



September 29, 2009

Marcel Salive, MD
Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

This letter should serve as a formal request for a National Coverage Determination (NCD) for pulmonary rehabilitation services. This request is submitted by the American Association for Respiratory Care, the American Association of Cardiovascular and Pulmonary Rehabilitation, the American College of Chest Physicians, the American Thoracic Society and the National Association for Medical Direction of Respiratory Care. Currently there is no national policy for coverage of pulmonary rehabilitation services and, therefore, this should be regarded as a new request (Track #1) even though we collectively submitted a similar request in April, 2003 and again in November, 2006.

Benefit category: We believe pulmonary rehabilitation services are authorized under one distinct provision of Title XVIII of the Social Security Act as enacted in July, 2008 as part of PL 110-275. Section 144 of the statute establishes pulmonary rehabilitation services as a distinct benefit category under Section 1861(fff).

The Centers for Medicare and Medicaid Services has specifically referenced an intent to create an NCD in two distinct and related proposed regulations – the rule for 2010 Physician Fee Schedule and a companion proposal, the Hospital Outpatient Prospective Payment rule, both of which were published in July, 2009.

The proposed Physician Fee Schedule for 2010 published in the *Federal Register* of July 13, 2009 (p. 33612) states, “We are proposing to use the national coverage determination process as authorized under Section 1871(1) of the Act to consider expanding coverage to items and services furnished by PR programs.”

The proposed Hospital Outpatient Prospective Payment System rule for 2010 published in the *Federal Register* of July 20, 2009 (p. 35360) states, “... we are using the MPFS and the OPFS rulemaking processes, and may use the national coverage determination (NCD) process as well to implement the amendments made by section 144(a) of Public Law 110-275.

This request focuses on the specific reference in the proposed physician fee schedule to use the NCD process for expanding coverage beyond the criteria identified in the proposed regulation. That document recommends coverage of beneficiaries with a diagnosis of moderate or severe COPD patients. We believe this proposal is problematic because it does not reflect the standards of care in the clinical literature, including all major evidence-based guidelines nor does it reflect the coverage rules in place via the Local Coverage Determination (LCD) process by several CMS contractors.

To ensure that Medicare beneficiaries who are clinically eligible for pulmonary rehabilitation services under existing LCDs continue to benefit from access to this important and effective service, we believe that CMS should move as expeditiously as possible to promulgate an NCD that addresses a coverage expansion beyond the coverage identified in the July 13, 2009 proposed rule. As we recommended in our written comments in response to the physician fee schedule proposals, our societies recommend coverage of --

- Very Severe COPD (GOLD IV) as $FEV_1/FVC < 70\%$ and $FEV_1 < 30\%$ predicted or $FEV_1 < 50\%$ plus chronic respiratory failure.
- Cystic fibrosis
- Non cystic fibrosis bronchiectasis
- Interstitial lung disease
- Restrictive chest wall disease
- Pulmonary hypertension
- Lung cancer/lung surgery
- Neuromuscular disease

NOTE: All of these diagnoses are covered under existing LCDs promulgated by Medicare contractors

Further, in accordance with requirements identified in the September 26, 2003 *Federal Register* revising the process for development of NCD requests, we are providing CMS with information to meet its mandate for –

- A full and complete description of the item or service in question;
SEE ATTACHMENT #1
- A specific, detailed description of the proposed use of the item or service, including the target Medicare population and the medical condition(s) for which it can be used;

- SEE ATTACHMENT #2
- A compilation of the supporting medical and scientific information currently available that measures the medical benefits of pulmonary rehabilitation.
SEE ATTACHMENT #3
- A compilation of current criteria (approved ICD-9 codes) in place from Medicare contractors that authorize coverage beyond the proposal in the 2010 Proposed Physician Fee Schedule.
- SEE ATTACHMENT #4

Sincerely,



Timothy R. Meyers, BS, RRT-NPS
President
American Association for Respiratory Care



Murray Low, EdD
President
American Association of Cardiovascular and Pulmonary Rehabilitation



James A.L. Mathers, Jr., MD
President
American College of Chest Physicians



Steve G. Peters, MD
President
National Association for Medical Direction of Respiratory Care

A handwritten signature in black ink, reading "J. Randall Curtis". The signature is written in a cursive style with a large initial "J" and a stylized "C".

J. Randall Curtis, MD, MPH
President
American Thoracic Society