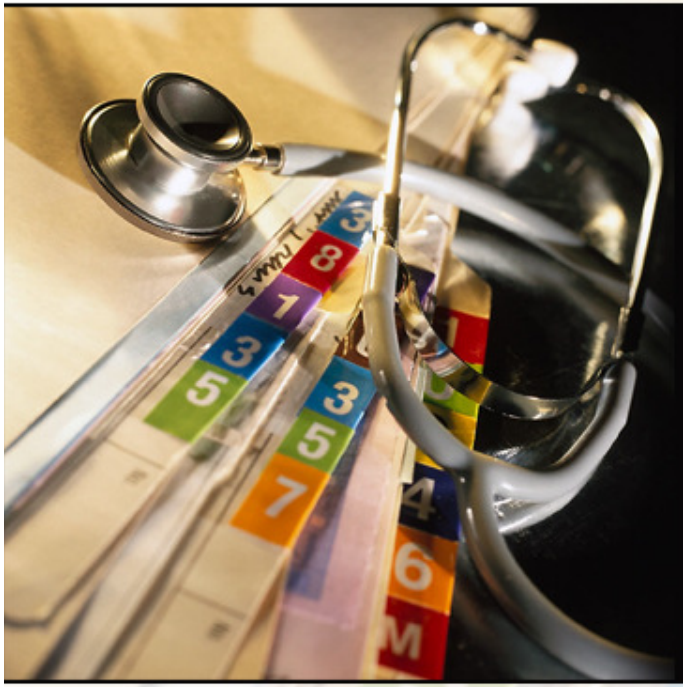


The Medical Review Process

Trying to understand the process

The Medical Review Process

The Centers for Medicare and Medicaid Services (CMS) Medical Review (MR) program is designed to promote a structured approach in the interpretation and implementation of Medicare policy.

The ultimate goal of the MR program is to identify and reduce Medicare program vulnerabilities (areas of potential fraud or abuse) relating to coverage and by taking the necessary action to prevent or address these areas.

Who Performs the Reviews?

CERT- Comprehensive Error Rate Testing

RAC - Recovery Audit

ZPIC – Zone Program Integrity Contractors Contractors

CERT

The Medicare Comprehensive Error Rate Testing (CERT) program measures the quality and accuracy of Medicare claims submission, processing and payment. Under this program, the Centers for Medicare & Medicaid Services randomly selects claims each year for review.

The the results are used to characterize and quantify local, regional, and national error rate patterns; and creates educational and interventional programs to address the error rate.

RAC

Recovery Audit Contractors (RACs) are private companies contracted by CMS and tasked to identify Medicare overpayments and underpayments and return Medicare overpayments to the Medicare Trust Funds.

RACs are highly motivated to identify overpayments and other improper payments, as the RACs are compensated on a contingency-fee basis.

ZPIC

The Zone Program Integrity Contractors (ZPIC) audit live claims in an effort to ferret out fraud.

They handle external fraud referrals and they do both post- and pre-pay reviews.

Unlike the RAC, ZPIC's are paid a contract fee and do not work on a contingency basis.

Claims Review Process

In 2004, CMS provided training to contractor medical review staff on the use of clinical judgment . . .

Reviewers were instructed that medical record documentation must:

1. *reflect* the care provided;
2. is not expected to record every aspect of the care provided; and
3. at a minimum, must enable a clinical reviewer to *reasonably infer* the care that was provided.

Reasonable inference was defined as:

a. a conclusion made by a reviewer with clinical experience in the area under review; and

b. an interpretation of the claim after considering the totality of the circumstances.

Error Rate

The DME-specific paid claims error rate reported by CMS for FYs 2003 through 2009 are as follows:

FY 2003: 13.6%
FY 2004: 11.1%
FY 2005: 8.6%
FY 2006: 7.5%
FY 2007: 10.3%
FY 2008: 9.0%
FY 2009: 51.9%

The error rate for DME increased by nearly 600% in FY 2009.

What has Changed?

A more strict enforcement of documentation requirements rather than allowing for clinical review judgment.

Physician Orders

There was a time that orders executed by a patient's treating physician that followed the national coverage determinations ("NCD") or the DME MAC's local coverage determinations ("LCD") were given the appropriate weight and allowed.

NOW

CMS inexplicably insists that documentation of medical necessity arise organically from the patient's medical record and not be specifically tailored to satisfying the applicable NCD or LCD.

New Verbal Instructions in 2009

February 23, 2009: CMS directed the CERT contractor that clinical review judgment cannot override statutory and regulatory provisions and all documentation and policy requirements must be met before clinical review judgment applies.

May 15, 2009: CMS provided guidance on a variety of issues related to review of durable medical equipment claims. This included guidelines on period of medical necessity documentation requirements, policy requirements added after the original order, and medical necessity requirements for DME accessories, repairs, and maintenance.

May 31, 2009: Based on CMS policy a claim must be denied if the signature on the medical record is absent or illegible. CMS provided guidance to the CERT contractor that claims should be counted as an error if the reviewer could not identify the author of the medical record entry.

Are there Magic Words?

Provider signature authentication

- *Definitive Interpretation*: Apply clinical review judgment in considering medical record entries with missing or illegible signatures.

- *Revised Interpretation*: Disallow entries if a signature is missing or illegible.

Are there Magic Words?

Reliance on physician order:

- *Definitive Interpretation*: Review available documentation, including physician orders, supplier documentation, and patient billing history, and apply clinical review judgment.

- *Revised Interpretation*: Require medical records from the treating physician and do not review other available documentation or utilize clinical inference.

Are there Magic Words?

Continued use / need:

- *Definitive Interpretation*: Patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement.

- *Revised Interpretation*: Medical record must contain express evidence of continued use and need of the DME.

Are there Magic Words?

Hard copy test results:

- *Definitive Interpretation*: For oxygen therapy, claims were paid if oxygen saturation levels from a blood gas study were reported on the CMN.

- *Revised Interpretation*: DME claims are denied for a failure to produce hard copies of test results.

Are there Magic Words?

Invalidity of patient billing history:

- *Definitive Interpretation*: Medical necessity can be inferred from claims history.

- *Revised Interpretation*: Claims history not a valid source for review information.

What is the Responsibility of the Supplier?

THE PHYSICIAN ORDER

Who knows the patient better than the physician?

- It is unreasonable to require suppliers to second-guess and overrule the prescribing physician's clinical judgment as to medical necessity.
- The prescribing physician has both the expertise and is in the best position to make the decision about the patient's need for DME items or services and to evaluate the patient's medical record.
- The DME supplier does not have the information or the clinical competence to second-guess or overrule the ordering physician's medical judgment.

Medical Necessity – Clinical Inference

Denying claims that clearly are medically necessary.

Physicians will produce different medical notes and order different tests and treatment. It is unlikely that medical records will fit into a neat package and meet the contractors requirements.

The supplier has no control over the ordering practices or the documentation practices of the physician.

Medical Necessity – Continued Need

The very nature of the illness suggests continued need.

The requirement that documentation repeatedly demonstrate continuing use and need imposes an unreasonable burden on DME suppliers, beneficiaries, and providers and is nonsensical from a clinical perspective in the case of many chronic conditions.

Ongoing Continued Use

Demonstrated continued need every 6 months.

The requirement that documentation repeatedly demonstrate continuing use and need imposes an unreasonable burden on DME suppliers, beneficiaries, and providers and is nonsensical from a clinical perspective in the case of many chronic conditions.

What about the Patient?

Continued Use/Need Requirement Imposes Unreasonable Burdens on Beneficiaries

The very nature of the diagnosis of chronic obstructive pulmonary disease suggests it is chronic and "continued use/need" should be presumed. It is unreasonable to ask patients with demonstrated chronic breathing conditions to visit their physician to chart "continued use/need" of their respiratory equipment.

Many patients in this population have mobility restrictions, so it is more difficult—and in some cases, impossible—for them to make frequent trips to their doctors' offices and these trips are pointless.

How do I prepare?

Conduct an internal review of the primary services you provide and make sure your documentation is in order.

At a minimum you need:

1. A dispensing order
2. A detailed written order
3. Proof of delivery
4. Supporting medical necessity documentation for the service provided
5. Make sure all items are clearly listed on the orders prior to dispensing and make sure your delivery documentation is very detailed and includes brand name, model, and serial numbers.

How do I prepare?

Review the Documentation Requirements section of the LCD for each item you provide. Utilize the documentation checklists provided by the DME MAC to assure you always have all the necessary documentation.

DME MAC Jurisdiction C Documentation Checklist

Oxygen and Oxygen Equipment — Beneficiaries Meeting Group I Criteria

Required Documentation in Supplier's File *

All Claims for Oxygen: Initial Certification

- ☐ Documentation of Dispensing Order (preliminary written or verbal order) that contains:
  - ○ Description of the item ○ Name of the beneficiary ○ Name of the physician ○ Start date of the order
- ☐ Detailed Written Order That Contains:
  - ○ Beneficiary's name
  - ○ The item(s) to be dispensed – Must include all separately billed accessories/supplies and specify quantity to provide and replacement frequency
  - ○ The means of oxygen delivery (cannula, mask, etc.)
  - ○ The specifics of varying oxygen flow rates and/or noncontinuous use of oxygen
  - ○ Length of need
  - ○ The treating physician's signature
  - ○ The date the treating physician signed the order
  - ○ The start date of the order - if different than the signature date
- ☐ Certificate of Medical Necessity for Home Oxygen (The CMN may act as a substitute for a written order if it is sufficiently detailed)
- ☐ Beneficiary Authorization
- ☐ Proof of Delivery

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
• Beneficiary's name • Quantity delivered • Detailed description of item(s) • Brand • Serial number • Signature of person accepting delivery • Relationship to beneficiary	• Shipping invoice - Beneficiary's name - Delivery address - Detailed description of item(s) shipped - Quantity shipped - Brand - Serial number • Tracking slip - References each individual package - Delivery address - Package I.D. #number - Date shipped - Date delivered • A common reference number links the invoice and tracking slip – may be entered by supplier	• Shipping invoice - Beneficiary's name - Delivery address - Detailed description of item(s) shipped - Quantity shipped - Brand - Serial number - Date shipped - Signature of person accepting delivery - Relationship to beneficiary - Signature date

- ☐ Medical Records supporting that the patient meets the basic coverage criteria specified in the Coverage and Payment Rules section of the Oxygen and Oxygen Equipment LCD*
  - ○ The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, **AND**
  - ○ The patient has had a blood gas study that meets one of the following criteria:
    - △ At rest (awake but sitting or lying down), the arterial PO2 is at or below 55 mm Hg or the arterial oxygen saturation is at or below 88%; **or**
    - △ While awake, the patient's arterial PO2 is ≥ 56 mm Hg or the arterial oxygen saturation is ≥ 89% **but**, for at least 5 minutes during sleep, the arterial PO2 falls to ≤ 55 mg Hg or the arterial oxygen saturation to ≤ 88%; **or**
    - △ During sleep, there is a decrease in the arterial PO2 of more than 10mm Hg or a decrease in the arterial oxygen saturation of more than 5% for at least 5 minutes **and** the decrease in PO2 or O2 saturation is associated with symptoms or signs reasonably attributable to hypoxemia; **or**

NOTE: The value reported on the CMN must be the lowest value (not related to artifact) during the 5 minute qualifying period. Beneficiaries may self-fed minister home based overnight oximetry tests under the direction of a Medicare-enrolled IDTF. The oximeter provided to the patient must be tamper-proof and must have the capability to download data that allows documentation of the duration of oxygen desaturation below a specified value. See the LCD (http://www.cignagovernmentservices.com/ic/coverage/LCDinfo.html) for complete details on the rules regarding home sleep oximetry studies.

- △ At rest, the patient's arterial PO2 is ≥ 56 mm Hg or the arterial oxygen saturation is ≥ 89% on room air **but**, during exercise, the arterial PO2 falls to < 55 mm Hg or the arterial oxygen saturation is < 88% **and**, oxygen administration improves the hypoxemia **and**, medical record includes **all** of the following:
  - ☐ Blood gas study performed at rest without oxygen;
  - ☐ Blood gas study performed during exercise without oxygen; and
  - ☐ Blood gas study performed during exercise with oxygen applied that demonstrates improvement of the hypoxemia

NOTE: All three qualifying blood gas reading should be taken during a single testing session. The blood gas reading obtained during exercise, while breathing room air, is the number that should be recorded on the CMN. However, all three readings must be recorded in the medical record and available to the DME MAC or other Medicare contractors upon request.

AND

- ○ The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services (blood gas studies performed by a supplier are not acceptable)

AND

- ○ The qualifying blood gas study was obtained under one of the following conditions:
  - △ Performed during an inpatient hospital stay, no earlier than 2 days prior to the hospital discharge date, and was the last test obtained prior to discharge; **or**
  - △ Was not performed during an inpatient hospital stay **and** was performed while the patient was in a chronic stable state, not during a period of acute illness or an exacerbation of their underlying disease

AND

- ○ The qualifying blood gas study was the most recent study obtained prior to the Initial Date indicated in Section A of the CMN and this study was obtained within 30 days prior to the Initial Date

AND

- ○ The patient was seen and evaluated by the treating physician within 30 days prior to the date of initial certification.

AND

- ○ Alternative treatment measures have been tried or considered and deemed clinically ineffective

Recertification (Required 12 months after Initial Certification)

- ☐ Recertification CMN
- ☐ Copy of blood gas study* (Should be the most recent test prior to the 13th month of therapy)
- ☐ Medical records documenting that the patient was seen and re-evaluated by the treating physician within 90 days prior to the date of the Recertification *

Please refer to the LCD (http://www.cignagovernmentservices.com/ic/coverage/LCDinfo.html) for complete details regarding when an Initial, Recertification or Revised CMN is required.

Portable Oxygen Systems

Medical records* that support:

- ☐ The patient is mobile within the home; and
- ☐ The qualifying blood gas study was performed at rest (awake) or during exercise

Liter Flow Greater Than 4 LPM

- ☐ A copy of a blood gas study showing blood gas levels in the Group I or Group II range while the patient was receiving oxygen at the rate of 4 LPM*

Additional Resources on the Web

- Supplier Documentation Requirements http://www.cignagovernmentservices.com/ic/pubs/pdf/Chpt3.pdf
- Local Coverage Determinations (LCDs) and Policy Articles http://www.cignagovernmentservices.com/ic/coverage/LCDinfo.html
- Certificate of Medical Necessity: CMS-484 – Oxygen http://www.cms.hhs.gov/mcd/kcd_attachments/11446_33/OxygenCMNCMS484DMEMAC484.03.pdf

* **Note:** It is expected that the patient's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

Disclaimer: This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the DME MAC Jurisdiction C Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.

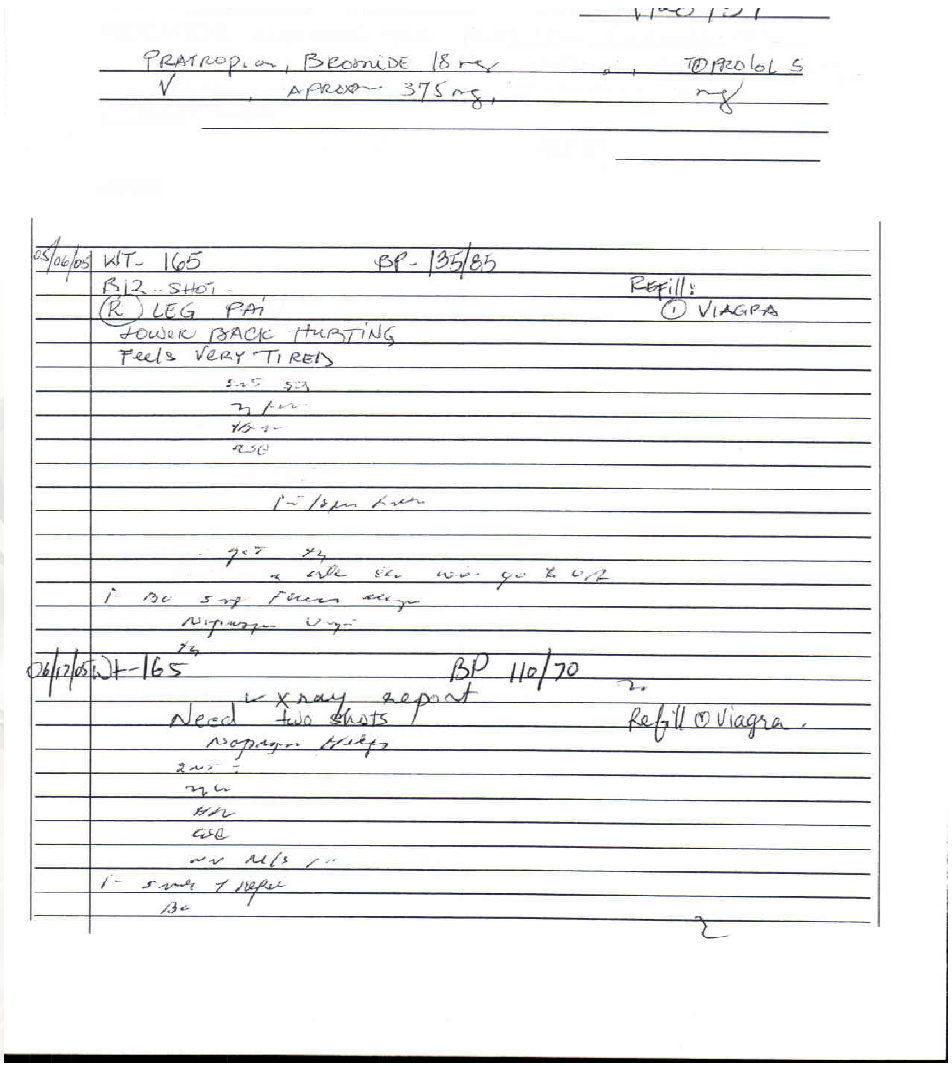
How do I prepare?

Whenever possible, get as much clinical documentation up front for the services you provide.

It is much easier to get the documentation you need at the time the service is ordered rather than having to go back if faced with one of these audits.

Read the documentation before you send to the auditor.

A note like this DOES NOT help!



How do I prepare?

Make sure your referral sources know the guidelines and required medical conditions for each item they order. Help them understand the requirements.

Audits are based upon a combination of claims data from multiple sources, the reviews are based on the patient care. Documentation needs to support the medical need.

Help your referral sources understand we are all in this together.

How do I prepare?

GET RID OF ALL SUPPLIER GENERATED FORMS.

Do not rely on supplier-generated forms to document medical necessity. They are not considered part of the medical record.

The reviewer will discount any supplier generated forms that are used to validate medical necessity.

How do I prepare?

Perform Internal Reviews

Make sure you and your staff understand the rules and the requirements.

Everyone in the office needs to understand the expectations.

Do not wait until you are being audited before beginning a review process.

It is much easier and more cost effective to review documentation in advance to determine if you have any issues rather than wait for an auditor to come in and audit a sample of your claims and extrapolate the overpayment.

Where do you go from here?

What do you need to do to make sure you meet the review requirements?

- Make sure everyone in your organization understands the review process
- Help your physicians understand the review process
- Develop an internal review process.
- Stay informed