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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.

There are more than one billion claims processed for the Medicare FFS program 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).

The Centers for Medicare & Medicaid Services (CMS) releases 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): LUMBAR SACRAL ORTHOSIS (LSO)

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

**Background:** LSO is a covered item under the Medicare Braces Benefit ([Social Security Act Section 1861(s)(9)]). For coverage under this benefit, the LSO must be rigid or semi-rigid to support a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Items that aren’t rigid enough to be capable of providing the necessary immobilization or support to the body part that it’s designed for do not meet the statutory definition of the Braces Benefit.

There are three types of LSOs: Off-The-Shelf (OTS), custom fitted, and custom fabricated.

- **OTS LSOs** are prefabricated, may or may not be supplied as a kit, require minimal self-adjustment for fitting at the time of delivery and the fitting doesn’t require the expertise of a certified orthotist or an individual with equivalent training.

- Custom fitted LSOs are also prefabricated, may or may not be supplied as a kit, and require more than minimal self-adjustment for fitting at the time of delivery by the expertise of a certified orthotist or an individual with equivalent training.

- Custom fabricated LSOs are individually made for the specific beneficiary (no other beneficiary would be able to use this orthosis) starting with the basic materials and involves substantial modification work. For custom fabricated orthoses, there must be detailed documentation in the medical record to support the medical necessity of custom fabricated rather than a prefabricated orthosis.

The term “minimal self-adjustment” is defined in [42 CFR 414.402](#) as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist or an individual who has specialized training.

An LSO is covered by Medicare when it’s ordered for one of the following reasons:

- To reduce pain by restricting mobility of the trunk
- To help healing following an injury to the spine or related soft tissues
- To help healing following a surgical procedure on the spine or related soft tissue
- To otherwise support weak spinal muscles or a deformed spine or both

When providing these items, suppliers must:

- Provide the product that is specified by the prescribing practitioner
- Be sure that the prescribing practitioner’s medical record justifies the need for the type of product (that is, prefabricated versus custom fabricated)
• Only bill for the HCPCS code that accurately reflects both the type of orthosis and the appropriate level of fitting
• Have detailed documentation in supplier’s records that justifies the HCPCS code selected

42 CFR 414.402 shows that correct coding of a spinal orthosis is dependent upon whether there’s a need for “minimal self-adjustment” during the final fitting at the time of delivery. For prefabricated orthoses, there’s no physical difference between orthoses coded as custom fitted versus those coded as OTS. The difference is in the fitting at time of delivery. There must be detailed documentation in the medical record to support the adjustments or modifications made at the time of delivery. Items requiring more than minimal self-adjustment by a qualified practitioner are coded as custom fitted and documentation must be sufficiently detailed to include, but not limited to a detailed description of the modifications necessary at the time of fitting. If a custom prefabricated fit code is billed when minimal self-adjustment was provided at final delivery, or if an OTS code is billed when more than minimal self-adjustments were made at final delivery, Medicare will deny the claims.

Finding: Insufficient Documentation Causes Improper Payments
According to the 2018 Medicare Fee-For-Service (FFS) Supplemental Improper Payment Data report, the improper payment rate for LSOs was 46.1 percent, accounting for 0.4 percent of the overall Medicare FFS improper payment rate. The projected improper amount for LSOs during the 2018 report period was $132.1 million. The majority (63.3 percent) 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. Those claims with insufficient documentation, based on Medicare guidelines, lacked one or more of the following:

• Documentation for the fitting of the orthosis at time of delivery (that is, minimal or more than minimal self-adjustment)
• A valid provider’s order that includes all elements required by regulation, Medicare program manuals, and Medicare Administrative Contractor (MAC) specific guidelines
• Proof of delivery is missing or inadequate per regulations and Medicare program manuals

Example of Improper Payments due to Insufficient Documentation – Missing or inadequate documentation for the fitting of the orthosis at the time of delivery

A supplier billed for HCPCS L0637 (LSO, sagittal-coronal control, prefabricated item that has been customized to fit a specific patient by an individual with expertise) and in response to the CERT review contractor’s request for documentation, submitted the following for the billed date of service:

• Detailed written order
• Plan of Care
• Physician’s clinical record documenting low back pain post-fall with x-rays documenting Grade II degenerative joint disease
• Proof of delivery
An additional request for documentation returned duplicate documentation. There was no documentation to support the prefabricated orthosis had more than minimal self-adjustment by an individual with expertise at the time of delivery as required per Medicare policy. 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 a valid provider’s order and documentation for the fitting of the orthosis at the time of delivery

A supplier billed for HCPCS L0631 (LSO, sagittal control, prefabricated item that has been customized to fit a specific patient by an individual with expertise) and in response to the CERT review contractor’s request for documentation, submitted the following for the billed date of service:

- Physician’s clinical record supporting beneficiary with back pain, MRI findings supporting the beneficiary has spondylosis with radiculopathy, and plan for the billed item
- Proof of delivery

An additional request for documentation returned duplicate documentation. There was no order submitted as required per Medicare policy, and the documentation to support the prefabricated orthosis had more than minimal self-adjustment by an individual with expertise at the time of delivery was also missing. The CERT review contractor scored this claim as an insufficient documentation error, and the MAC recouped payment from the provider.

Resources:

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

- Social Security Act Section 1861(s)(9) (Medicare Braces Benefit), which is available at https://www.ssa.gov/OP_Home/ssact/title18/1861.htm
- 42 CFR 414.402 which is available at https://ecfr.io/Title-42/cfr414_main
- The CERT provider website at https://certprovider.admedcorp.com/
- The CERT program website at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/index.html
Provider Types Affected: Outpatient hospitals, Physicians, and Non-Physician Practitioners (NPPs)

**Background:** The Recovery Auditors reviewed claims for Trastuzumab over the last three years to assure compliance with Medicare policy. They found numerous instances where multi-use vials were billed incorrectly with medication wastage.

**Finding:** Provider claims for Trastuzumab (Herceptin) were billed incorrectly by providers for one or more reasons. The Recovery Auditor review, which spanned a period of less than 3 years, revealed that reasons for improper payments included:

- Denial Reason Code (DRC) 1600 (No documentation)
- DRC 1610 (Provider indicated no such patient exist)
- DRC 2100 (Insufficient documentation)
- DRC 2120 (Records for the wrong Date of Service were submitted)
- DRC 3100 (Service incorrectly coded)
- DRC 4100 (Services billed were not rendered)
- DRC 4500 (Duplicate Payment)
- DRC 6100 (Number of units incorrectly billed)

Claims for Trastuzumab (Herceptin) multi-dose vials billed with medication wastage will be denied based on Medicare guidelines found in Chapter 17, Section 40 of the Medicare Claims Processing Manual.

**Note:** Multi-use vials are not subject to payment for discarded amounts of drug or biological.

**Recommendations:** To avoid claims denials and improper payments, providers should not bill Trastuzumab (Herceptin) multi-dose vials with medication wastage. Providers should review the language presented in [Chapter 17, Section 40 of the Medicare Claims Processing Manual](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf) for more information. Providers should study the Manual language to determine how to use the JW modifier for how to bill for unused prescribed medication doses on a claim.

**Resources:**

You should review the following information to help avoid errors in billing related to Trastuzumab (Herceptin) billing, as well as drug and biological billing in general.