# Medicare Quarterly Provider Compliance Newsletter

Guidance to Address Billing Errors

Volume 11, Issue 3

## Table of Contents

<table>
<thead>
<tr>
<th>Page</th>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Introduction</td>
</tr>
<tr>
<td>2</td>
<td>Comprehensive Error Rate Testing (CERT): Continuous Positive Airway Pressure (CPAP) Therapy for the Treatment of Obstructive Sleep Apnea (OSA)</td>
</tr>
<tr>
<td>5</td>
<td>RECOVERY AUDITOR FINDING: 0067 – Inpatient Psychiatric Facility Services: Medical Necessity and Documentation Requirements</td>
</tr>
<tr>
<td>8</td>
<td>RECOVERY AUDITOR FINDING: 0074 – Drugs and Biologicals: Incorrect Units Billed (Single-Dose Vials)</td>
</tr>
</tbody>
</table>

[Archive of previous Medicare Quarterly Provider Compliance Newsletters]
INTRODUCTION

Learn about avoiding common billing errors and other erroneous activities when dealing with the Medicare Fee-For-Service (FFS) Program. This newsletter includes guidance to help health care professionals address and avoid the top issues of the particular quarter.

The Medicare FFS program processes more than one billion claims each year. Medicare Administrative Contractors (MACs) process these claims, make payments to more than one million health care professionals in accordance with Medicare regulations, and provide education on how to submit accurately coded claims.

Despite actions to prevent improper payments, it is impossible to prevent them all due to the large volume of claims. The Medicare Learning Network's® Medicare Quarterly Provider Compliance Newsletter helps health care professionals to understand the latest findings identified by MACs and other contractors such as Recovery Auditors and the Comprehensive Error Rate Testing (CERT) review contractor, in addition to other governmental organizations such as the Office of the Inspector General (OIG).

We (CMS) release the newsletter on a quarterly basis. An archive of previously issued newsletters, which includes keyword and provider-specific indices, is available on the CMS website.

COMPREHENSIVE ERROR RATE TESTING (CERT): CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) THERAPY FOR THE TREATMENT OF OBSTRUCTIVE SLEEP APNEA (OSA)

Provider Types Affected: Durable Medical Equipment (DME) Suppliers and Physicians/Non-Physician Practitioners (NPPs) who write prescriptions for CPAPs.

Background:
Medicare covers a CPAP device under the DME Benefit (Social Security Act §1861(s) (6)). CPAP is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in OSA.

Apnea is defined as the cessation of airflow for at least 10 seconds. The Apnea Hypopnea Index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour. The Respiratory Disturbance Index (RDI) is equal to the average number of respiratory disturbances per hour.

Medicare covers the use of a CPAP device when used in adult patients with OSA. Medicare limits coverage of CPAP initially to a 12-week period to identify beneficiaries diagnosed with OSA who benefit from CPAP. Coverage continues for CPAP only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.
Initial coverage
Medicare covers a CPAP device for the treatment of OSA if the beneficiary meets the following criteria:

- The beneficiary has an in-person clinical evaluation by the treating practitioner prior to the sleep test to assess the beneficiary for OSA.
- The beneficiary has a sleep test that meets either of the following criteria:
  - The AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events
  - The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia
    - Hypertension, ischemic heart disease, or history of stroke
- The supplier of the device gave instruction to the beneficiary and/or their caregiver in the proper use and care of the equipment.

If you submit a claim for a CPAP device and the beneficiary didn’t meet all of the criteria above, CMS will deny the claim as not reasonable and necessary.

We cover accessories used with a CPAP device when the coverage criteria for the device are met. If the beneficiary doesn’t meet the coverage criteria, we will deny claims for the accessories as not reasonable and necessary.

Continued coverage beyond first 3 months of therapy
Continued coverage of a CPAP device beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from CPAP therapy.

For CPAP devices, documentation of clinical benefit shows:

- In-person clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved
- The treating practitioner reviewed objective evidence of adherence to use of the CPAP device

We define adherence to therapy as use of the CPAP device greater than or equal to 4 hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial usage.

If the beneficiary doesn’t meet the above criteria, we will deny continued coverage of a CPAP device and related accessories as not reasonable and necessary.

If the treating practitioner re-evaluation doesn’t occur until after the 91st day but the re-evaluation demonstrates that the beneficiary is benefiting from CPAP therapy as specified in the criteria for continued coverage beyond the first 3 months of therapy, continued coverage of the CPAP device will start with the date of that re-evaluation.
Finding: Insufficient Documentation Causes Improper Payments

According to the 2020 Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report, the improper payment rate for CPAP device and accessories was 32.8% accounting for 1.0% of the overall Medicare FFS improper payment rate. The projected improper amount for CPAP device and accessories during the 2020 report period was $280.1 million. The majority (89.9%) of the improper payments were due to insufficient documentation which means that something was missing from the medical records that suppliers submitted to support the payment for the item(s) billed.

CPAP claims with insufficient documentation, based on Medicare guidelines, most commonly lacked one or more of the following:

- Documentation didn’t show the treating practitioner reviewed objective evidence of adherence to use of the CPAP device
- Documentation doesn’t show the treating practitioner performed a clinical re-evaluation
- Documentation from the treating practitioner in the preceding 12 months that supports coverage criteria such as the beneficiary was assessed for OSA

Example of Improper Payments due to Insufficient Documentation – Inadequate documentation of objective evidence of adherence to use of the CPAP device reviewed by the treating practitioner and missing documentation of an in-person clinical re-evaluation.

A supplier billed for HCPCS E0601 (CPAP device) and in response to the CERT review contractor’s request for documentation, submitted the following for the billed date of service:

- Physician’s in-person clinical evaluation that documents beneficiary assessed for OSA
- Sleep test report documenting AHI of 38.1 per hour
- Written order for the billed item
- Proof of delivery and beneficiary received instructions on proper use of device
- Device download indicating beneficiary is adhering to therapy greater than 6 hours per night on 90.3% of nights during a consecutive 30-day period

There was no documentation to support that the treating practitioner reviewed the objective evidence of adherence to therapy. Also, there was no documentation the treating practitioner conducted the re-evaluation no sooner than the 31st day but no later than the 91st day after initiating therapy with documentation that the beneficiary is benefiting from the therapy. The CERT review contractor scored this claim as an insufficient documentation error and the MAC recouped payment from the provider.

Example of Improper Payments due to Insufficient Documentation – Missing documentation that supports all coverage criteria required by regulations, Medicare program manuals, and Medicare Administrative Contractor (MAC)
A supplier billed for HCPCS A4604 (heated tubing), A7034 (nasal interface), A7033 (nasal pillow), and A7038 (disposable filter). In response to the CERT review contractor’s request for documentation, the supplier submitted the following for the billed date of service:

- Written order for items billed
- Sleep test report documenting AHI of 64 per hour
- Proof of Delivery for items billed

There was no documentation in the preceding 12 months from the treating practitioner that supports coverage criteria. The CERT review contractor scored this claim as an insufficient documentation error and the MAC recouped payment from the provider.

You may want to review the following information to help avoid these billing errors:

- Local Coverage Article entitled Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (A52467)
- Local Coverage Article entitled Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)
- Local Coverage Determination entitled Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718)
- Medicare Program Integrity Manual, Chapter 5, Section 2
- Medicare Program Integrity Manual, Chapter 5, Section 10
- Medicare Program Integrity Manual, Chapter 4, Section 26
- National Coverage Determination (NCD) for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) CMS PUB 100-03, Chapter 1, Section 240.4
- SSA 1861(s) (6) (Durable Medical Equipment Benefit)

RECOVERY AUDITOR FINDING: 0067 – INPATIENT PSYCHIATRIC FACILITY SERVICES: MEDICAL NECESSITY AND DOCUMENTATION REQUIREMENTS

Provider Types Affected: Inpatient Hospitals, Inpatient Psychiatric Facilities (IPFs)

Problem Description: Recovery auditors will review inpatient hospital services furnished to Medicare beneficiaries of an IPF to determine that services were medically reasonable and necessary.

Background: For Medicare to cover inpatient services that IPFs provide, admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in ICD-10.
As a Medicare condition of participation, IPFs have special medical record-keeping requirements. IPFs must maintain documentation that permits the determination of the intensity and level of treatment they provide. The medical record must include:

- A psychiatric evaluation completed within 60 hours of admission
- An individualized treatment plan and updates
- Multidisciplinary progress notes oriented to the treatment plan
- A discharge summary

The certification period begins with the order for inpatient admission. CMS requires recertification as of the 12th day of hospitalization (with subsequent recertifications required at intervals established by the IPF’s Utilization Review committee on a case-by-case basis, but no less frequently than every 30 days).

Guidance for Providers to meet Medical Necessity and Documentation Requirements: Special medical record requirements for psychiatric hospitals

The medical records an IPF maintains must permit determination of the degree and intensity of the treatment provided to individuals who the institution serves.

Development of assessment/diagnostic data: Medical records must stress the psychiatric components of the record, including history of findings and treatment you provide for the psychiatric condition of the inpatient.

- You must include the inpatient’s legal status as part of their identification information
- You must make a provisional or admitting diagnosis on every inpatient at the time of admission to include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses
- You must document clearly the reasons for admission as stated by the inpatient and/or others significantly involved
- The social service records, including reports of interviews with inpatients, family members, and others, must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history
- When indicated, you must record a complete neurological examination at the time of the admission physical examination

Psychiatric evaluation: Each inpatient must receive a psychiatric evaluation that must:

- Be completed within 60 hours of admission
- Include a medical history
- Contain a record of mental status
- Note the onset of illness and the circumstances leading to admission
- Describe attitudes and behavior
- Estimate intellectual functioning, memory functioning, and orientation
- Include an inventory of the inpatient’s assets in descriptive, not interpretative, fashion
Treatment plan:
Each inpatient must have an individual comprehensive treatment plan based on an inventory of the inpatient's strengths and disabilities. The written plan must include:

- A substantiated diagnosis
- Short-term and long-range goals
- The specific treatment modalities used
- The responsibilities of each member of the treatment team
- Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities you carried out

You must document the treatment you give the inpatient assuring you include all active therapeutic efforts. The unit must provide a therapeutic activities program. The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning. The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.

Recording progress: As 42 CFR Section 412.27(c)(4) specifies, progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the inpatient, a nurse, social worker and, when appropriate, others significantly involved in active treatment modalities.

The condition of the inpatient determines the frequency of progress notes, but you must record at least weekly for the first 2 months and at least once a month thereafter. You must include recommendations for revisions in the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan.

Certification and recertification: Upon admission, or as soon as practicable thereafter, the physician must certify that the inpatient admission is medically necessary for either diagnostic study or treatment that one could reasonably expect to improve the inpatient's condition.

As of the 12th day of a hospitalization, and no less frequently than every 30 days thereafter, the physician must recertify the stay.

The requirements for the recertification are different from those for the initial certification. In the recertification, the physician must state that:

- The inpatient psychiatric services furnished since the previous certification or recertification were, and continue to be, medically necessary for either diagnostic study or for treatment that one could reasonably expect to improve the inpatient's condition
- The IPF records indicate that the services furnished were one of the following:
  - Admission and related services necessary for diagnostic study
  - Intensive treatment services
  - Equivalent services
• The inpatient continues to need daily active treatment either furnished directly by or requiring the supervision of IPF personnel.

CMS doesn’t require any specific form, format, or language for a certification or recertification, if the medical record demonstrates the required content with entries signed by the physician. The format of all certifications and recertifications and the method by which they are obtained is determined by the individual facility. No specific procedures or forms are required. The provider may adopt any method that permits verification of all the IPF’s requirements to continue treatment.

Discharge planning and discharge summary: The record of each inpatient you discharge must have a discharge summary that includes a recapitulation of the inpatient’s hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient’s condition on discharge.

Resources
• 42 CFR 412.27, Excluded psychiatric units: Additional requirements
• 42 CFR 482.14, Requirements for inpatient services of inpatient psychiatric facilities
• 42 CFR 482.12, Condition of participation: Governing body
• 42 CFR 482.61, Condition of Participation: Special Medical Record Requirements for Psychiatric Hospitals
• Compliance Programs/Recovery-Audit-Program
• Inpatient Psychiatric Facility Prospective Payment System, MLN Booklet
• Medicare Benefit Policy Manual, Chapter 2 – Inpatient Psychiatric Hospital Services, Sections 20, 30, 30.1, 30.2, 30.2.1, 30.2.1.2, 30.2.1.3, 30.3, 30.3.1, 30.3.2, 30.4, 30.5
• Medicare General Information, Eligibility, and Entitlement Manual, Chapter 4 – Physician Certification and Recertification of Services, Section 10.9 – Inpatient Psychiatric Facility Services Certification and Recertification
• OIG Report dated April 2020, A-01-16-00508

RECOVERY AUDITOR FINDING: 0074 – DRUGS AND BIOLOGICALS: INCORRECT UNITS BILLED (SINGLE-DOSE VIALS)

Provider Types Affected: Outpatient hospitals, Physicians, and Non-Physician Practitioners (NPPs)

Background: CMS encourages physicians, hospitals, and other providers and suppliers to care for and administer drugs and biologicals to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner.

Drugs and Biologicals are billed in multiples of the dosage specified in the HCPCS code long descriptor. If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided. When a physician, hospital or other provider or supplier must discard the remainder of a
single use vial or other single use package after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded as well as the dose administered, up to the amount of the drug or biological as indicated on the vial or package label.

Effective January 1, 2017, when processing claims for drugs and biologicals (except those provided under the Competitive Acquisition Program (CAP) for Part B drugs and biologicals), your Medicare Administrative Contractor requires the use of the modifier JW to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological.

**Finding:** The Recovery Auditors perform complex claim reviews for single dose vials to assure compliance with Medicare policy. They reviewed claims to determine the actual amount administered and the correct number of billable/payable units.

**Recommendations:** You may want to review the language in Chapter 17, Section 40 of the Medicare Claims Processing Manual for more information.

**For example:** A single use vial that’s labeled to contain 100 units of a drug has 95 units administered to the patient and 5 units discarded. Bill the 95-unit dose on one line and bill the discarded 5 units on another line by using the JW modifier. Medicare will process both line items for payment. You must record the discarded amounts of drugs and biologicals in the patient’s medical record.

The JW modifier is only applied to the amount of drug or biological that is discarded. A situation in which the JW modifier isn’t permitted is when the actual dose of the drug or biological administered is less than the billing unit.

**For example:** One billing unit for a drug is equal to 10mg of the drug in a single use vial. A 7mg dose is administered to a patient while 3mg of the remaining drug is discarded. The 7mg dose is billed using one billing unit that represents 10mg on a single line item. The single line item of one (1) unit would be processed for payment of the total 10mg of drug administered and discarded. Billing another unit on a separate line item with the JW modifier for the discarded 3mg of drug isn’t permitted because it would result in overpayment. When the billing unit is equal to or greater than the total actual dose and the amount discarded, Medicare doesn’t allow the use of the JW modifier.

**NOTE:** Multi-use vials aren’t subject to payment for discarded amounts of drug or biological.

**Resources:**
- Compliance Programs/Recovery-Audit-Program
- Medicare Alpha-Numeric HCPCS File
- Medicare Claims Processing Manual Chapter 17 – Drugs and Biologicals, Sections 10, 40, 70, 90, and 100.2.9
- Medicare Part B Drug Average Sales Price