Program Memorandum Carriers

Department of Health and Human Services (DHHS) HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal B-01-40 Date: JUNE 15, 2001

CHANGE REQUEST 1455

SUBJECT: Expanded Coverage of Diabetes Outpatient Self-Management Training (This change request replaces the draft change request 1423 and includes full implementation instructions.)

The purpose of this Program Memorandum (PM) is to inform carriers and durable medical equipment regional carriers (DMERCS) of the coding and payment requirements based on the final rule implementing the expansion of the diabetes outpatient self-management training benefit (65 FR83130,12/29/2000). The effective date of the final rule is February 27, 2001. This PM includes instructions for carriers to follow for enrolling suppliers of durable medical equipment, prosthetics, orthotics or supplies (DMEPOS) for payment for diabetes training services provided to beneficiaries. This PM also contains additional claims processing information with respect to this benefit as described in the final rule.

Background

Section 4105 of the Balanced Budget Act of 1997 permits Medicare coverage of diabetes outpatient self-management training services when these services are furnished by a certified provider who meets certain quality standards. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in the self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the skills for self-management of their diabetes.

Diabetes outpatient self-management services may be covered by Medicare only if the physician or qualified non-physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed by sending an original referral form to the diabetes education program. The referral for education must be done under a comprehensive plan of care related to the beneficiary's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) in the management of the beneficiary's conditions. The specific coverage requirements are addressed below and can be found at 42 CFR 410.140 - 146.

All certified providers that provide other individual items or services on a fee for service basis and that meet quality standards can receive reimbursement for diabetes training.. (As with all fee forservice benefits, M+COs may only be reimbursed for diabetes outpatient self-management training if they meet all the requirements and are billing for services provided to beneficiaries not enrolled in a Medicare+Choice plan.) Certified providers must be currently receiving payment for other Medicare services.

The statute states that a 'certified provider' is a physician or other individual or entity designated by the Secretary that, in addition to providing diabetes outpatient self-management services, provides other items or services for which payment may be made under title XVIII such as medical services or durable medical equipment, and meets certain quality standards. HCFA is designating all providers and suppliers that bill Medicare for other individual services such as hospital outpatient departments, renal dialysis facilities, and durable medical equipment suppliers as certified.

General Conditions of Coverage

The training must be ordered by the physician or qualified nonphysician practitioner treating the beneficiary's diabetes. The order must be part of a comprehensive plan of care established by the physician or qualified nonphysician practitioner and describe the training that the referring physician or qualified non-physician practitioner is ordering and/or any special concerns such as the need for general training, or insulin-dependence. The referring physician or qualified non-physician practitioner must maintain the plan of care in the beneficiary's medical record and documentation substantiating the need for training on an individual basis when group training is typically covered, if so ordered. The order must also include a statement signed by the physician that the service is needed. The provider of the service must maintain documentation in file that includes the original order from the physician and any special conditions noted by the physician.

When the training under the order is changed, the change must be signed by the physician or qualified nonphysician practitioner treating the beneficiary and maintained in the beneficiary's file at the provider of the training.

Outpatient diabetes self-management training is classified as initial or follow-up training. When a beneficiary has not yet received initial training meeting the quality standards of this section, they are eligible to receive 10 hours of initial training within a continuous 12-month period. The 12-month period does not need to be on a calendar-year basis. Nine hours of initial training must be provided in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries unless the ordering physician or nonphysician practitioner certifies that a special condition exists that makes it impossible for the beneficiary to attend a group training session. Those conditions include but are not limited to:

- No group session is available within 2 months of the date the training is ordered.
- The beneficiary has special needs resulting from problems with hearing, vision, or language limitations.

For all beneficiaries, one hour of initial training may be provided on an individual basis for the purpose of conducting an individual assessment and providing specialized training. The 10 hours of initial training may be provided in any combination of half-hour increments within the 12-month period and less than 10 hours of initial training may be used in the 12-month period if, for example, the beneficiary does not attend all of the sessions or the physician does not order the full training program.

Medicare also covers 2 hours of follow-up training each year starting with the calendar year following the year in which the beneficiary completes the initial training. The 2-hours of training may be given in any combination of half-hour increments within each calendar year on either an individual or group basis without the certification of the ordering physician or nonphysician practitioner that special conditions exist.

Beneficiaries Eligible for Coverage

Medicare covers initial training for beneficiaries who have the following medical conditions present prior to the physician's or nonphysician practitioner's order for the training.

- New onset diabetes.
- Inadequate glycemic control as evidenced by a glycosylated hemoglobin (HBA1c) level of 8.5 percent or more on two consecutive HbA1c determinations 3 or more months apart in the year before the beneficiary begins receiving training.
- A change in treatment regimen from diet control to oral diabetes medication, or from oral diabetes medication to insulin.

- High risk for complications based on inadequate glycemic control (documented acute episodes of sever hypoglycemia or acute severe hyperglycemia occurring in the past year during which the beneficiary needed emergency room visits or hospitalization).
- High risk based on at least one of the following:
 - Lack of feeling in the foot or other foot complications such as foot ulcers, deformities, or amputation.
 - Pre-proliferative or proliferative retinopathy or prior laser treatment of the eye.
 - Kidney complications related to diabetes, when manifested by albuminuria, without other cause, or elevated creatinine.

The condition requiring training must be documented in the beneficiary's medical record maintained by the referring physician or qualified nonphysician practitioner.

Beneficiaries are eligible to receive follow-up training each calendar year following the year in which they have been certified as requiring initial training.

NOTE: Beneficiaries with diabetes, becoming newly eligible for Medicare, can receive diabetes outpatient self-management training in this program.

Provider/Supplier Eligibility to Provide the Training

The provider/supplier billing for the service must be eligible to provide and bill for other individual Medicare services. The types of providers/suppliers include but are not limited to, physicians, durable medical equipment suppliers, renal dialysis facilities, and hospital outpatient departments.

Quality Standards

The outpatient diabetes self-management training program must be accredited as meeting approved quality standards, except during the first 18-months after February 27, 2001, HCFA will accept recognition of the American Diabetes Association (ADA) as meeting the National Standards for Diabetes Self-Management Training Programs. Programs without ADA recognition or accreditation by a HCFA-approved national accreditation organization are not covered after February 27, 2001.

Enrollment of DMEPOS Suppliers

DMEPOS suppliers are reimbursed for diabetes training through local carriers. In order to file claims for diabetes education, a DMEPOS supplier must be enrolled in the Medicare program with the National Supplier Clearinghouse (NSC). The supplier must also meet the quality standards of aHCFA-approved national accreditation organization. During the first 18 months after the effective date of the final rule (February 27, 2001), organizations may meet these quality standards by submitting documentation of recognition by the American Diabetes Association (ADA) as having met the National Standards for Diabetes Self-Management Education Programs as published inDiabetes Care, Volume 23 Number 5.

DMERCS are required to include the following language in their newsletters/bulletins and on web sites to inform DMEPOS suppliers how to qualify to be reimbursed for providing this service.

"Diabetes Outpatient Self-Management Training is now a covered Medicare service for a wider variety of Medicare providers/suppliers. To qualify for payment under this benefit, the supplier of durable-medical equipment, prosthetics, orthotics, or supplies (DMEPOS) must first be enrolled in the Medicare program and currently eligible to receive reimbursement for Medicare covered

services. All suppliers must meet the American Diabetes Association's (the successor to the National Diabetes Advisory Board) National Standards for Diabetes Self-Management Education Programs that was published in Diabetes Care, Volume 23 Number 5. If you are a DMEPOS supplier that wants to receive Medicare reimbursement for diabetes education, and meet the above qualification, you should contact the local Medicare carrier who services your area. See http://www.hcfa.gov/Medicare/incardir.htm to determine the local carrier for your area. The carrier will require you to submit a completed Form HCFA-855, along with your ADA recognition certificate. After it has been determined that you meet the quality standards, you will be sent your billing number. Once you have received your billing, (PIN) number, you can begin receiving reimbursement for this service."

Carriers, when you receive an application from a DMEPOS supplier, you must contact the National Supplier Clearinghouse (NSC) to verify that the applicant is currently enrolled and eligible to receive direct payment from the Medicare program. Contact the NSC via e-mail over secured lines at Medicare.nsc@palmettogba.com. In your request for this information, provide your E-mail address, the carrier identification, supplier's name, NSC number of the applicant, its tax identification number, and all owners listed on the Form HCFA 855. The NSC will confirm the information within 3 working days of receiving the request. The entity or organization that enrolls with the carrier must be the same as the one that is enrolled as a DMEPOS supplier. The owners have to be the same and the tax ID has to be the same. If they are not, reject the application giving the reason for your disapproval and record it as a denial. Once you verify that it is an approved supplier, enrolled with the NSC, and has the same identification information, process the application in accordance with the Medicare Carriers Manual, Part 4, §1030. When you notify the applicant of its PIN, you must also provide the PIN to NSC via e-mail over secured lines along with the NSC number of the applicant. Enroll the applicant using specialty code 87 to allow claims to be processed in most carrier systems. If you have coding that will require changes in your system before claims can be processed, you must begin making changes immediately.

If a DMEPOS supplier has its billing privileges deactivated or revoked by the NSC, the billing number of the DMEPOS supplier at the carriers must also be deactivated. The NSC will notify carriers of any DMEPOS supplier with an approved diabetes education program if its billing privileges are deactivated or revoked by the NSC.

NOTE: The enrollment process should begin as soon as possible after the receipt of this instruction.

Enrollment of Entities Other Than DMEPOS

Any qualified provider (other than DMEPOS) currently enrolled with you that wishes to be reimbursed for this new service, must provide you with a Form HCFA-855, along with the ADA recognition certificate. Local contractors must notify all current suppliers enrolled with them that if they wish to be reimbursed for the service, they must file a Form HCFA-855. For those providers/suppliers who are already receiving Medicare reimbursement for this service, and have submitted their ADA recognition certificate, continue to process claims without the Form HCFA-855 and notify them that they should submit the Form HCFA-855. Use the supplier's existing specialty code. (Code 87 should be used only for DMEPOS suppliers.)

NOTE: All providers and suppliers including DMEPOS suppliers are eligible to receive retro-active payment for this service back to the later of February 27, 2001, or the date of recognition by the ADA.

HCPCS Coding and Diabetes Training Hours

No new HCPCs codes have been created for diabetes outpatient self-management training under the final rule. The coding descriptions have been revised. Deductible and coinsurance apply.

G0108—Diabetes outpatient self-management training services, individual, per 30 minutes.

G0109—Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes.

As stated above, under the final rule for diabetes education, beneficiaries with diabetes can initially receive one hour of individual training and/or assessment and nine hours of group training. This can be followed by 2 hours of follow-up training in each subsequent calendar year. Nine hours of initial training must be provided in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries.

EXCEPTION: Medicare covers training on an individual basis for a Medicare beneficiary under any of the following conditions. These conditions include, but are not limited to:

- No group session is available within 2 months of the date the training is ordered;
- The beneficiary has special needs resulting from problems with hearing, vision or language limitations, or other such special conditions as identified by the treating physician or non-physician practitioner; or
- Additional insulin instruction is needed.

The need for individual training should be identified by the physician or non-physician practitioner in the referral.

NOTE: If individual training has been provided to a Medicare beneficiary and subsequently you determine that training should have been provided in a group, downcoding the reimbursement from individual to the group level and educating the provider would be appropriate actions instead of denying the service as billed.

For all beneficiaries, 1 hour of initial training may be provided on an individual basis for the purpose of conducting an individual assessment and/or providing specialized training such as insulin instruction. For example, the 1 hour could be ½ hour of individual assessment and ½ hour of insulin instruction.

Medicare also covers 2 hours of follow-up training each year starting with the calendar year following the year in which the beneficiary completes the initial training. The 2 hours of training may be given in any combination of half-hour increments within each calendar year on either an individual or group basis without the certification of the ordering physician or non physician practitioner that special conditions exist.

Provide information on diabetes outpatient self-management training services in your next scheduled provider bulletin/newsletter and place on you web site. Providers need to be educated on the amount of hours of diabetes training both initial and follow up that Medicare allows and that the diabetes training can be billed in various combinations, i.e., $\frac{1}{2}$ hour, one hour, or $2\frac{1}{2}$ hours etc. of training depending on the length of time of the various sessions with the beneficiary. The provider must be educated on using the units field on the claim form. In addition, educate physicians on the beneficiary eligibility requirements.

General Payment Conditions

To receive reimbursement, providers/suppliers must meet the following conditions:

• Payment may only be made for diabetes training services actually attended by the beneficiary and documented on attendance sheets, and a referral from the treating physician or non-physician practitioner must be part of the patient's file maintained by the provider of the diabetes outpatient self-management training. Periodic post-payment review is appropriate for determining that these requirements are met.

- Bills for payment for diabetes training from DMEPOS suppliers must be submitted to and processed by local carriers.
- If billing for initial diabetes training, the beneficiary must not have already received initial training from an ADA recognized program.
- For initial or follow-up diabetes training, the beneficiary must not be receiving services as an inpatient in a hospital, skilled nursing facility, under a hospice or home health benefit, or be a resident of a nursing home.
- For initial or follow-up diabetes training, the beneficiary must not be receiving services as an outpatient in a rural health clinic or a federally qualified health center.

Questions and Answers (Qs & As)

Attached are some general questions and answers that may be helpful.

Contact persons for this PM for enrollment are Patti Snyder at (410) 786-5991 and Chip Gillespie at (410) 786-5996. For Part B carrier claims processing questions, contact Pat Gill at (410) 786-1297. For coverage questions, contact Mary Stojak (410) 786-6939.

This instruction should be implemented within your current operating budget.

Effective date of this PM is February 27, 2001.

Implementation date of this PM is July 17, 2001.

This PM may be discarded after May 31, 2002.

Attachment

Questions and Answers

Q1. Would DMEPOS suppliers have to complete a Form HCFA-855 the same as any other organization?

Yes, they would be required to complete an application the same as any other organization.

Q2. What should be the effective date of the suppliers' provider number? Should carriers use the effective date from the American Diabetes Association (ADA) certificate as the suppliers' effective date on the provider file?

The carrier must make sure that the DMEPOS supplier has a current billing number from the National Supplier Clearinghouse (NSC) and its ADA certificate. Without meeting either one of these criteria, the carrier cannot establish an effective date. Once the DMEPOS supplier meets both of these criteria, and completes an enrollment application that is approved, the effective date of the enrollment of the DMEPOS supplier at the carrier is the later of February 27, 2001, the date of ADA recognition or the effective date of enrollment of the provider as a DMEPOS supplier. For example, if a supplier received ADA certification on March 3 but did not become a DMEPOS supplier until March 15, after the supplier receives a provider number from the local carrier, the effective date of that new provider number would be March 15.

Q3. Will carriers be allowed to accept certificates from an entity other than the ADA?

Currently, only ADA certificates are recognized by Medicare for providers meeting quality standards. However, HCFA will evaluate other organizations that may meet the quality standards. A list of possible organizations will be released in the future.

Q4. Where on the Form HCFA-855 should the NSC number be entered?

On the current form it should be listed in section 1. "Applicant Identification", D1. The form requires the supplier to provide all current Medicare identification numbers.

Q5. If carriers are required to deny the supplier's application based on information received from the NSC, who would be responsible for resolving the issue, the carrier or NSC? Are carriers allowed to refer the supplier back to NSC to resolve the issue?

The only information that the carrier is receiving from the NSC is a confirmation that the organization has a current DMEPOS number. If during the enrollment process, a carrier determines that the ADA certificate was not submitted, it would be the carrier's responsibility to deny the application. Also, if the carrier determines that the supplier has been sanctioned, the carrier would deny the application but should also inform the NSC that this organization has been sanctioned. At which time the NSC should take steps to revoke its DMEPOS supplier number, (if it has not already done so). These issues must be evaluated on a case-by-case basis.

Q6. If carriers need to deny an application from the supplier, is there a particular denial message that should be used? For example, are carriers allowed to provide information received from the NSC to the supplier to document the reason for the denial?

The reasons for the denial are the same for any organization. If the organization has not obtained a DMEPOS number or ADA certificate, the carrier would deny the application based on Denial 4 (The applicant does not meet HCFA regulatory requirements for the specialty.) In the denial letter, you would list the regulatory citation that states that the applicant must have a DMEPOS supplier number and a certificate in order to bill for this service.

Q7. Can a beneficiary who is not newly diagnosed with diabetes (i.e., has had diabetes for a number of years) qualify for this benefit?

As long as a beneficiary has a referral from the treating physician or non-physician practitioner for diabetes training and the beneficiary has not had the 10 hours of initial training under G0108 or G0109, the beneficiary would qualify. Thereafter, the beneficiary is allowed 2 hours of follow-up training each year.