Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must:

1) be eligible for a defined Medicare benefit category,
2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and
3) meet all other applicable Medicare statutory and regulatory requirements.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

A Group 1 mattress overlay or mattress
(E0181, E0182, E0184, E0185, E0186, E0187, E0188, E0189, E0196, E0197, E0198, E0199 and A4640)

is covered if one of the following three criteria are met:

1. The beneficiary is completely immobile - i.e., beneficiary cannot make changes in body position without assistance, or
2. The beneficiary has limited mobility - i.e., beneficiary cannot independently make changes in body position significant enough to alleviate pressure and at least one of conditions A-D below, or
3. The beneficiary has any stage pressure ulcer on the trunk or pelvis and at least one of conditions A-D below.

Conditions for criteria 2 and 3 (in each case the **medical record must document the severity of the condition** sufficiently to demonstrate the medical necessity for a pressure reducing support surface):

A. Impaired nutritional status
B. Fecal or urinary incontinence
C. Altered sensory perception
D. Compromised circulatory status

When the coverage criteria for a Group 1 mattress overlay or mattress are not met, the claim will be denied as not reasonable and necessary.

GENERAL

A **Standard Written Order (SWO)** must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior

to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.
An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.
Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.