Program Memorandum Intermediaries/Carriers

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

Transmittal AB-00-108 **Date: DECEMBER 1 , 2000**

CHANGE REQUEST 1362

SUBJECT: Glucose Monitoring

This Program Memorandum (PM) reviews Medicare coverage and payment policy for glucose monitoring for a patient whose stay is not covered by Medicare Part A but who is eligible for services under Medicare Part B. During the past year, program integrity efforts have identified a significant increase in the number of claims submitted to intermediaries for glucose monitoring using a home-use device. We also have received inquiries from contractors, providers, and beneficiaries reporting encouragement of home-use glucose monitoring devices for more patients, more often and in more health care settings, specifically nursing homes and home health agencies, than in the past so that a review of the service is warranted. This PM incorporates and supplements material previously issued in a prior PM, AB-00-99, CR 1407, "Glucose Monitoring Note." It provides instructions on payment that supplement AB-00-109, CR 1377, "2001 Clinical Laboratory Fee Schedule."

Glucose monitoring measures blood sugar levels for the purpose of managing insulin therapy (shots, medication, and diet). The service often involves the use of an inexpensive hand-held device to evaluate a small sample of the patient's blood acquired through a finger stick. The device measures blood glucose values immediately on a digital display so as to permit self-administration in the home. If a physician separately orders the performance of a glucose monitoring service for a patient who can not self-administer, clinical staff generally will administer a glucose monitoring service along with their other duties.[1] Administration of the service several times a day is common in order to maintain tight control of glucose to prevent heart disease, blindness, and other complications of diabetes. This device is on the list of instruments that can be administered by providers registered under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including providers registered with only a certificate of waiver.[2]

[1] Medicare Part B may pay for a glucose monitoring device and related disposable supplies under its durable medical equipment benefit if the equipment is used in the home or in an institution that is used as a home. A hospital or SNF is not considered a home under this benefit. §1861(h) of the Social Security Act. §42 Code of Federal Regulations (CFR) 410.38.

[2] Section 353 of the Public Health Service Act codified at §42 CFR 493. The most recent PM identifying CLIA-waived instruments under CLIA is PM AB-00-61, dated July 2000.

The Current Procedural Terminology (CPT) code that most often describes the service is 82962 *Glucose, blood by glucose monitoring device(s) cleared by the FDA (Food and Drug Administration) specifically for home use.*[3] Section 1862(a)(1)(A) of the Social Security Act requires the service to be reasonable and necessary for diagnosis and treatment in order to be covered by Medicare. Sections 42 CFR 410.32 and 411.15 specify that for a laboratory service to be reasonable and necessary, it must not only be ordered by the physician but the ordering physician must also use the result in the management of the beneficiary's specific medical problem. Implicitly, the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care; this includes the physician's order for another laboratory service. Compliance program guidance for laboratory services sets forth conditions under which a physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service. A standing order is not usually acceptable documentation for a covered laboratory service. A national coverage policy on blood glucose monitoring has not been finalized. Carriers and intermediaries have been responsible for making coverage determinations and many have developed a local coverage policy to assist with payment determinations. However, during the past two years, experts involved in the clinical laboratory negotiated rulemaking process determined that blood glucose laboratory testing warrants a national coverage policy. These experts reached a consensus on a proposed national coverage policy, which was described in the March 10, 2000 *Federal Register*, volume 65, number 48, pages 13127-13131. This document can be obtained at the web site http://www.access.gpo.gov Intermediaries and carriers can refer to coverage policy developments at the web site http://www.hcfa.gov/quality/docs/labsd-d.htm Contractors should review their local coverage policy for glucose testing in light of the proposed national coverage policy in order to prepare for the adoption of a national coverage policy. Also, contractors should review their local coverage policy to clarify, if necessary, that a glucose monitoring laboratory service must be performed in accordance with laboratory service coverage criteria including the order and clear use of a laboratory result prior to a similar subsequent laboratory order to qualify for separate payment under the Medicare laboratory benefit.

If a glucose monitoring service is administered for a patient who is hospitalized and eligible for Medicare Part B but who is not in a Part A covered hospital stay, a Form HCFA-1450 is submitted to the intermediary using type of bill (TOB) 12x and revenue code 30x and is paid under the clinical laboratory fee schedule.[4] If a patient is eligible for Part B, but is not in a Part A covered nursing home stay, §541 of the Skilled Nursing Facility (SNF) Manual explains that a laboratory service is separately payable either on a reasonable cost basis (if the patient is in a certified bed) or under the clinical laboratory fee schedule (if the patient is in a non-certified bed). If a Part B only patient resides in a nursing home certified bed, a Uniform Bill-92 (UB92) using TOB 22x and revenue code 30x is submitted to the intermediary. The laboratory cost center of the cost report must reflect the corresponding glucose monitoring costs and charges even when the provider is registered for laboratory testing with only a certificate of waiver from CLIA. The beneficiary is liable for the deductible and coinsurance. If a Part B only patient resides in a non-certified bed, payment is made under the clinical laboratory fee schedule. Until further instructions regarding Part B only patient are implemented, a UB92 is submitted using TOB

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[3] CPT code 82962 represents a method when whole blood is obtained (usually by finger stick device) and assayed by glucose oxidase, hexaokinase, or electrochemical methods and spectrophotometry using a small portable device designed for home blood glucose monitoring use. The device(s) are now also used in physician offices, nursing homes, hospitals, and during home health visits. CPT code 82947-QW describes instruments that measure quantitative glucose levels but are not cleared by the FDA for home glucose monitoring. Development of hand-held device(s) using a noninvasive biosensor or other micromethod for more rapid glucose monitoring is underway; however, to date these devices are not categorized by FDA as CLIA-waived tests. The term *continuous glucose monitoring* does not refer to CLIA-waived test but to a procedure that implants needle probes into the patient and provides measurements to a computer screen. This lengthy procedure, reviewing and interpreting the measurements is performed by a physician or appropriately licensed practitioner similar to a 24-hour electrocardiographic monitoring and payment is made under the physician fee schedule.

[4] Medicare Intermediary Manual, §§3604 and 3628.

23x and revenue code 30x to the intermediary when the SNF provides a laboratory service either directly or under arrangement with an outside laboratory. The beneficiary is not liable for a deductible or coinsurance. Nursing and physician duties, include observing, ordering, administering and interpreting the patient's health status are paid predominately under other payment systems, such as the state nursing home payment system or the physician payment system. If home-use glucose monitoring devices are used in the hospital and nursing home settings, a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for separate payment under the Medicare laboratory benefit. As noted above, for a laboratory service to be reasonable and necessary, it must be ordered by the physician, the ordering physician must use the result in the management of the beneficiary's specific medical problem, and the laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care.When a glucose monitoring service meets the criteria to be a covered laboratory service for a Part B only patient, regardless of whether the nursing home patient resides in a certified or non-certified bed, payment must be made. Denial of payment for a Part B covered laboratory service cannot be made on the basis that the service is routine care. Under Medicare, routine care determinations are applicable only for Part A nursing home services.

A covered home health service requires a home health employee to supervise, assist, record, and report on the patient's daily/weekly functional and medical activities. For some patients, their daily/weekly activities include glucose monitoring, often self administered or administered with the help of a care giver who is not an employee of or affiliated with the home health provider. If the patient maintains a home-use glucose monitoring device, a home health employee's supervision and assistance of a glucose monitoring service is encompassed in the payment for the home health service. However, if a physician separately orders the employee to administer a glucose monitoring service for a Part B only patient who does not administer daily/weekly glucose monitoring and does not maintain a glucose monitoring device, the glucose monitoring service is not encompassed in the home health benefit. [5] If a home health agency receives a supplier number, a Form HCFA-1500 may be submitted to the carrier in accordance with physician and supplier billing instructions for filing Part B claims at MCM 3001.[6] Corresponding laboratory costs and charges must be reported on the cost report even when the home health agency is registered for CLIA testing with only a certificate of waiver. Sections 42 CFR 410.32 and 411.15 apply equally to a laboratory service in the home health setting. Therefore, if a home health employee carries and assists with the use of a home-use glucose monitoring device during a home health visit, a glucose monitoring service must be performed in accordance with laboratory coverage criteria to qualify for separate payment under the Medicare laboratory benefit. The blood glucose monitoring service must not only be ordered by the physician but the ordering physician must also receive and use the order's result in the management of a specific medical problem. The laboratory result must be reported to the physician promptly in order for the physician to use the result and instruct continuation or modification of patient care. Compliance program guidance for laboratory services sets forth the conditions under which a physician's order for a repeat laboratory service can qualify as an order for another covered laboratory service. Program integrity efforts should review for medical necessity a claim for a glucose monitoring laboratory service received at the same time as a claim for glucose test strips indicating the patient is maintaining a home-use device for self monitoring.

At certain times a physician may also order a separate quantitative blood glucose test to enhance a physician evaluation and management service for the patient. A specimen collection of venous blood may be sent to an independent laboratory for testing and the laboratory reports the result to the provider and the ordering physician. This is a separate laboratory service billed with a different code than a home-use glucose monitoring service and is also paid under the laboratory fee schedule. Instructions regarding the clinical diagnostic laboratory fee schedule are at §3628 of the Medicare Intermediary Manual and §5114 of the Medicare Carriers Manual.

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[5] §1861(m) of the Act governs the extent of Medicare home health services that may be provided to eligible beneficiaries by or under arrangements made by a participating home health agency (HHA).

[6] Home Health Manual, §465.

As stated above, the CPT code that most often describes the glucose monitoring service using a laboratory testing device designed for home use is 82962 *Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use.* This CPT code has been included in the clinical laboratory fee schedule since January 1, 1993. The payment amount established for this CPT code was mapped from a previously existing code representing a quantitative glucose test using a device that is not cleared by the FDA for home use. Since that time, the payment amount has been subject to the prescribed updates for the clinical laboratory fee schedule.[7] During the past year, we have reviewed the test and have determined that administering a glucose monitoring service with a home-use device is substantially different than a quantitative glucose test and therefore our earlier mapping of the CPT code 82962 for a device approved for home use to a quantitative blood glucose test was erroneous.

In order to allow Medicare to base the laboratory fee schedule payment amount for CPT code 82962 code on the best available data nationwide, carriers must gap-fill CPT code 82962 for the year 2001. To establish an appropriate gap-fill amount for 2001, carriers should receive assistance from their corresponding intermediaries to consider the cost and the charge for the service as it is administered for Part B patients in a variety of settings such as hospitals, home health agencies, nursing homes, and physician offices. Gap-filling should consider, as appropriate, the costs of professional and clerical labor, device amortization, supplies, and overhead for this service. While these costs can be difficult to distinguish from other nursing and clinical services provided to the patient, the gap-fill amount must be established to carefully reflect only the Medicare laboratory service. Carriers should also evaluate any information that may be submitted to the carrier by other interested parties in establishing the gap-fill amount. In accordance with instructions for laboratory gap-fill codes in PM AB-00-109, CR 1377, "2001 Clinical Laboratory Fee Schedule," the gap-fill amount is established by the carrier on a flow basis as claims are received for the code. For CPT code 82962, the local fee amount field and the National Limitation Amount field are zero-filled in the year 2001 clinical laboratory fee schedule date file that was issued to carriers on November 1, 2000, and to intermediaries on November 21, 2000. Carriers should establish a gap-fill amount not later that March 31, 2001, communicate the amount to the corresponding intermediary as necessary, and report the amount to their Regional Office by May 4, 2001. The gap-fill amounts establish the local laboratory fee schedule amounts for CPT code 82962 and will be used to develop the year 2002 national limitation amount for this code.

NOTE: Claims for dates of service prior to the effective date of this PM should be processed in accordance with local medical review policy in effect on the date of service. Medicare Intermediary Manual §3600.2 explains that a claim must be filed on or before December 31 of the calendar year following the year in which the service was furnished. Do not search for previously adjudicated claims, however, timely filed claims may be adjusted if brought to your attention.

The effective date for this PM is January 1, 2001.

The implementation date for this PM is January 1, 2001.

These instructions should be implemented within your current operating budget.

For questions regarding this document, contact Anita Greenberg on (410) 786-4601.

This PM may be discarded after December 31, 2001.

[7] §1833(h) of the Act; Medicare Carriers Manual, §5114.1C.