is not recommended because elderly patients are more likely to have decreased hepatic function, they are at higher risk for CAD, and blood pressure increases may be more pronounced in the elderly (see WARNINGS: Risk of Myocardial Ischemia and/or Infarction and Other Adverse Cardiac Events)."
http://us.gsk.com/products/assets/us_imitrex_injection.pdf (page 14). (Emphasis added)

To design a new study around these drugs would thus impose an unethical, and thus unacceptable, cardiovascular and cerebrovascular risk on Medicare patients willing to participate in the research project. Indeed, with appropriate disclosure of these risks, it seems unlikely that patients would be willing to participate. CMS's decision to cover oxygen therapy only for Medicare

patients enrolled in a clinical trial compounds the ethical problem, since those who might enroll despite the risks of randomization might well be doing so only in the desperate hope to gain access to a treatment that CMS otherwise denies them. Alternatively, so many potential trial participants would need to be barred from the study that any study results would be applicable only to a pre-selected group of low risk Medicare patients, and by design, would not be generalizable to the Medicare patient population at large.

• To do a study with a greater enrollment of the elderly population using oxygen vs. a placebo is also ethically unacceptable. Randomization to placebo is generally considered ethical only in cases where there is no known effective treatment or standard of care. Otherwise, patients would be denied treatment for a treatable condition, with the attendant risks and suffering, for the sake of research unlikely to meet the high burden of proof needed to change practice. Since strong evidence already exists to support the use of oxygen therapy, and randomization to placebo would leave extremely painful attacks untreated, a research trial against placebo is unethical and unacceptable.

• Clinicians have few treatments to abort a cluster headache in any population, and of the few we have, the only one that is largely safe and largely effective in the elderly population is oxygen. To demand more and "better" studies in these circumstances smacks of comparative

effectiveness research at the expense of the most vulnerable of patients. The most likely outcome of such a course is that no study will be done, or will be deferred for many years. Meanwhile, patients needlessly suffer despite the availability of an eminently "reasonable" and for these patients clearly "necessary" therapy.

To summarize, and with all due respect to your staff, the proposed decision gives clinicians and researchers no option that seems ethically sound or reasonably practical. There is strong evidence to support the administration of oxygen to elderly patients with cluster headache, and it represents the only feasible treatment to relieve this severely painful condition for most Medicare patients. It would be limited to use in patients without contraindication to oxygen, and it has been the treatment of choice for over 40 years by experts in this condition. We see no reasonable basis for denying coverage.

Respectfully submitted,
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American Headache Society