

July 20, 2021

Tamara Syrek Jensen, JD Director, Coverage and Analysis Group Centers for Medicare & Medicaid Services Baltimore, MD 21244

Re: Proposed Decision to Remove National Coverage Determination for Home Oxygen Use to Treat Cluster Headache (NCD 240.2.2) and to Modify National Coverage Determination for Home Use of Oxygen (NCD 240.2)

Dear Ms. Jensen:

Thank you for the opportunity to provide comments on the proposed decision memo regarding Medicare coverage of home oxygen use. The American Academy of Family Physicians (AAFP), representing more than 133,500 family physicians and medical students, supports the proposal from the Centers for Medicare and Medicaid Services (CMS) to:

- Remove its National Coverage Determination (NCD) at section 240.2.2 of the Medicare NCD Manual, ending coverage with evidence development, and allow the Medicare Administrative Contractors (MACs) to make coverage determinations regarding the use of home oxygen and oxygen equipment for cluster headache (CH), and;
- Modify its NCD for Home Use of Oxygen at section 240.2 of the Medicare NCD Manual to
 expand patient access to oxygen and oxygen equipment in the home, and to permit
 contractors to cover the use of home oxygen and oxygen equipment in order to treat CH and
 other acute conditions.

Together, these coverage modifications will expand Medicare coverage of home oxygen for beneficiaries with CH and other acute and chronic conditions for which home oxygen is medically necessary. The AAFP believes these modifications will also reduce family physicians' confusion and administrative burden when trying to prescribe home oxygen. We recommend CMS finalize these proposed decision memos.

The current coverage requirements for home oxygen for patients with CH are unnecessarily restrictive and burdensome. Supplemental oxygen for the treatment of CH has an evidence rating of A, meaning that there is consistent, high-quality, patient-oriented evidence supporting its use (Weaver-Agostoni J. Cluster Headache, Am Fam Physician. 2013 Jul 15;88(2):122-128). Based on the effectiveness of oxygen treatment, the AAFP agrees that patients should not have to participate in a prospective clinical study to receive coverage of home oxygen when medically necessary. We also agree that the MACs should be equipped to determine medical necessity of home oxygen for patients with CH, though we urge CMS to ensure that the MACs refrain from requiring overly burdensome documentation requirements for this evidence-based treatment.

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The AAFP supports the proposal to revise NCD 240.2 to expand the coverage of oxygen and oxygen equipment in the home for short as well as long term use in both acute and chronic diseases of respiratory and non-respiratory origin, as is medically necessary. Previously, the NCD only permitted oxygen use at home for those in a "chronic stable state," which, in the absence of a public health emergency, would have excluded patients recovering from COVID-19 at home who benefited from oxygen therapy. We appreciate CMS swiftly incorporating new evidence and lessons learned during the COVID-19 pandemic and agree that this modification will give physicians more options to provide the best course of treatments for their patients. Family physicians regularly see patients with conditions for which oxygen could be medically necessary, even if the patient is not in a chronic stable state. Examples include (but are not limited to): congestive heart failure, chronic obstructive pulmonary disease, sleep apnea, pneumonia, cystic fibrosis, and pulmonary fibrosis. As such, we believe this coverage expansion will improve Medicare beneficiaries' access to evidence-based treatments and we urge CMS to finalize it.

Thank you for the opportunity to provide public comment. Should you have any questions, please contact Meredith Yinger, Senior Regulatory Strategist, at myinger@aafp.org or (202) 235-5126.

Sincerely,

Gary LeRoy, MD, FAAFP

Board Chair

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Lary X. Le Ray, MD, FAAFD