Table of Contents

2 Introduction
3 Comprehensive Error Rate Testing (CERT): Glucose Testing Supplies
6 Recovery Auditor Review – 0181: Bone Marrow or Stem Cell Transplant: Medical Necessity and Documentation Requirements
7 Recovery Auditor Review – 0081: Negative Pressure Wound Therapy – Medical Necessity and Documentation Requirements
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 1 billion claims each year. Medicare Administrative Contractors (MACs) process these claims and make payments to more than 1 million health care professionals in accordance with Medicare regulations. They also 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 understand the latest findings by MACs and other contractors such as Recovery Auditors and the Comprehensive Error Rate Testing (CERT) review contractor identify. Also, other governmental organizations, such as the Office of the Inspector General (OIG), conduct reviews and identify issues.

We (CMS) release the newsletter on a quarterly basis.
COMPREHENSIVE ERROR RATE TESTING (CERT): GLUCOSE TESTING SUPPLIES

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

Background: Medicare covers blood glucose monitors and testing supplies under the Durable Medical Equipment benefit (Social Security Act, Section 1861(s)(6)) for people with Type I or Type II diabetes.

Medicare covers blood glucose testing supplies for people with diabetes whether or not they use insulin. The quantity of supplies we cover depends on the usual medical needs of the patient and whether or not their treatment includes insulin. If the patient uses insulin, usual supplies include up to 300 test strips and lancets every 3 months. If the patient doesn’t use insulin, usual supplies include up to 100 test strips and lancets every 3 months. If you document the medical necessity of additional testing, and the patient meets the criteria below, Medicare will cover additional test strips and lancets above usual utilization (that’s, high utilization).

The basic coverage criteria that the patient must meet to receive blood glucose supplies are:

- The patient has diabetes
- The patient’s treating practitioner concludes the patient (or the patient’s caregiver) has sufficient training using the device you prescribed for the appropriate supplies and frequency of blood glucose testing

For Medicare to cover any testing supplies:

- You must communicate a Standard Written Order (SWO) to the supplier before a claim is submitted
- Supplier must have proof of delivery
- Supplier must receive a valid, documented refill request

An SWO must contain all the following elements:

- Patient's name or Medicare Beneficiary Identifier (MBI)
- Order Date
- General description of the item
- Quantity to be dispensed, if applicable
- Frequency of testing
- Treating Practitioner Name or National Provider Identifier (NPI)
- Treating practitioner's signature
For Medicare to cover testing supplies at high utilization:

- The treating practitioner must have had an in-person visit with the patient to evaluate their diabetes control and their need for the specific quantity of supplies that exceeds the usual utilization amounts described above within 6 months prior to ordering strips and lancets that exceed the usual utilization guidelines
- Every 6 months, for continued dispensing of quantities of testing supplies that exceed the usual utilization amounts, the treating practitioner must verify adherence to the high utilization testing regimen

**Finding: Insufficient Documentation and Coding Errors Cause Improper Payments**

According to the 2020 Medicare Fee-for-Service (FFS) Supplemental Improper Payment Data report, the improper payment rate for glucose monitors and testing supplies was 34.2%, accounting for 0.4% of the overall Medicare FFS improper payment rate. The projected improper amount for glucose monitors and testing supplies during the 2020 report period was $103.9 million. The majority (72.6%) of the improper payments were due to insufficient documentation, which means that something was missing from the submitted medical records to support payment for the item(s) billed. Claims with insufficient documentation most frequently lacked one or more of the following:

- Documentation to support medical necessity of diabetic testing supplies
- A valid provider’s order that includes all elements required by regulation, Medicare program manuals, and Medicare Administrative Contractor (MAC) specific guidelines

Another frequent source of errors were coding errors, which means that the medical record documentation supports a different code than that billed. Claims with coding errors most frequently lacked the following:

- Documentation to support the need for quantities of testing supplies that exceed the usual utilization guidelines

**Example of Improper Payments due to Insufficient Documentation – Documentation to support medical necessity is missing**

A supplier billed for 1 unit of HCPCS A4259 (box of 100 lancets). In response to the CERT review contractor’s request for documentation, the supplier submitted the following:

- Order for lancets with instructions for blood glucose testing once daily
- Proof of delivery

Because the supplier submitted no evidence to support a diabetes diagnosis, the CERT review contractor scored this claim as an insufficient documentation error and the MAC recouped payment from the supplier.

**Example of Improper Payments due to Insufficient Documentation – Order is inadequate**

A supplier billed for 1 unit of HCPCS A4259 (box of 100 lancets). In response to the CERT review contractor’s request for documentation, the supplier submitted the following:

- Order signed by the physician that’s missing the testing frequency
- Physician’s clinical record documenting diabetes diagnosis
- Proof of delivery
Because there was no testing frequency on the order, the CERT review contractor scored this claim as an insufficient documentation error and the MAC recouped payment from the supplier.

**Example of Improper Payments due to Coding Errors – Documentation to support medical necessity of exceeding usual utilization guidelines**

A supplier billed for 2 units of HCPCS A4259 (box of 100 lancets) and 4 units of A4253 (box of 50 test strips). In response to the CERT review contractor’s request for documentation, the supplier submitted the following:

- Physician’s order with instructions to test twice daily
- Physician’s clinical record supporting a non-insulin treated diabetes diagnosis but no documentation to support testing supplies quantities that exceed usual utilization
- Proof of delivery

The CERT review contractor scored this claim as a coding error and downcoded the units paid to 1 unit of HCPCS A4259 (box of 100 lancets) and 2 units of HCPCS A4253 (box of 50 test strips) to correspond to usual utilization. The MAC recouped partial payment from the supplier.

**Resources:**

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

- SSA 1861(s)(6) (Durable Medical Equipment Benefit)
- 42 CFR 424.57
- The Medicare Program Integrity Manual, Chapter 3, Section 3.6.2.4 (Coding Determinations)
- The Medicare Program Integrity Manual, Chapter 4, Section 4.26 (Supplier Proof of Delivery Documentation Requirements)
- The Medicare Program Integrity Manual, Chapter 5, Section 5.2 (Rules Concerning DMEPOS Orders/Prescriptions)
- The Medicare Program Integrity Manual, Chapter 5, Section 5.7 (Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs)
- The Medicare Program Integrity Manual, Chapter 5, Section 5.9 (Documentation in the Patient’s Medical Record)
- The Medicare Program Integrity Manual, Chapter 5, Section 5.10 (Supplier Documentation)
- The Medicare Program Integrity Manual, Chapter 5, Section 5.11 (Rules Concerning DMEPOS Orders/Prescriptions)
- Local Coverage Determination for Glucose Monitors (L33822)
- Local Coverage Article for Glucose Monitors (A52464)
- Local Coverage Article for Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)
- The CERT provider website
- The CERT program website
RECOVERY AUDITOR REVIEW – 0181: BONE MARROW OR STEM CELL TRANSPLANT: MEDICAL NECESSITY AND DOCUMENTATION REQUIREMENTS

Provider Types Affected: Inpatient Hospital

Problem Description: This review determines if a bone marrow or stem cell transplant was reasonable and necessary for the patient’s condition based on the documentation in the medical record. Medicare denies claims that don’t meet the indications of coverage or medical necessity.

Background: Stem cell transplantation is a process in which one harvests stem cells from either a patient’s (autologous) or donor’s (allogeneic) bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplantation (AuSCT) is a technique for restoring stem cells using the patient's own previously stored cells. AuSCT may be performed to effect hematopoietic reconstitution following:

- Severely myelotoxic doses of chemotherapy (HDCT)
- Radiotherapy used to treat various malignancies

Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor’s stem cell or bone marrow is obtained and prepared for intravenous infusion. Allogeneic HSCT may be used to restore function in recipients having an inherited or acquired deficiency or defect. Hematopoietic stem cells are multi-potent stem cells that give rise to all the blood cell types. These stem cells form blood and immune cells. A hematopoietic stem cell is a cell isolated from blood or bone marrow that can renew itself, differentiate to a variety of specialized cells, can mobilize out of the bone marrow into circulating blood, and can undergo programmed cell death, called apoptosis - a process by which cells that are unneeded or detrimental will self-destruct.

Resources:

- Medicare NCD Manual, Chapter 1, Section 110.23
- Medicare Fee for Service Recovery Audit Program
- Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services, Chapter 32, Section 90 - Stem Cell Transplantation
- Allogeneic Hematopoietic Stem Cell Transplant for MDS
- Decision Memo for Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease) (CAG-00444R)
RECOVERY AUDITOR REVIEW 0081: NEGATIVE PRESSURE WOUND THERAPY (NPWT) – MEDICAL NECESSITY AND DOCUMENTATION REQUIREMENTS

Provider Types Affected: Durable Medical Equipment (DME) suppliers, and physicians who provide Durable Medical Equipment (DME) to Medicare patients

Problem Description: Providers should be aware of the medical necessity criteria and documentation requirements when billing for NPWT. The RACs review documentation to determine whether NPWT is reasonable and necessary for the beneficiary’s condition. Claims that don’t meet the indications of coverage, medical necessity, and documentation requirements will be recovered.

Background: The HCPCS codes for this review were:

- **E2402** (negative pressure wound therapy electrical pump, stationary or portable)
- **A6550** (wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories)
- **A7000** (canister, disposable, used with suction pump, each)

Recommendations:

- In order to prevent claim denials and improper payments for NPWT claims, follow all published documentation and medical necessity guidelines when billing for NPWT. Review the guidelines in LCD L33821. Review the resources presented below on providing NPWT to Medicare patients.
- When you receive official requests for additional information, respond to them promptly and completely. This will give you an opportunity to correct any documentation errors, submit requested documentation, and ensure all records demonstrating medical necessity for NPWT are included in the claim.

Resources:

DME and HH providers and suppliers can read more about this topic in the following publications:

- Medicare Fee for Service Recovery Audit Program
- MLN Matters Article - SE17027: Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device
- Medicare Compliance Newsletters - ICN MLN 9130552: Comprehensive Error Rate Testing (CERT): Negative Pressure Wound Therapy (NPWT) for the Treatment of Wounds (July 2019)
- MLN Fact Sheets - MLN 909484: Provider Compliance Tips for Negative Pressure Wound Therapy (February 2021)
- Medicare Benefit Policy Manual - Chapter 7, Section 50.4.4 – Negative Pressure Wound Therapy Using a Disposable Device (January 10, 2020)
- Medicare Claims Processing Manual - Chapter 10, Section 90.3 – Billing Instructions for Disposable Negative Pressure Wound Therapy Services (November 10, 2016)
- Local Coverage Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs
- Local Coverage Determination (LCD) L33821: Negative Pressure Wound Therapy Pumps