Vial Electronic Mail

November 25, 2015

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Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Room 5309
Washington D.C. 20201

RE: Medicare Contractor Audits on Ventilators

Dear Ms. Hoffman:

We are writing to express our very serious concerns about recent durable medical equipment (DME) Medicare Administrative Contractor (MAC) audits of claims for noninvasive positive pressure ventilators coded under Health Care Common Procedure Coding System (HCPCS) code E0464. The DME MACs are routinely denying coverage for these ventilators stating that the beneficiary must be in "imminent" danger of death unless he or she is using the ventilator 24 hours a day, seven (7) days a week (24/7). There is no Medicare requirement for a beneficiary to use a ventilator 24/7 as a condition of coverage. The MACs are denying gravely ill beneficiaries access to ventilators without any appropriate justification.

These are across-the-board denials even though beneficiaries present with diagnoses that satisfy the Medicare national coverage determination (NCD) for ventilators;[1] their medical records meet Medicare technical documentation requirements[2] and fully support the beneficiary's medical necessity. The sole

[1] Medicare National Coverage Determinations Manual (NCD Manual), pub. 100-3, 4 § 280.1, List of Covered DMEPOS, available at: http://www.cms.gov.

[2] Medicare technical documentation requirements pertain to nonmedical necessity documentation like proof of delivery (POD), technical requirements for orders and other such paperwork.

coverage criterion for the denial is whether the beneficiary uses the ventilator 24/7 to avoid the risk of death or serious injury.

These claim denials are contrary to the Medicare NCD for ventilators. The NCD identifies the conditions for which Medicare covers ventilators and the beneficiaries whose claims have been denied have a condition listed in the NCD. More importantly, the NCD does not require, and cannot be understood to require, beneficiaries to use a ventilator 24/7 to qualify for coverage. The DME MACs cannot unilaterally restrict coverage for the class of ventilators that Medicare's most vulnerable patients use without first giving notice to patients, their doctors, caretakers and suppliers.

We request that CMS direct its contractors to stop these groundless audits. And we request that the E0464 claims denied improperly be reversed and promptly the recoupments to suppliers promptly refunded. This is the only way to redress the contractors' erroneous actions because the appeals backlog effectively denies suppliers any remedies they may have had under the Medicare appellate process.

A. Medicare contractors are bound to follow all NCDs when they adjudicate or audit Medicare claims.

Contractors may develop local coverage determinations (LCDs) that do not conflict with NCDs. But they must follow notice and comment procedures when they issue a new LCD or when new provisions of an LCD will restrict coverage.

1. Background

E0464 ventilators are state-of-the-art noninvasive ventilators that meet a patient's ventilation needs humanely, without intubation, allowing them greater mobility, the ability to communicate and decreasing their risk of infection and other complications associated with intubation or a tracheostomy. Medicare patients who use E0464 ventilators are among the most fragile of beneficiaries. They suffer from neuromuscular diseases, thoracic restrictive diseases and advanced chronic obstructive pulmonary disease (COPD). These beneficiaries use E0464 ventilators during the most vulnerable period in their lives.

NCDs establish the rules contractors must use to adjudicate and audit Medicare claims.[3] Contractors are also bound by Federal statutes, all Medicare regulations, and coverage requirements in Medicare interpretive manuals like the Medicare claims processing manual or the PIM.[4] Contractors cannot change the terms of an NCD, but they can clarify its application through an LCD if the LCD does not conflict with the NCD and clearly references the NCD on which it is based. Contractors must give notice and solicit public comments on new LCDs and when they revise an LCD to restrict existing coverage policies.

The NCD manual states explicitly that Medicare covers ventilators for beneficiaries with muscular thoracic and neuromuscular diseases and advanced COPD.[5] Notably, the NCD manual does not include

[3] Medicare Program Integrity Manual (PIM), pub. 100-8, § 13.1.1, available at: http://www.cms.gov
[4] *Ibid.*
[5] NCD Manual, pub. 100-3, 4 § 280.1, states that ventilators are:

any other condition for Medicare coverage of ventilators. But the MACs are aggressively auditing and denying claims for E0464 ventilators for beneficiaries with these conditions unless beneficiaries can show they are using the ventilators 24/7 to avoid the risk of imminent death. In a similar formulation, the contractors have also held that only beneficiaries on invasive ventilators qualify for Medicare reimbursement of a ventilator because intubated patients never remove their ventilators.

An appendix which includes some examples that highlight how far the MACs have deviated from the terms of what is a patently clear, easy to understand NCD will be mailed hard copy on Monday due to size. The beneficiaries in these examples have extensive medical record documentation to support medical necessity for the ventilator, but the contractors denied their claims notwithstanding copious records documenting the extent and severity of their disease.[6]

2. **The DME MACs cannot restrict Medicare coverage for ventilators simply by posting a bulletin on their websites.**

   A requirement for beneficiaries to use E0464 ventilators 24/7 is not inferable from the frequent and substantial service (FSS) fee schedule payment category for ventilators.

There is no legal or clinical rational to support the contractors' actions. But a recent DME MAC bulletin proposes to remind suppliers of correct coding and "coverage" for ventilators. A notice on one contractor's web site states:

> Suppliers are reminded that ventilators fall in the "Frequent and Substantial" servicing category. It is expected that a beneficiary being provided a ventilator would require usage 24 hours per day, seven days per week for a condition that is life-threatening if there were to be interruption in respiratory support.[7]

The notice essentially establishes a two pronged coverage policy for all ventilators (not just E0464): the beneficiary must use the ventilator 24/7, and his condition must be such that without the ventilator, even for short periods, he would likely die. This unwritten coverage policy establishes a *de facto* requirement for invasive ventilation as a prerequisite for Medicare ventilator coverage because intubated patients do not remove their ventilators for any amount of time.

> Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary Disease. Includes both positive/negative pressure types.

[6] In Jurisdiction D, the contractor denies claims for E0464 using the following boilerplate:

> The medical record documentation does not support requirements for ventilator therapy. The medical records do not indicate that the beneficiary would be in danger of succumbing to death without a ventilator.

[7] ACT Questions and Answers, September 2015, available at: https://med.noridianmedicare.com/web/jddme/education/act/act-qa-09101

And the notice apparently conflates a DME item's payment category under the Social Security Act (Act) with coverage for the item.[8] As you know, the Act distinguishes between coverage and reimbursement for items and services beneficiaries receive. While the Secretary has extensive authority to make coverage determinations under the "reasonable and necessary" clause of the Act, Congress expects him to strictly follow the reimbursement methodologies it created.[9] The DME contractors cannot extrapolate from the FSS payment class for ventilators to an implicit coverage policy that requires beneficiaries to use the ventilator 24/7 as a condition of payment. Coverage and payment for DME are simply not interlinked in that way.

And contractors cannot implement restrictive coverage policies like this one without first giving the public notice and an opportunity to comment on the policy.[10] In this case, the contractors have virtually foreclosed Medicare access to noninvasive ventilators for the beneficiaries who need them the most simply by posting a bulletin on their websites.

Equally disturbing is that the criteria contractors are using to deny coverage are so vague that they are unenforceable and provide no guidance to patients or physicians for when these ventilators might be covered. Our members who work with ventilator patients tell us that patients' need for ventilation progresses as their conditions deteriorate. That these beneficiaries do not use the ventilator 24/7 at first does not negate the severity or the terminal nature of their condition. But in addition to showing that she uses her ventilator 24/7; a beneficiary must also establish the likelihood that she will die soon if she removes the ventilator even for short periods during the day or uses it only when she sleeps at night. Proximity to death is an unscientific and unpredictable measure for establishing coverage for any device, especially one that patients actually do use so close to the end of their lives.

To highlight how unworkable the contractors' "imminent death" standard is as a coverage criterion, the Appendix includes an example of a beneficiary who died within a month of having his claim for an E0464 ventilator denied. But no matter whether criteria the MACs are using to deny claims have any basis in science or clinical practice, the denials are nonetheless improper because they restrict coverage from what is available under the Medicare NCD. We request that CMS direct its contractors to immediately cease these unfounded audits, reverse improperly denied claims for E0464 ventilators and promptly refund monies they have recouped from suppliers.

B. The DME contractors cannot use a CMS decision memorandum from a coverage action for respiratory assist devices (RADs) to restrict coverage for E0464 ventilators from what is afforded to beneficiaries under the Medicare ventilator NCD.

The contractors also support E0464 audits and claim denials by referring to the CMS decision memorandum for the RAD.[11] They have zeroed in on a single phrase from the memorandum to conclude

[8] 42 USC § 1395m (a).
[9] See *Hays v. Sebelius*, 508 F.3d 1279 (DC Cir 2009).
[10] See PIM § 13.1.1., establishing the circumstances when contractors must us notice and comment procedures when they issue new LCDs or restrict coverage by revising existing LCDs.
[11] Decision Memo for Noninvasive Positive Pressure RADs for COPD (CAG-00052N), available at:

that Medicare does not cover ventilators unless a beneficiary is in imminent danger of death without it. The decision memo states:

> It [noninvasive ventilation] is distinguished from the invasive ventilation administered via a securely intubated airway, in a patient for whom interruption or failure of respiratory support leads to death.[12]

Contractors have focused on this phrase to deny coverage for beneficiaries using noninvasive ventilators, which by definition do not require intubation, reasoning that these beneficiaries do not risk death or serious injury by using the ventilator only intermittingly or only while they sleep at night. The RAD LCD refers to the decision memorandum in what appears to be a roundabout attempt to establish noncoverage for E0464 ventilators.

The LCD states that, unless the beneficiary's condition is such that: "interruption of respiratory support would *quickly* lead to serious harm or death," "*any* type" of ventilator would be noncovered.[13]

> CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 saying that RAD is "distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death."
>
> The conditions described in the Respiratory Assistance Devices (RAD) local coverage determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, *any type ventilator would not be eligible* for reimbursement for any of the conditions described in the RAD LCD. . . [.][14, 15]

The Medicare NCD manual cautions contractors to distinguish between NCDs and CMS decision memoranda. Decision memoranda are not coverage determinations; they only explain the rational for coverage actions the Agency undertakes. And decision memoranda are not binding on contractors or

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https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=56&viewAMA=Y&bc=AAAAAAAAEAAA&

[12] *Ibid*.

[13] Respiratory Assist Devices (L33800), available at: http://www.medicarenhic.com/dme/mrlcdcurrent.aspx

[14] *Ibid*.

[15] DME MAC for Jurisdiction C relies on this rational to support its denials of E0464 ventilators. Rederterminations from Jurisdiction C state:

> The medical records received lack sufficient information concerning the beneficiary's condition to determine if medical necessity coverage criteria have been met. (LCD L5023-Respiratory Assist Devices, Documentation Requirements).

administrative law judges (ALJs).[16] A decision memorandum for one device cannot establish or deny coverage for another, unrelated device.

Importantly, RADs and ventilators are distinct respiratory devices that are not interchangeable as the RAD LCD contends. It is true that physicians use RADs and E0464 ventilators to treat patients with some of the same conditions. But while the conditions these devices treat might overlap, beneficiaries who require E0464 devices are far sicker – they are the "sickest of the sick" – than beneficiaries who use RADs. Beneficiaries who need noninvasive ventilators are farther along in the progression of their disease and have a need for the higher level of ventilation that only E0464 noninvassive ventilators can provide.

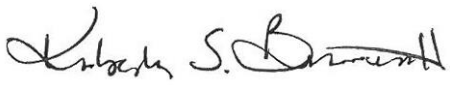
The only way that the DME MACs can apply coverage criteria to ventilators that are not in the NCD is for them to develop an LCD that clarifies, but does not restrict, the criteria CMS established under the NCD. First contractors must engage the public in a notice and comment process through which they reference their clinical and academic sources and clearly articulate the rationale for a draft LCD. And they must respond to the public's comments and allow for an orderly implementation of the new policies before a final LCD becomes effective.

In the absence of an applicable LCD, coverage for E0464 ventilators falls squarely within the NCD and a treating physician's or specialist's judgment of what is in a beneficiary's best interest. If the beneficiary presents with a qualifying diagnosis and his doctor carefully documents the severity of his disease, the DME MACs cannot arbitrarily say he lacks medical necessity for an E0464 ventilator.

Again, we request that CMS instruct its contractors to immediately stop these baseless audits, reverse all improperly denied E0464 claims and promptly refund recoupments to suppliers. Suppliers have no other reasonable remedies under the circumstances because the ALJ appeals backlog denies them any appellate relief.

Thank you for considering these important issues. I will be in touch in the next couple of weeks to follow-up on a resolution.

Sincerely,



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[16] NCD manual § 13.1.1.