



# Medicare Coverage of Home Glucose Monitors

**Jim Rollins MD, MSHA, PhD**

**Director of Division of Items and Devices**

**There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.**

**Rehabilitation Association of Virginia, Inc. v. Kozlowski, et al., 42 F. 3d 1444,1450 (4<sup>th</sup> Cir. 1994)**



# Medicare Coverage

**1862 (a)(1)(a) of SSA gives Medicare the authority to cover or non-cover items or services. In order for the item/service to be covered, it must:**

- **Fall within at least 1 benefit category established by the act,**
- **Item or service must not be specifically excluded by the act, and**
- **The item or service must be “reasonable and necessary”**



# Benefit Category Determination

**Social Security Act generally describes Medicare benefits (categories), examples**

- **Hospital Services**
- **Physician Services or “incident to”**
- **Drugs and Biologicals that are not self-administered**

# Benefit Category

- **Home Glucose Monitoring (HGM) falls within the Durable Medical Equipment (DME) category**
  - Can withstand repeated use; i.e., could normally be rented and used by successive patients;
  - Is primarily and customarily used to serve a medical purpose;
  - Generally is not useful to a person in the absence of illness or injury; and,
  - Is appropriate for use in a patient's home.
- **HGM is not a clinical laboratory service**

## Social Security Act 1862(a)(1)(A)

R & N

“...no payment may be made...for items or services - which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”



# Reasonable and Necessary

---

**CMS considers an item or service to be Reasonable and Necessary if there is: Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population.**



# Reasonable and Necessary

---

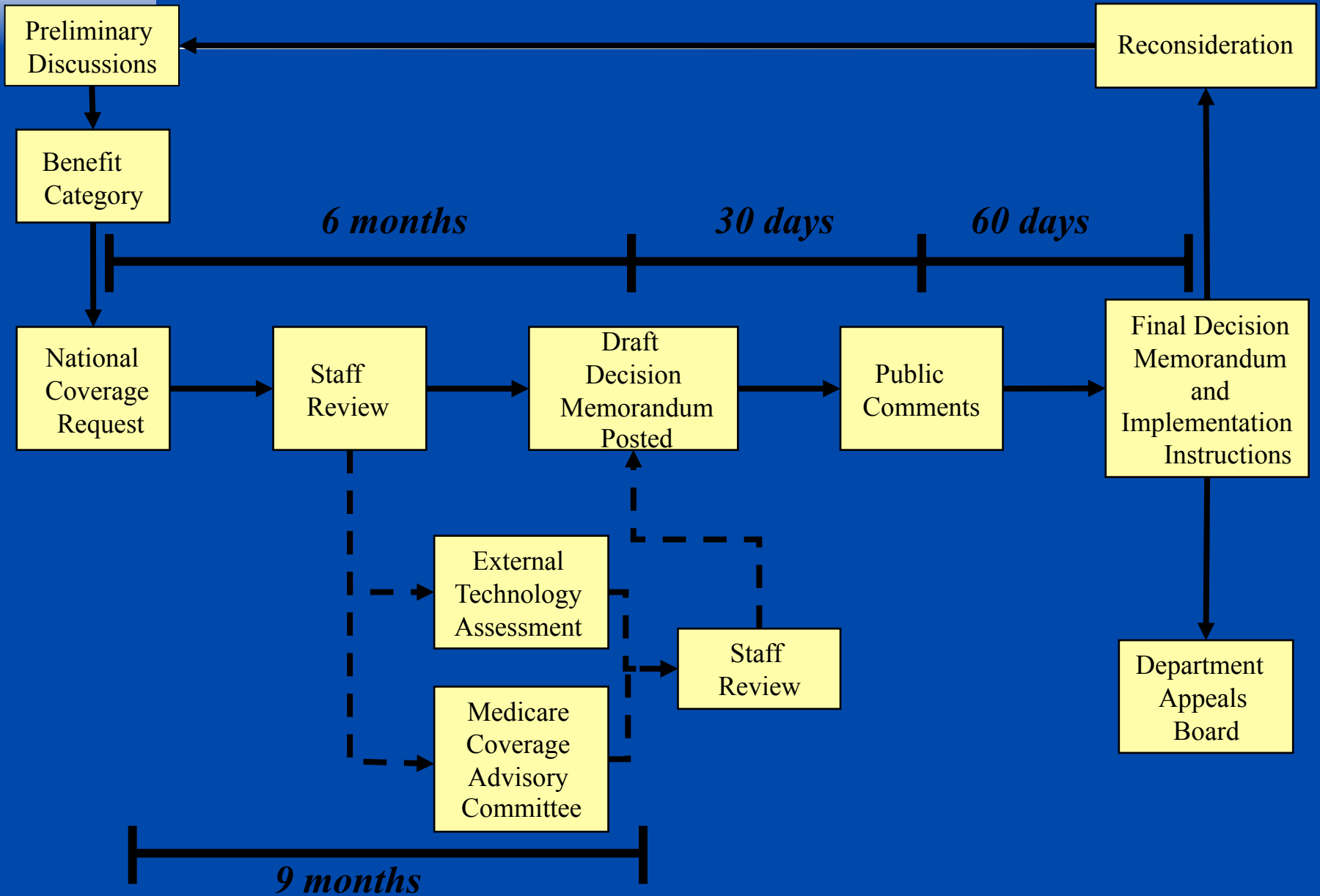
**Sufficient level of confidence that the evidence is adequate to conclude that the item or service:**

- **Improved health outcomes**
- **Is generalizable to the Medicare population**
- **Is generalizable to general provider community**





# MEDICARE NATIONAL COVERAGE PROCESS



## 42 CFR 410.32(a)

“All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem...”



## Cost related to home monitoring and supplies

---

- In 2009, glucose testing and testing supplies cost Medicare \$1.7 billion in allowable charges nationally with over 16.6 million claims.
- By comparison oxygen and equipment supplies totaled Medicare \$2.2 billion, and power mobility devices (PMD) totaled \$787 million.



# History of Coverage for home glucose monitoring

- Traditional glucose monitors and supplies are reimbursed under 2 separate benefits (DME and Diabetic supplies).
- Prior to Balanced Budget Act 1997, home blood glucose monitors and supplies were covered only for insulin-dependent diabetics.
- 1997 Balanced Budget Act (section 4105) expanded coverage of blood glucose monitoring and supplies to all beneficiaries with diabetes.



# Home Glucose Monitoring

CMS has both NCDs as well as LCD addressing the use of home glucose monitoring:

- NCD defines the device, patient criteria for use of the device,
- LCD defines accessories and supplies, utilization of the device.



## NCD for Home Glucose Monitors (40.2)

Coverage of home blood glucose monitors is limited to patients meeting the following conditions:

- The patient has been diagnosed as having diabetes;
- The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and
- The device is designed for home rather than clinical use.



## NCD for Home Glucose Monitors (40.2)

There are special blood glucose monitoring systems designed especially for the visually impaired. They are reliable and accurate, have voice synthesizers and automatic timers, and specially designed arrangements of supplies and materials to enable the visually impaired to use the equipment without assistance.

These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:

- The patient and device meet the three conditions listed above for coverage of standard home blood glucose monitors; and
- The patient's physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.



# LCD for Home Glucose Monitoring

Local Coverage Determination also provides instructions on documentation and utilization

- Patient must have a diagnosis of diabetes (ICD-9 codes 249.00 to 250.93),
- Glucose monitor/accessories/supplies must be ordered by physician who is treating the patient's diabetes, and must maintain records reflecting care provided,
- Patient/caregiver training (successfully completed or is scheduled to begin training),





# LCD requirements for home glucose testing

---

- Patient to maintain a record of their blood glucose reading results, either through a logbook or download test from glucose monitor,
- The device is designed for home use.



# Utilization Guidelines

- For non-insulin diabetic patients, up to 100 test strips and up to 100 lancets every 3 months.
- For insulin dependent diabetics (injections or infusion pumps), up to 400 test strips and up to 400 lancets every 3 months.
- Higher amounts are allowed and covered if justified with clinical documentation by treating provider.



# Supplies and Accessories for Glucose Monitoring requirements:

1. Coverage criteria for glucose monitor is met,
2. The treating physician has seen the patient and addressed diabetes care within 1 year prior to dispensing the supplies, and
3. During that visit, documentation of patient's type of therapy prescribed (e.g. oral, insulin injections), and if insulin, # of daily injections,
4. The Beneficiary has nearly exhausted the supply of items previously dispensed.



# In Summary

---

- Medicare has the authority to cover home glucose monitoring devices,
- CMS has both NCDs as well as LCDs governing the use of home glucose monitoring,