



April 13, 2016

Sylvia M. Burwell, Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

RE: Concerns with prescribing diabetic testing supplies and their efficacy

Dear Secretary Burwell,

I am writing on behalf of the American Academy of Family Physicians (AAFP), which represents 120,900 physicians and medical students across the country, to seek relief from the burdensome Medicare requirements associated with the prescribing of diabetic supplies and to discuss growing concerns with the efficacy of unbranded diabetic testing supplies.

Diabetes is one of the most common, costly, and deadliest of chronic illnesses, and patients with diabetes need accurate diabetic testing supplies to adequately care for themselves. Difficulty in obtaining appropriate diabetic supplies can actually lead to poorer health outcomes for patients.

Decrease Prescribing Burdens

The AAFP calls on CMS to simplify the current Medicare rules surrounding prescription of diabetic supplies so that patients and physicians would benefit without compromising the integrity of the Medicare program. Family physicians simply want to be able to prescribe efficiently and effectively what their diabetic patients need to help manage their condition in a way that maintains their health. Unfortunately, the current Medicare rules surrounding prescription of diabetic supplies impede this goal and add no discernible value to the care of such patients. The following documentation is currently required for Medicare glucose testing supplies:

1. Detailed written order, including
 - a. Patient name;
 - b. Detailed description of the items being provided, including:
 - i. The specific frequency of testing (“as needed” or “PRN orders” are not acceptable), and
 - ii. The length of need;
 - c. Treating physician’s signature and date order signed; and

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- d. Start date of the order (only required if the start date is different from the signature date).
2. Documentation that supports the fact that the patient meets all of these five basic coverage criteria:
 - a. The patient has a documented diagnosis of diabetes and is being treated by a physician for the condition.
 - b. The glucose monitor, related accessories, and supplies are ordered by the physician responsible for the patient's diabetes management. The physician maintains records that reflect the care and include the medical necessity for the prescribed frequency of testing.
 - c. The patient or caregiver has successfully completed training or is scheduled to begin training in the use of the glucose monitor and supplies.
 - d. The patient or caregiver is capable of using the test results to assure appropriate blood glucose control.
 - e. The glucose monitor is designed for home use.

Further, if the physician is prescribing blood glucose testing supplies in quantities above the maximum monthly allowances, Medicare requires supporting documentation that meets criteria A-F, as follows:

- A. Coverage criteria 2.a-e (as noted above) are met.
- B. The supplier's files contain a copy of the treating physician's order.
- C. The patient has nearly exhausted the supply of test strips and lancets, or exhausted the useful life of one lens shield cartridge previously dispensed.
- D. The treating physician's order for testing frequency exceeds utilization guidelines, and the medical record documentation supports the need for testing frequency above utilization guidelines (i.e. the physician has documented the specific reason for the higher testing frequency).
- E. The treating physician has seen the patient and evaluated his or her diabetes control within six months of the date of the order for the quantities of supplies exceeding utilization guidelines.
- F. The physician/supplier's records contain a copy of the patient's testing log or other physician records, such as a narrative statement, that adequately documents the patient's testing frequency.

If the patient regularly uses quantities of supplies that exceed the utilization guidelines, new documentation to support these supply quantities must be obtained every six months. We understand that glucose testing and other diabetic supplies are an identified area of claims processing errors within the Medicare program and that physicians have a role to play in fraud prevention. However, the related requirements have become overly burdensome with little to no value added to the actual care of the diabetic patient.

Ideally, it should be acceptable for a physician to write for "diabetic supplies," which would encompass syringes, needles, test strips, lancets, glucose testing machine, etc., with only a need to provide a diagnosis and an indication such a prescription is good for the patient's lifetime. When treating diabetes, diabetic supplies are part of data gathering and medication delivery regardless of the brand. Clinical relevance is the medication and frequency of use/testing. As long as physicians are clear in describing the frequency, they should be able to write the generic terms for these items without having the hassle of knowing exactly which one is on the formulary of a particular health plan such as Medicare.

In practice, the documentation requirements are onerous to our members and consume valuable physician time that is not germane to the actual care of the patient. Clearly, the documentation requirements add administrative cost to both Medicare and the family physician and diminish the opportunity for better diabetic care. Family physicians' time is better spent helping patients manage their diabetes, not providing additional paperwork to justify what the patient needs.

In recent years, CMS has shown a willingness to reconsider its current rules and to seek opportunities for simplification that benefit patients and providers without compromising the integrity of the Medicare program. We believe that there is an opportunity to do that with the rules surrounding prescription of diabetic supplies, and we expect that by streamlining this process, patients will have better outcomes at a lower cost to the program.

Stopping Unsolicited Requests

The AAFP urges HHS to take actions to halt the practice by some durable medical equipment (DME) suppliers of directly contacting individuals about the purchase of supplies that the individual does not want and that a physician did not prescribe. These suppliers encourage patients to request potentially unneeded equipment from their physicians. Meanwhile these suppliers also repeatedly contact physicians with unsolicited requests to get their items prescribed. The AAFP opposes these unsolicited requests unless such equipment has been prescribed and discussed between the physician and the patient.

Efficacy of Unbranded Diabetic Testing Supplies

The AAFP is concerned with the safety of our patients who obtain unbranded or inaccurate glucose diabetes testing supplies from the mail-order diabetes suppliers under the CMS competitive bidding process. We have heard from members that some durable medical equipment (DME) suppliers have switched from using branded to unbranded meters and glucose strips as a way to increase their profits. The AAFP therefore calls for:

- The U.S. Food and Drug Administration (FDA) to better enforce existing regulations during the approval and the post-marketing surveillance processes;
- The FDA to have the authority to immediately remove inaccurate strips from the market.
- The FDA and CMS to better communicate about the quality and safety of blood glucose monitoring systems sold under the CMS competitive bidding program.

Taking these steps would help prevent potential beneficiary disruption to the care plan for blood glucose testing. We appreciate the opportunity to discuss these concerns. If you have any questions, please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or rbennett@aafp.org.

Sincerely,



Robert L. Wergin, MD, FAAFP
Board Chair