Program Memorandum Intermediaries

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

Transmittal A-01-112

Date: SEPTEMBER 18, 2001

CHANGE REQUEST 1842

SUBJECT: Removal of Category Code C1723 from the Pass-Through Device Category List Under the Hospital Outpatient Prospective Payment System (OPPS)

This Program Memorandum (PM) announces the removal of category code C1723 (catheter, ablation, non-cardiac) from the pass-through device category list.

Transmittal A-01-41, Change Request 1610, dated March 22, 2001, provided information on categories for pass-through devices under the hospital OPPS. Attachment II of this PM contained a listing of the categories eligible for pass-through status effective April 1, 2001. Attachment III of Transmittal A-01-41 provided a listing of specific devices mapped to the new category codes. C1723 was one of the categories approved for pass-through status effective April 1, 2001. Only one device was mapped to this category code, specifically the Gynecare Thermachoice II catheter.

Based on a subsequent review of the application for pass-through status that was submitted on behalf of the Gynecare Thermachoice II catheter, we have determined that this specific item does not meet the pass-through criteria set forth in the **Federal Register** on August 3, 2000 and November 13, 2000. As provided in 42 CFR 419.43(e)(4)(iv), a device must be surgically implanted or inserted, whether or not it remains with the patient when the patient is released from the hospital outpatient department. We explained in the November 13, 2000, **Federal Register** (65 FR 67805) that we consider a device to be surgically implanted or inserted "if it is introduced into the human body through a surgically created incision." The Gynecare Thermachoice II catheter does not meet this pass-through criterion.

As provided in the Benefits Improvement and Protection Act (BIPA) of 2000, in order for a device to be a category code effective April 1, 2001, the device must have met the pass-through criteria and we must have received the application by December 1, 2000. Because we have now determined that the Gynecare Thermachoice II catheter did not meet the criteria for eligibility as a pass-through device and because we are not aware of any other device described by category code C1723 that does meet the criteria, C1723 will be removed from the list of eligible category codes effective January 1, 2002. Device manufacturers are encouraged to submit applications if they believe they have non-cardiac ablation catheters that meet our criteria for pass-through payment eligibility.

Note that although we generally allow a 90-day grace period when we remove a code, we do not grant grace periods when we terminate eligibility for a code. In this case, there will be no grace period for category code C1723 beyond the January 1, 2002 termination date.

The effective date for this PM is January 1, 2002.

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

This PM may be discarded after January 1, 2003.

These instructions should be implemented within your current operating budget.

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