Program Memorandum Intermediaries

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHANGE REQUEST 2207

SUBJECT: July 2002 Update to the Hospital Outpatient Prospective Payment System (OPPS)

This Program Memorandum (PM) provides new information to the July 2002 update and on the device category codes under the hospital OPPS. Included in this PM is a comprehensive list of current device category codes and their expiration dates, new co-pay information for HCPCS codes J1440 and J1441, new information on the April 2002 outlier logic revision, and a clarification on HCPCS code J9266 under the hospital OPPS.

I. New HCPCS Codes and Their Status Under the Hospital OPPS

The HCPCS codes listed in this section have been added to the Outpatient Code Editor (OCE) effective July 1, 2002. The payment rate associated with each APC can be found in Addendum A of the OPPS Final Rule that was published in a *Federal Register* notice dated March 1, 2002. Addendum A is available on the CMS website for downloading, specifically at http://www.hcfa.gov/regs/hopps/ChangeF4CY2002.htm.

For further information on reporting HCPCS codes G0245 – G0247, consult Transmittal AB-02-042 dated April 1, 2002, and for HCPCS codes G0248 – G0250, consult Transmittal AB-02-064 dated May 2, 2002.

HCPCS	SI	APC	Short Descriptor	Long Descriptor
G0245	V	600	Initial foot exam PTLOPS	Initial physician evaluation of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: 1. the diagnosis of LOPS; 2. a patient history; 3. a physical examination that consists of at least the following elements: (a) Visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, (e) evaluation and recommendation of footwear, and 4. patient education

HCPCS	SI	APC	Short Descriptor	Long Descriptor
G0246	V	600	Follow-up eval of foot PT LOP	Follow-up evaluation of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: 1. a patient history; 2. a physical examination that includes: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, (e) evaluation and recommendation of footwear, and 3. patient education
G0247	T	009	Routine footcare PT w LOPS	Routine foot care of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include if present, at least the following: (1) local care of superficial wounds, (2) debridement of corns and calluses, and (3) trimming and debridement of nails. **NOTE:** Code G0247 must be billed on the same date of service with either G0245 or G0246 in order to be considered for payment.
G0248	S	707	Demonstrate use home INR mon	Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient ability to perform testing
G0249	S	707	Provide test material, equipm	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests
G0250	E	0	MD review interpret of test	Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service)

II. New Co-Pay Information for HCPCS Codes J1440 and J1441

The co-pay for HCPCS codes J1440 and J1441 have been revised effective July 1, 2002. This change applies to dates of service on or after July 1, 2002. The payment rates for these codes have not changed since they were published in Addendum B of the OPPS Final Rule that was published in a *Federal Register* notice dated March 1, 2002. The electronic version of Addendum B may be downloaded from the CMS website, specifically at http://www.hcfa.gov/regs/hopps/ChangeF4CY2002.htm.

HCPCS Code	SI	APC	Short Descriptor	Old Co-Pay	New Co-Pay (Min. Unadj.)
J1440	G	0728	Filgrastim 300 mcg injection	$ 23.00	$ 25.64
J1441	G	7049	Filgrastim 480 mcg injection	$ 36.65	$ 40.85

III. New Pass-Through Device Category Codes

As of July 1, 2002, C-codes C1783, C1888, and C1900 will be reportable under the hospital OPPS. The C-codes and APCs will be in the July 2002 OCE and OPPS PRICER. However, fiscal intermediaries must add these C-codes to the HCPCS file in their internal claims processing systems. Note that these codes are also listed in the comprehensive list in section III.

HCPCS	SI	APC	Short Descriptor	Long Descriptor
C1783	H	1783	Ocular imp, aqueous drain dev	Ocular implant, aqueous drainage assist device
C1888	H	1888	Endovas non-cardiac abl cath	Catheter, ablation, non-cardiac, endovascular (implantable)
C1900	H	1900	Lead, coronary venous	Lead, left ventricular coronary venous system

IV. Comprehensive List of Category Codes Currently in Effect

Section 402(a) of the Benefits Improvement and Protection Act of 2000 (BIPA), which was enacted on December 21, 2000, required the creation of categories for pass-through devices under the hospital OPPS. As a result of BIPA, new category codes were created for pass-through devices that became effective April 1, 2001.

Note that payment for pass-through devices is based on the charge on the individual bill, converted to cost by application of a provider specific cost-to-charge ratio, and subject (in some instances) to a reduction that offsets the cost of similar devices already included in the APC payment rate. Effective April 1, 2002 through December 31, 2002, transitional pass-through payments for devices are subject to a 63.6 percent pro rata reduction. Please refer to Table 1 of the March 1, 2002 Final Rule, pp. 9557-9558, for a list of APCs that have device offsets applied to pass-through payments.

As indicated in section 1833(t)(6) of the Social Security Act, payments for pass-through devices are limited to at least two years but no more than three years.

While the category codes became effective April 1, 2001, many of the item-specific C-codes that were cross-walked in Transmittal A-01-41 and Transmittal A-01-97 to the new category codes were approved for pass-through status before April 1, 2001. In determining the expiration dates for the pass-through device category codes listed in this section, we determined when item specific devices that are described by the categories were paid as pass-through devices prior to the creation of the categories, pursuant to the statute, section 1833(t)(6)(iii)(I). These dates are listed in the column below entitled "Date First Populated." Thus, many of the category codes that were made effective April 1, 2001, will expire on December 31, 2002. This section provides a list of the existing device category codes along with their expected expiration dates.

Although we generally allow a 90-day grace period when we remove a HCPCS code, we will not grant grace periods for these codes because they are transitional pass-through device category codes. Therefore, there will be no grace period allowed for the device category codes listed below which will expire after 12/31/02, and will no longer be reportable under the hospital OPPS for dates of service after 12/31/02. Explanations on the asterisks placed next to the HCPCS codes are annotated at the end of this table.

	HCPCS Codes	Category Long Descriptor	Date First Populated	Expiration Date
1	C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)	8/1/00	12/31/02
2	C1765**	Adhesion barrier	10/01/00 – 3/31/01; 7/1/01	12/31/03
3	C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)	8/1/00	12/31/02
4	C1715	Brachytherapy needle	8/1/00	12/31/02
5	C1716	Brachytherapy seed, Gold 198	10/1/00	12/31/02
6	C1717	Brachytherapy seed, High Dose Rate Iridium 192	1/1/01	12/31/02
7	C1718	Brachytherapy seed, Iodine 125	8/1/00	12/31/02
8	C1719	Brachytherapy seed, Non-High Dose Rate Iridium 192	10/1/00	12/31/02
9	C1720	Brachytherapy seed, Palladium 103	8/1/00	12/31/02
10	C2616	Brachytherapy seed, Yttrium-90	1/1/01	12/31/02
11	C1721	Cardioverter-defibrillator, dual chamber (implantable)	8/1/00	12/31/02
12	C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)	8/1/00	12/31/02
13	C1722	Cardioverter-defibrillator, single chamber (implantable)	8/1/00	12/31/02
14	C1888	Catheter, ablation, non-cardiac, endovascular (implantable)	7/1/02	12/31/04
15	C1726	Catheter, balloon dilatation, non-vascular	8/1/00	12/31/02
16	C1727	Catheter, balloon tissue dissector, non-vascular (insertable)	8/1/00	12/31/02
17	C1728	Catheter, brachytherapy seed administration	1/1/01	12/31/02
18	C1729	Catheter, drainage	10/1/00	12/31/02
19	C1730	Catheter, electrophysiology, diagnostic, other than 3D mapping (19 or fewer electrodes)	8/1/00	12/31/02
20	C1731	Catheter, electrophysiology, diagnostic, other than 3D mapping (20 or more electrodes)	8/1/00	12/31/02
21	C1732	Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping	8/1/00	12/31/02
22	C1733	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip	8/1/00	12/31/02

	HCPCS Codes	Category Long Descriptor	Date First Populated	Expiration Date
23	C2630	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip	10/1/00	12/31/02
24	C1887	Catheter, guiding (may include infusion/perfusion capability)	8/1/00	12/31/02
25	C1750*	Catheter, hemodialysis/peritoneal, long-term	8/1/00	12/31/02
26	C1752*	Catheter, hemodialysis/peritoneal, short-term	8/1/00	12/31/02
27	C1751	Catheter, infusion, inserted peripherally, centrally or midline (other than hemodialysis)	8/1/00	12/31/02
28	C1759	Catheter, intracardiac echocardiography	8/1/00	12/31/02
29	C1754	Catheter, intradiscal	10/1/00	12/31/02
30	C1755	Catheter, intraspinal	8/1/00	12/31/02
31	C1753	Catheter, intravascular ultrasound	8/1/00	12/31/02
32	C2628	Catheter, occlusion	10/1/00	12/31/02
33	C1756	Catheter, pacing, transesophageal	10/1/00	12/31/02
34	C2627	Catheter, suprapubic/cystoscopic	10/1/00	12/31/02
35	C1757	Catheter, thrombectomy/embolectomy	8/1/00	12/31/02
36	C1885	Catheter, transluminal angioplasty, laser	10/1/00	12/31/02
37	C1725	Catheter, transluminal angioplasty, non-laser (may include guidance, infusion/perfusion capability)	8/1/00	12/31/02
38	C1714	Catheter, transluminal atherectomy, directional	8/1/00	12/31/02
39	C1724	Catheter, transluminal atherectomy, rotational	8/1/00	12/31/02
40	C1758	Catheter, ureteral	10/1/00	12/31/02
41	C1760	Closure device, vascular (implantable/insertable)	8/1/00	12/31/02
42	L8614	Cochlear implant system	8/1/00	12/31/02
43	C1762	Connective tissue, human (includes fascia lata)	8/1/00	12/31/02
44	C1763	Connective tissue, non-human (includes synthetic)	10/1/00	12/31/02
45	C1881	Dialysis access system (implantable)	8/1/00	12/31/02
46	C1764	Event recorder, cardiac (implantable)	8/1/00	12/31/02
47	C1767	Generator, neurostimulator (implantable)	8/1/00	12/31/02
48	C1768	Graft, vascular	1/1/01	12/31/02
49	C1769	Guide wire	8/1/00	12/31/02
50	C1770	Imaging coil, magnetic resonance (insertable)	1/1/01	12/31/02
51	C1891	Infusion pump, non-programmable, permanent (implantable)	8/1/00	12/31/02
52	C2626	Infusion pump, non-programmable, temporary (implantable)	1/1/01	12/31/02
53	C1772	Infusion pump, programmable (implantable)	10/1/00	12/31/02
54	C1893	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, other than peel-away	10/1/00	12/31/02
55	C1766	Introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away	1/1/01	12/31/02
56	C1892	Introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, peel-away	1/1/01	12/31/02
57	C1894*	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, non-laser	8/1/00	12/31/02
58	C2629*	Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser	1/1/01	12/31/02
59	C1776	Joint device (implantable)	10/1/00	12/31/02

	HCPCS Codes	Category Long Descriptor	Date First Populated	Expiration Date
60	C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)	8/1/00	12/31/02
61	C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)	8/1/00	12/31/02
62	C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)	8/1/00	12/31/02
63	C1900	Lead, left ventricular coronary venous system	7/1/02	12/31/04
64	C1778	Lead, neurostimulator (implantable)	8/1/00	12/31/02
65	C1897	Lead, neurostimulator test kit (implantable)	8/1/00	12/31/02
66	C1898	Lead, pacemaker, other than transvenous VDD single pass	8/1/00	12/31/02
67	C1779	Lead, pacemaker, transvenous VDD single pass	8/1/00	12/31/02
68	C1899	Lead, pacemaker/cardioverter-defibrillator combination (implantable)	1/1/01	12/31/02
69	C1780	Lens, intraocular (new technology)	8/1/00	12/31/02
70	C1878	Material for vocal cord medialization, synthetic (implantable)	10/1/00	12/31/02
71	C1781	Mesh (implantable)	8/1/00	12/31/02
72	C1782	Morcellator	8/1/00	12/31/02
73	C1784	Ocular device, intraoperative, detached retina	1/1/01	12/31/02
74	C1783	Ocular implant, aqueous drainage assist device	7/1/02	12/31/04
75	C2619	Pacemaker, dual chamber, non rate-responsive (implantable)	8/1/00	12/31/02
76	C1785	Pacemaker, dual chamber, rate-responsive (implantable)	8/1/00	12/31/02
77	C2621	Pacemaker, other than single or dual chamber (implantable)	1/1/01	12/31/02
78	C2620	Pacemaker, single chamber, non rate-responsive (implantable)	8/1/00	12/31/02
79	C1786	Pacemaker, single chamber, rate-responsive (implantable)	8/1/00	12/31/02
80	C1787	Patient programmer, neurostimulator	8/1/00	12/31/02
81	C1788	Port, indwelling (implantable)	8/1/00	12/31/02
82	C2618	Probe, cryoablation	4/1/01	12/31/03
83	C1789	Prosthesis, breast (implantable)	10/1/00	12/31/02
84	C1813	Prosthesis, penile, inflatable	8/1/00	12/31/02
85	C2622	Prosthesis, penile, non-inflatable	10/1/01	12/31/02
86	C1815	Prosthesis, urinary sphincter (implantable)	10/1/00	12/31/02
87	C1816	Receiver and/or transmitter, neurostimulator (implantable)	8/1/00	12/31/02
88	C1771	Repair device, urinary, incontinence, with sling graft	10/1/00	12/31/02
89	C2631	Repair device, urinary, incontinence, without sling graft	8/1/00	12/31/02
90	C1773	Retrieval device, insertable	1/1/01	12/31/02
91	C2615	Sealant, pulmonary, liquid (Implantable)	1/1/01	12/31/02
92	C1817	Septal defect implant system, intracardiac	8/1/00	12/31/02
93	C1874	Stent, coated/covered, with delivery system	8/1/00	12/31/02
94	C1875	Stent, coated/covered, without delivery system	8/1/00	12/31/02
95	C2625	Stent, non-coronary, temporary, with delivery system	10/1/00	12/31/02
96	C2617	Stent, non-coronary, temporary, without delivery system	10/1/00	12/31/02
97	C1876	Stent, non-coated/non-covered, with delivery system	8/1/00	12/31/02
98	C1877	Stent, non-coated/non-covered, without delivery system	8/1/00	12/31/02
99	C1879	Tissue marker (implantable)	8/1/00	12/31/02
100	C1880	Vena cava filter	1/1/01	12/31/02

* Long descriptor for this category code has been revised. The underlined word(s) reflect an addition to the long descriptor.
** The item-specific device code associated with this category code was initially approved as a pass-through but removed from pass-through status after it was determined that the procedure codes associated with the device were listed in the "inpatient only" list under OPPS. The category code was later added as a new category code when the procedure codes associated with the device were removed from the "inpatient only" list.

V. Explanation of Terms/Definitions for Specific Category Codes

3D mapping catheter (C1732) - Refers to a catheter used for mapping the electrophysiologic properties of the heart. Signals are identified by a specialized catheter and changed into a 3-dimensional map of a specific region of the heart.

Adaptor for a pacing lead (C1883) - Interposed between an existing pacemaker lead and a new generator. The end of the adaptor lead has the appropriate connector pin that will enable utilization of the existing pacemaker lead with a new generator that has a different receptacle. These are required when a generator is replaced or when two leads are connected to the same port in the connector block.

Adhesion barrier (C1765) - A bioresorbable substance placed on and around the neural structures, which inhibits cell migration (fibroblasts) and minimizes scar tissue formation. It is principally used in spine surgeries, such as laminectomies and diskectomies.

Anchor for opposing bone-to-bone or soft tissue-to-bone (C1713) - Implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone. Screws oppose tissues via drilling as follows: soft tissue-to-bone, tendon-to-bone, or bone-to-bone fixation. Pins are inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone. This may include orthopedic plates with accompanying washers and nuts. This category also applies to synthetic bone substitutes that may be used to fill bony void or gaps (i.e., bone substitute implanted into a bony defect created from trauma or surgery).

Balloon dilatation catheter, non-vascular (C1726) - Catheter used to dilate strictures or stenoses through the insertion of an uninflated balloon affixed to the end of a flexible catheter, followed by the inflation of the balloon at the specified site (e.g., common bile duct, ureter, small or large intestine). [For the reporting of vascular balloon dilatation catheters, see category "Transluminal angioplasty catheter" (C1725 and C1885).]

Balloon tissue dissector catheter (C1727) - Balloon tipped catheter used to separate tissue planes, used in procedures such as hernia repairs.

Catheter, ablation, non-cardiac, endovascular (implantable) (C1888) - Used to obliterate or necrose tissues in an effort to restore normal anatomic and physiologic function.

Cardioverter-defibrillator, other than single or dual chamber (C1882) - Includes cardiac resynchronization devices.

Coated stent (C1874, C1875) - Refers to a stent bonded with drugs (e.g., heparin) or layered with biocompatible substances (e.g., phosphorylcholine).

Connective tissue, human (C1762) - These tissues include a natural, cellular collagen or extracellular matrix obtained from autologous rectus fascia, decellularized cadaveric fascia lata, or decellularized dermal tissue. They are intended to repair or support damaged or inadequate soft tissue. They are used to treat urinary incontinence resulting from hypermobility or Intrinsic Sphincter Deficiency (ISD), pelvic floor repair, or for implantation to reinforce soft tissues where weakness exists in the urological anatomy. Note this excludes those items that are used to replace skin. For reporting mesh when used to treat urinary incontinence, see the category "Mesh." For reporting urinary incontinence repair device when used to treat urinary incontinence, see the category "Urinary incontinence repair device."

Connective tissue, non-human (includes synthetic) (C1763) - These tissues include a natural, acellular collagen matrix typically obtained from porcine or bovine small intestinal submucosa, or pericardium. This bio-material is intended to repair or support damaged or inadequate soft tissue. They are used to treat urinary incontinence resulting from hypermobility or Intrinsic Sphincter Deficiency (ISD), pelvic floor repair, or for implantation to reinforce soft tissues where weakness exists in the urological or musculoskeletal anatomy. [This excludes those items that are used to replace skin.] [For reporting mesh when used to treat urinary incontinence, see the category "Mesh."] [For reporting urinary incontinence repair device when used to treat urinary incontinence, see the category "Urinary incontinence repair device."]

Cool-tip electrophysiology catheter (C2630) - Ablation catheter that contains a cooling mechanism and has temperature sensing capability.

Covered stent (C1874, C1875) - Refers to a stent layered with silicone or a silicone derivative (e.g., PTFE, polyurethane).

Drainage catheter (C1729) - Intended to be used for percutaneous drainage of fluids. (**Note**: This category does NOT include Foley catheters or suprapubic catheters. Refer to category C2627 to report suprapubic catheters.)

Electrophysiology catheter (C1730, C1731, C1732, C1733, C2630) - Assists in providing anatomic and physiologic information about the cardiac electrical conduction system. Electrophysiology catheters are categorized into two main groups: (1) diagnostic catheters that are used for mapping, pacing, and/or recording only, and (2) ablation (therapeutic) catheters that also have diagnostic capability. The electrophysiology ablation catheters are distinct from non-cardiac ablation catheters.

Electrophysiology catheters designated as "cool-tip" refer to catheters with tips cooled by infused and/or circulating saline. Catheters designated as "other than cool-tip" refer to the termister tip catheter with temperature probe that measures temperature at the tissue catheter interface.

Extension for a pacing lead (C1883) - Provides additional length to an existing pacing lead but does not have the capability of an adaptor.

Extension for a neurostimulator lead (C1883) - Conducts electrical pulses from the power source (generator or neurostimulator) to the lead. The terms neurostimulator and generator are used interchangeably.

Guiding catheter (C1887) - Intended for the introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems. It can be used to inject contrast material, function as a conduit through which other devices pass, and/or provide a mechanism for measuring arterial pressure, and maintain a pathway created by the guide wire during the performance of a procedure.

Infusion pump, non-programmable, temporary (implantable) (C2626) - Short-term pain management system that is a component of a permanent implantable system used for chronic pain management.

Intraocular lens (new technology) (C1780) - Refers to the intraocular lenses approved by CMS as "new technology IOL." A list of these lenses is published periodically in the *Federal Registe*r. The latest publication can be found on page 25740 of the *Federal Register* notice dated May 3, 2000.

Intraoperative ocular device for detached retina (C1784) - A perfluorocarbon substance instilled during a vitreoretinal procedure to treat detached retina.

Joint device (C1776) - An artificial joint such as a finger or toe that is implanted in a patient. Typically, a joint device functions as a substitute to its natural counterpart and is not used (as are anchors) to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone.

Left ventricular coronary venous system lead (C1900) - Designed for left heart placement in a cardiac vein via the coronary sinus and is intended to treat the symptoms associated with heart failure.

Liquid pulmonary sealant (C2615) - An absorbable, synthetic solution that forms a seal utilizing a photochemical polymerization process. It is used to seal visceral pleural air leaks incurred during pulmonary resection.

Material for vocal cord medialization, synthetic (C1878) - Synthetic material that is composed of a non-absorbable substance such as silicone and can be injected or implanted to result in vocal cord medialization.

Mesh (C1781) - A mesh implant or synthetic patch composed of absorbable or non-absorbable material that is used to repair hernias, support weakened or attenuated tissue, cover tissue defects, etc. [For reporting connective tissue (human or non-human) when used to treat urinary incontinence, see the category “Connective tissue, human” or “Connective tissue, non-human.”] [For reporting urinary incontinence repair device when used to treat urinary incontinence, see the category “Urinary incontinence repair device.”]

Morcellator (C1782) - Used for cutting, coring, and extracting tissue in laparoscopic procedures. These are distinct from biopsy devices because morcellators are used for the laparoscopic removal of tissue.

Pacemaker, other than single or dual chamber (C2621) - Includes cardiac resynchronization devices as well as other pacemakers that are neither single or dual chamber.

Patient programmer (C1787) - Programmer that allows the patient to operate their neurostimulator, for example, programming the amplitude and rate of stimulation of a neurostimulator system. Only a non-console patient programmer is eligible for transitional pass-through payments.

Peel-away introducer/sheath (C1892) - A non-absorbable sheath or introducer that separates into two pieces. This device is used primarily when removal of the sheath is required after a catheter or lead is in the desired position.

Retrieval device, insertable (C1773) - A device designed to retrieve other devices or portions thereof (e.g., fractured catheters, leads) lodged within the vascular system. This can also be used to retrieve fractured medical devices or to exchange introducers/sheaths.

Septal defect implant system (C1817) - An intracardiac metallic implant used for closure of various septal defects within the heart. The septal defect implant system includes a delivery catheter. The category code for the septal defect implant system (C1817) includes the delivery catheter; therefore, the delivery catheter should not be reported separately.

Stents with delivery system (C1874, C1876, C2625) - Stents packaged with delivery systems generally include the following components: stent mounted or unmounted on a balloon angioplasty catheter, introducer, and sheath. These components should not be reported separately.

Temporary non-coronary stent (C2617, C2625) - Usually composed of a substance, such as plastic or other non-absorbable material, designed to permit removal. Typically, this type of stent is placed for a period of less than one year.

Tissue marker (C1879) - A material that is placed in subcutaneous or parenchymal tissue (may also include bone) for radiopaque identification of an anatomic site. These markers are distinct from topical skin markers, which are positioned on the surface of the skin to serve as anatomical landmarks.

Transluminal angioplasty catheter (C1725, C1885) - Designed to dilate stenotic blood vessels (arteries and veins). For vascular use, the terms “balloon dilatation catheter” and “transluminal angioplasty catheter” are frequently used interchangeably. [For the reporting of non-vascular balloon dilatation catheters, see the category "Balloon dilatation catheter" (C1726).]

Transvenous VDD single pass pacemaker lead (C1779) - A transvenous pacemaker lead that paces and senses in the ventricle and senses in the atrium.

Urinary incontinence repair device (C1771, C2631) - Used to attach or insert a sling graft for the purpose of strengthening the pelvic floor. It consists of the device components used to deliver (suprapubically or transvaginally) and/or fixate (via permanent sutures or bone anchors) the sling graft. The device may or may not be packaged with a sling graft. Report the appropriate category for a device with or without a sling graft. NOTE: For reporting connective tissue (human or non-human) when used to treat urinary incontinence, see the category “Connective tissue, human” (C1762) or “Connective tissue, non-human” (C1763). For reporting mesh when used to treat urinary incontinence, see the category “Mesh” (C1781).

Vascular closure device (implantable/insertable) (C1760) - Used to achieve hemostasis at arterial puncture sites following invasive or interventional procedures using biologic substances (e.g., collagen) or suture through the tissue tract.

Vector mapping catheter (C1732) - Refers to an electrophysiology catheter with an "in-plane" orthogonal array of electrodes. This catheter is used to locate the source of a focal arrhythmia.

VI. General Coding and Billing Instructions and Explanations For Pass-Through Devices

Devices Implanted, Removed, and Implanted Again, Not Associated With Failure (Applies to Transitional Pass-through Devices Only): In instances where the physician is required to implant another device because the first device fractured, the hospitals may bill for both devices – the device that resulted in fracture and the one that was implanted into the patient. We realize that there may be instances where an implant is tried but later removed due to the device's inability to achieve the necessary surgical result or due to inappropriate size selection of the device by the physician (i.e., physician implants an anchor to bone and the anchor breaks because the bone is too hard or must be replaced with a larger anchor to achieve desirable result). In such instances, Medicare will provide separate reimbursement for both devices. This situation does not extend to devices that result in failure or are found to be defective. For failed or defective devices, hospitals are advised to contact the vendor/manufacturer. NOTE: This applies to transitional pass-through devices only and not to devices packaged into an APC.

Kits: Manufacturers frequently package a number of individual items used in a particular procedure in a kit. Generally, to avoid complicating the category list unnecessarily and to avoid the possibility of double coding, we have not established codes for such kits. However, hospitals are free to purchase and use such kits. If the kits contain individual items that separately qualify for transitional pass-through payments, these items may be separately billed using applicable codes. Hospitals may not bill for transitional pass-through payments for supplies that may be contained in kits.

Multiple units: Hospitals must bill for multiple units of items that qualify for transitional pass-through payments when such items are used with a single procedure by entering the number of units used on the bill.

Reporting of multiple categories: For items with multiple component devices that fall in more than one category (e.g., kits or systems other than those explicitly identified in the long descriptors), hospitals should code the appropriate category separately for each component. For example, the "Rotablator Rotational Angioplasty System (with catheter and advancer)" consists of both a catheter as well as an advancer/sheath. Hospitals should report category C1724 for the catheter and C1894 for the advancer/sheath.

Also, for items packaged as kits that contain a catheter and an introducer, hospitals should report both appropriate categories. For example, the "Clinicath 16G Peripherally Inserted Central Catheter (PICC) Dual-Lumen PolyFlow Polyurethane" contains a catheter and an introducer. To appropriately bill for this item, hospitals should report category C1751 for the catheter and C1894 for the introducer.

Reprocessed devices: Hospitals may bill for transitional pass-through payments only for those devices that are "single use." Reprocessed devices may be considered "single use" if they are

reprocessed in compliance with enforcement guidance of the Food and Drug Administration (FDA) relating to the reprocessing of devices applicable at the time the service is delivered. The FDA is phasing in new enforcement guidance relating to reprocessing during 2001 and 2002. For further information, see FDA's guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," published August 14, 2000, and subsequent FDA guidance or regulatory documents.

VII. April 2002 Outlier Logic Revision

We have revised the outlier logic to add charges for packaged services with a Status Indicator of P retroactive to April 1, 2002. CMHCs should be instructed to resubmit claims for this period if they believe the outlier amount was computed incorrectly.

VIII. Clarification On HCPCS J9266 (Pegaspargase/single dose vial)

We indicated in Section IX.B. of Transmittal A-02-026 dated March 28, 2002 that HCPCS code J9266 (Pegaspargase/singl dose vial; APC 843; SI: G) would no longer be eligible for pass-through status since this drug is no longer manufactured. However, due to additional information received which indicated that this drug is still manufactured, we have decided not to remove this drug from the pass-through list for the April 2002 update but continue to recognize it as a pass-through under the hospital OPPS.

The *effective date* for this PM is July 1, 2002.

The *implementation date* for this PM is July 1, 2002.

These instructions should be implemented within your current operating budget.

This PM may be discarded after July 1, 2003.

If you have any questions, contact your regional office.