

TABLE 39—HCPCS CODES REMOVED FROM THE INPATIENT LIST AND THEIR APC ASSIGNMENTS FOR CY 2009—Continued

CY 2009 HCPCS Code	CY 2009 Long descriptor	Final CY 2009 APC	Final CY 2009 SI
21386	Open treatment of orbital floor blowout fracture; periorbital approach.	0256	T
21387	Open treatment of orbital floor blowout fracture; combined approach.	0256	T
27479	Arrest, epiphyseal, any method (eg, epiphysiodesis); combined distal femur proximal tibia and fibula.	0050	T
43420	Closure of esophagostomy or fistula; cervical approach	0254	T
50727	Revision of urinary-cutaneous anastomosis (any type urostomy)	0165	T
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, Stamey, Raz, modified Pereyra).	0202	T
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	0162	T
54332	One stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap.	0181	T
54336	One stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap.	0181	T
54535	Orchiectomy, radical, for tumor; with abdominal exploration	0181	T

**XII. OPSS Nonrecurring Technical and Policy Changes and Clarifications**

*A. Physician Supervision of HOPD Services*

In the CY 2009 OPSS/ASC proposed rule (73 FR 41518), we provided a restatement and clarification of the requirements for physician supervision of diagnostic and therapeutic hospital outpatient services that were set forth in the April 7, 2000 OPSS final rule with comment period (65 FR 18524 through 18526).

As we stated before, section 1861(s)(2)(C) of the Act authorizes payment for diagnostic services that are furnished to a hospital outpatient for the purpose of diagnostic study. We have further defined the requirements for diagnostic services furnished to hospital outpatients, including requirements for physician supervision of diagnostic services, in §§ 410.28 and 410.32 of our regulations. Section 410.28(e) states that Medicare Part B will make payment for diagnostic services furnished at provider-based departments of hospitals “only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii).” In addition, in the April 7, 2000 OPSS final rule with comment period (65 FR 18526), we stated that our model for the requirement was the requirement for physician supervision of diagnostic tests payable under the MPFS that was set forth in the CY 1998 MPFS final rule (62 FR 59048) that was published in the *Federal Register* on October 31, 1998. We also explained with respect to the supervision

requirements for individual diagnostic tests that we intended to instruct hospitals and fiscal intermediaries to use the MPFS as a guide pending issuance of updated requirements. For diagnostic services not listed in the MPFS, we stated that fiscal intermediaries, in consultation with their medical directors, would define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary. We have not subsequently issued new requirements for the physician supervision of diagnostic tests in provider-based departments of hospitals. Instead, we have continued to follow the supervision requirements for individual diagnostic tests as listed in the Physician Fee Schedule Relative Value File. The file is updated quarterly and is available on the CMS Web site at <http://www.cms.hhs.gov/PhysicianFeeSched/>.

Section 1861(s)(2)(B) of the Act authorizes payment for hospital services “incident to physicians” services rendered to outpatients.” We have further defined the requirements for outpatient hospital therapeutic services and supplies “incident to” a physician’s service in § 410.27 of our regulations. More specifically, § 410.27(f) states, “Services furnished at a department of a provider, as defined in § 413.65(a)(2) of this subchapter, that has provider-based status in relation to a hospital under § 413.65 of this subchapter, must be under the direct supervision of a physician. ‘Direct supervision’ means the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the

performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.” This language makes no distinction between on-campus and off-campus provider-based departments.

However, in the preamble of the April 7, 2000 OPSS final rule with comment period (68 FR 18525), we further discussed the requirement for physician supervision and the finalization of the proposed regulation text. In that discussion, we stated that the language of § 410.27(f) “applies to services furnished at an entity that is located off the campus of a hospital that we designate as having provider-based status as a department of a hospital in accordance with § 413.65.” We also stated that, for services furnished in a department of a hospital that is located on the campus of a hospital, “we assume the direct supervision requirement to be met as we explain in section 3112.4(a) of the Intermediary Manual.” We further stated that “we assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital.”

As we explained in the CY 2009 OPSS/ASC proposed rule (73 FR 41519), we restated the existing policy because we were concerned that some stakeholders may have misunderstood our use of the term “assume” in the April 7, 2000 OPSS final rule with comment period, believing that our statement meant that we do not require any supervision in the hospital or in an on-campus provider-based department for therapeutic OPSS services, or that we only require general supervision for those services. This is not the case. It

has been our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital. The expectation that a physician would always be nearby predates the OPSS and is related to the statutory authority for payment of hospital outpatient services—that Medicare makes payment for hospital outpatient services “incident to” the services of physicians in the treatment of patients as described in section 1861(s)(2)(B) of the Act. Longstanding hospital outpatient policy language states that “the services and supplies must be furnished as an integral though incidental part of the physicians’ professional services in the course of treatment of an illness or injury.” We refer readers to § 410.27(a) of our regulations and to the Medicare Benefit Policy Manual, Pub. 100–2, Chapter 6, Section 20.5.1, for further description of hospital outpatient services incident to a physician’s service. The Medicare Benefit Policy Manual also states in Chapter 6, Section 20.5.1, that services and supplies must be furnished on a physician’s order and delivered under physician supervision. However, the manual indicates further that each occasion of a service by a nonphysician does not need to also be the occasion of the actual rendition of a personal professional service by the physician responsible for the care of the patient. Nevertheless, as stipulated in that same section of the manual “during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often enough to assess the course of treatment and the patient’s progress and, where necessary, to change the treatment regimen.”

The expectation that a physician would always be nearby also dates back to a time when inpatient hospital services provided in a single hospital building represented the majority of hospital payments by Medicare. Since that time, advances in medical technology, changes in the patterns of health care delivery, and changes in the organizational structure of hospitals have led to the development of extensive hospital campuses, sometimes spanning several city blocks, as well as off-campus and satellite provider-based campuses at different locations. In the April 7, 2000 OPSS final rule with comment period (65 FR 18525), we described the focus of the direct physician supervision requirement on

off-campus provider-based departments. We will continue to emphasize the physician supervision requirement for off-campus provider-based departments. However, we note that if there were problems with outpatient care in a hospital or in an on-campus provider-based department where direct supervision was not in place (that is, the expectation of direct physician supervision was not met), we would consider that to be a quality concern. We want to ensure that OPSS payment is made for high quality hospital outpatient services provided to beneficiaries in a safe and effective manner and consistent with Medicare requirements.

The definition of direct supervision in § 410.27(f) requires that the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. In the April 7, 2000 OPSS final rule with comment period (65 FR 18525), we define “on the premises of the location” by stating “\* \* \* a physician must be present on the premises of the entity accorded status as a department of the hospital and therefore, immediately available to furnish assistance and direction for as long as patients are being treated at the site.” We also stated that this does not mean that the physician must be physically in the room where a procedure or service is furnished. Although we have not further defined the term “immediately available” for this specific context, the lack of timely physician response to a problem in the HOPD would represent a quality concern from our perspective that hospitals should consider in structuring their provision of services in ways that meet the direct physician supervision requirement for HOPD services.

*Comment:* Several commenters supported the clarification that was provided as a clear and warranted safeguard to individuals being served in on-campus and off-campus departments of hospitals. One commenter was concerned that the restatement and clarification of policy included in the proposed rule would interfere with its ability to provide services in PHP programs and rural CMHCs and stated that “the current policy is appropriate.” Another commenter stated that the clarification of policy would cause hospitals to incur significant costs and would result in physician contractual problems and suggested that CMS conduct a study to better understand outpatient settings and the physician supervision currently available to them.

*Response:* We agree with many of the commenters that appropriate supervision is a key aspect of the delivery of safe and high quality hospital outpatient services to Medicare beneficiaries. As for the concerns of commenters related to hospital staffing and costs, we note that the discussion in the CY 2009 OPSS proposed rule was not a proposed change in policy but was an intended clarification to assist providers who may have misunderstood the policy in the past.

*Comment:* One commenter requested clarification about whether a nonphysician practitioner can provide supervision of “incident to” services in the hospital outpatient setting when the “incident to service” is within the practitioner’s scope of practice.

*Response:* According to section 1861(r) of the Act, “[t]he term ‘physician’”, when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action \* \* \*; (2) a doctor of dental surgery or of dental medicine \* \* \*; (3) a doctor of podiatric medicine \* \* \*; (4) a doctor of optometry \* \* \*; or (5) a chiropractor. In addition, the conditions of participation for hospitals under § 482.12(c)(1)(i) through (c)(1)(vi) of our regulations require that every Medicare patient is under the care of a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, a chiropractor, or a clinical psychologist; each practicing within the extent of the Act, the Code of Federal Regulations, and State law. Further, § 482.12(c)(4) of our regulations requires that a doctor of medicine or osteopathy must be responsible for the care of each Medicare patient with respect to any medical or psychiatric condition that is present on admission or develops during hospitalization and is not specifically within the scope of practice of one of the other practitioners listed in § 482.12(c)(1)(ii) through (c)(1)(vi). Also, section 1861(s)(2)(B) of the Act authorizes payment for hospital services “incident to physicians’” services rendered to outpatients.” We have further defined the requirements for outpatient hospital therapeutic services and supplies “incident to” a physician’s service in § 410.27 of our regulations. Section 410.27(a)(1)(ii) describes payment for hospital outpatient services when they are “an integral though incidental part of a physician’s services.” Also, § 410.27(f) requires that hospital outpatient services provided in

provider-based departments must be under the direct supervision of a physician. Direct supervision is defined in this paragraph: "Direct supervision means that the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed." The language of the statute and regulations does not include other nonphysician practitioners. Therefore, it would not be in accordance with the law and regulations for a nonphysician practitioner to be providing the physician supervision in a provider-based department, even if a nurse practitioner's or a physician assistant's professional service was being billed as a nurse practitioner or a physician assistant service and not a physician service.

*Comment:* One commenter requested clarification of the supervision required for diagnostic services provided in a department of a hospital that is located on the hospital campus.

*Response:* As explained above, § 410.28(e) of our regulations states that Medicare Part B will make payment for diagnostic services furnished at provider-based departments of hospitals "only when the diagnostic services are furnished under the appropriate level of physician supervision specified by CMS in accordance with the definitions in §§ 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii)." We also explained that we have continued to follow the supervision requirements for individual diagnostic tests as listed in the Physician Fee Schedule Relative Value File, updated quarterly and maintained on the CMS Web site as shown above. For diagnostic services not listed in the MPFS, Medicare contractors, in consultation with their medical directors, would define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary. Section 410.28(e) does not distinguish between on-campus and off-campus provider-based departments. Therefore, all provider-based departments providing diagnostic services, whether on or off the hospital's main campus, should follow the requirements of the MPFS or their Medicare contractor, as appropriate, for individual diagnostic services.

*Comment:* Several commenters provided specific hypothetical scenarios related to the location of the physician and asked whether these situations would meet the definition of direct

supervision. One commenter asked for further clarification regarding the supervision level required for specific services.

*Response:* As stated above and in the CY 2009 OPFS/ASC proposed rule, we require direct supervision for therapeutic services provided in the hospital or in provider-based departments of the hospital. For diagnostic services furnished in provider-based departments, the MPFS level of supervision is applied or the Medicare contractor determines the level of supervision required for services not listed in the MPFS. The definition of direct supervision in § 410.27(f) requires that the physician must be present and on the premises of the location and immediately available to furnish assistance and direction throughout the performance of the procedure. In the April 7, 2000 OPFS final rule with comment period (65 FR 18525), we further clarified that "on the premises of the location" means that the physician must be present on the premises of the entity accorded status as a department of the hospital. This means that the physician must be present in the provider-based department. As we explained in the April 7, 2000 final rule with comment period (65 FR 18526), the direct supervision requirement for provider-based departments of hospitals was taken from and parallels the definition of direct supervision in § 410.32(b)(3)(ii), which requires that the physician must be present in the office suite.

*Comment:* A number of commenters requested that CMS change the level of physician supervision listed in the MPFS for CPT code 77421 (Stereoscopic X-Ray guidance for localization of target volume for the delivery of radiation therapy) from personal supervision to direct supervision.

*Response:* Changes to supervision requirements for specific CPT codes under the MPFS are outside of the scope of this CY 2009 OPFS/ASC final rule with comment period. We have referred these comments to the appropriate CMS component and would encourage individuals to work with the appropriate specialty society to bring future requests to CMS' attention.

In summary, direct physician supervision is the standard set forth in the April 7, 2000 OPFS final rule with comment period for supervision of hospital outpatient therapeutic services covered and paid by Medicare in hospitals and provider-based departments of hospitals. While we have emphasized and will continue to emphasize the direct supervision

requirement for off-campus provider-based departments, we do expect direct physician supervision of all hospital outpatient therapeutic services, regardless of their on-campus or off-campus location. Appropriate supervision is a key aspect of the delivery of safe and high quality hospital outpatient services that are paid based on the statutory authority of the OPFS.

#### *B. Reporting of Pathology Services for Prostate Saturation Biopsy*

Prostate saturation biopsy is a technique currently described by Category III CPT code 0137T (Biopsy, prostate, needle, saturation sampling for prostate mapping). Typically this service entails obtaining 40 to 80 core samples from the prostate under general anesthesia. The samples are reviewed by a pathologist, and the pathology service is reported with CPT code 88305 (Level IV—Surgical pathology, gross and microscopic examination). Since the beginning of the OPFS, Medicare has paid for the gross and microscopic pathology examination of prostate biopsy specimens using CPT code 88305. This CPT code has been paid separately under the OPFS and assigned to APC 0343 (Level III Pathology) with status indicator "X" since August 2000. For CY 2008, CPT code 88305 is assigned to APC 0343 with a payment rate of approximately \$33.

In view of the large number of samples that are taken from a single body organ during prostate saturation biopsy and that must undergo gross and microscopic examination by a pathologist, in the CY 2009 OPFS/ASC proposed rule (73 FR 41519 through 41520), we proposed to recognize four new more specific Level II HCPCS G-codes under the CY 2009 OPFS for these pathology services, consistent with the CY 2009 proposal for the MPFS. The proposed HCPCS codes were: GXXX1 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1–20 specimens); GXXX2 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling 21–40 specimens); GXXX3 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41–60 specimens); and GXXX4 (Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens). We stated in the CY 2009 OPFS/ASC proposed rule (73 FR 41520), that we believe that the descriptors of these proposed HCPCS G-codes more specifically reflect the