

commenter will be able to respond to that solicitation and submit these codes, as well as any additional services they believe need to be reviewed to ensure they are appropriately valued.

Stereotactic Radiosurgery and Stereotactic Radiotherapy

Comment: Two commenters requested that HCPCS codes G0173 and G0251, which are used for reporting stereotactic radiotherapy and stereotactic radiosurgery under the hospital outpatient prospective payment system, be activated for payment under the physician fee schedule.

Response: We are reluctant to establish payment for these services under the physician fee schedule at this time absent specific information on freestanding centers providing this service. We would welcome information and data from these commenters, and other individuals and providers, on the provision of these services in freestanding centers so that we can fully evaluate this issue.

Creation of G Codes

Comment: The AMA and several specialty organizations expressed concern about the establishment of the numerous G codes that were contained in the proposed rule. The commenters state that continual development of G codes, without consultation with the CPT Editorial Panel, the RUC or the physician community undermines the annual review process that CMS has established in the final rule. Further, the commenters argue that the establishment of G Codes undermines the requirements of the Health Insurance Portability and Accountability Act (HIPAA) for coding standardization and an open process for establishing codes.

Response: As we have stated in previous rulemaking, it is sometimes necessary to develop G codes to accommodate changes in legislation, regulation, coverage, and payment policy. We appreciate the input of the medical community and to the extent possible, will work with the CPT Editorial Panel, the RUC and the physician community prior to establishment of these codes.

Pain Management

Comment: The American Society of Interventional Pain Management commented on the differences in payment allowances for various pain management services and other non-pain management services furnished in conjunction with pain management services in various settings, including

the physician's office, the OPD and the ASC.

Response: In accordance with the law, we have established payment rates for office-based procedures, using the non-facility practice expense relative value units. However, the office does not represent a practice site where these services are usually performed.

Medicare payment under the physician fee schedule for the physician work is the same in all practice settings. However, the practice expenses are reimbursed differently depending on the practice site. Practice expenses associated with procedures performed in the outpatient departments (OPDs) or ambulatory surgical centers (ASCs) are paid under the OPD or ASC payment system respectively. Practice expenses associated with procedures performed in the physician's office are paid through the physician fee schedule payment system.

III. Other Issues

A. Definition of Diabetes for Diabetes Self-Management Training

In the August 15, 2003 rule we proposed to adopt the definition of diabetes used to determine beneficiary eligibility for Medical Nutrition Therapy (MNT) for purposes of coverage for outpatient diabetes self-management training when the beneficiary has a diagnosis of diabetes. Specifically, we stated that the criteria currently set forth at § 410.141(d), would be replaced with definition of diabetes used for medical nutrition therapy at § 410.130 which reads as follows:

Diabetes means diabetes mellitus consisting of two types. Type 1 is an autoimmune disease that destroys the beta cells of the pancreas, leading to insulin deficiency. Type 2 is familial hyperglycemia that occurs primarily in adults but can also occur in children and adolescents. It is caused by an insulin resistance whose etiology is multiple and not totally understood. Gestational diabetes is any degree of glucose intolerance with onset or first recognition during pregnancy. The diagnostic criterion for a diagnosis of diabetes for a fasting glucose intolerance test is greater than or equal to 126 mg/dL.

A technical error in the proposed rule on page 49070, placed the revised eligibility requirements in § 410.141(f). The eligibility requirements will replace those currently in § 410.141(d).

Comment: We received comment noting that the language for the actual regulatory language had the wrong section letter.

Response: As noted above, this was a technical error.

Final Decision: The following language will replace what was in the proposed rule. "Section 410.141 is amended by replacing paragraph (d) to read as follows: § 410.141 Outpatient diabetes self-management training. (d) Beneficiaries who may be covered. Medicare Part B covers outpatient diabetes self-management training for a beneficiary who has been diagnosed with diabetes."

Comment: The comments were very supportive of our efforts to streamline this requirement. Several commenters recommended that the definition of diabetes be revised to include patients who might not be classified as Type 1, Type 2, or gestational diabetes in the definition. Most commenters recommended the use of a fasting glucose test of greater than or equal to 126 mg/dL. One commenter suggested the measurement be taken on two occasions. Most commenters also recommended the addition of a random glucose test of greater than 200 mg/dL, with one commenter adding with symptoms of uncontrolled diabetes. Several commenters suggested use of an abnormal glucose tolerance test (GTT). One commenter also suggested the use of a 2 hour post-glucose challenge of greater than or equal to 200 mg/dL test on two different occasions. The American Association of Clinical Endocrinologists (AACE) also suggested that coverage of medical nutrition therapy be expanded to those with impaired fasting glucose.

Response: The definition of diabetes used in the MNT regulation was based on language found in the 2000 Institute of Medicine report entitled, "The Role of Nutrition in Maintaining Health in the Nation's Elderly. We did not have any other generally recognized definition of diabetes at that time and did not intend to limit our definition of diabetes. Regarding the laboratory tests, the characteristics of the commenters' suggestions are generally the same. The base measurement that is already in our MNT regulation, a fasting glucose of 126 mg/dL, is a common measure. Three commenters also noted the use of 200 mg/dL for a random glucose test. The major variation between the commenters was that one suggested multiple measurements. Also, we note that patients with an impaired fasting glucose level do not necessarily meet any of the popular definitions of diabetes.

Final Decision: We agree that in some ways our proposed definition may not include some patients diagnosed with diabetes. We also agree that our clinical