CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1147	Date: JANUARY 5, 2007
	Change Request 5432

SUBJECT: Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting

I. SUMMARY OF CHANGES: This CR provides coverage criteria and claims processing instructions for Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting. In addition, this CR manualizes billing instructions for existing policy (not communicated in the Internet Only Manual) regarding Investigational Device Exemptions (IDEs), clinical trials, and items provided free of cost.

NEW/REVISED MATERIAL
EFFECTIVE DATE: NOVEMBER 6, 2006
IMPLEMENTATION DATE: February 5, 2007

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/Table of Contents
N	32/67/No Cost Claims
N	32/67.1/Practitioner Billing for No Cost Items
N	32/67.2/Institutional Billing for No Cost Items
N	32/67.2.1/Billing No Cost Items Due to Recall, Replacement, or Free Sample
N	32/68/Investigational Device Exemption (IDE)
N	32/68.1/General
N	32/68.2/Notifying Contractors of an IDE Device Trial
N	32/68.3/Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE
N	32/68.4/Billing Requirements for Providers Billing Category B IDEs
N	32/68.5/Contractor Review of Category B IDEs
R	32/69.1/General

R	32/69.5/Billing Requirements - General
R	32/69.6/Billing Requirements for Clinical Trials (Effective January 1, 2002)
N	32/161/Intracranial PTA With Stenting

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1147	Date: January 5, 2007	Change Request: 5432

SUBJECT: Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting

Effective Date: November 6, 2006

Implementation Date: February 5, 2007

I. GENERAL INFORMATION

A. Background: In the past, PTA to treat obstructive lesions of the cerebral arteries was non-covered by Medicare because the safety and efficacy of the procedure had not been established. This national coverage determination (NCD) meant that the procedure was also non-covered for beneficiaries participating in Food and Drug Administration (FDA)-approved investigational device exemption (IDE) clinical trials. On February 9, 2006, a request for reconsideration of this NCD initiated a national coverage analysis. This change request communicates the findings and revised NCD resulting from that analysis.

B. Policy: The CMS has reviewed the evidence and determined that effective November 6, 2006, Medicare will cover PTA with stenting of intracranial arteries for treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with FDA-approved protocols governing Category B IDE clinical trials. Payment for intracranial PTA with stenting is considered reasonable and necessary under §1862(a)(1)(A) of the Social Security Act under these circumstances. All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain noncovered.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5432.1	Contractors shall identify covered Intracranial stenting claims to be paid by the following claim elements: • Discharge date is on or after November 6, 2006; and • ICD-9 CM Procedure codes 00.62 and 00.65 are both present; and • ICD-9 CM diagnosis code 437.0 is present; and • The IDE number is present on a 0624	X		X								

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	revenue code line.											
5432.2	Contractors shall hold covered Intracranial stenting claims until the next release of the Medicare Code Editor (MCE) and Grouper software (when ICD-9 CM procedure codes 00.62 and 00.65 are changed to "covered" and payable codes).	X		X								
5432.3	Contractors shall release and apply Condition Code 15 to held Intracranial stenting claims**,** upon installation of the Medicare Code Editor (MCE), version 25.0. Note: Version 25.0 of the MCE will contain retro-active capability to assure the held claims can process for dates of service prior to October 1, 2007.	X		X								
5432.4	Contractors shall pay the appropriate interest on the released Intracranial stenting claims.	X		X								
5432.5	Contractors shall pay covered Intracranial stenting claims with the following claim elements: • CPT code 37799 (Unlisted procedure, Vascular surgery): and • QA modifier; and • ICD-9 CM diagnosis code 437.0 is present; and • Appropriate IDE number.	X			X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
5432.6	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X							

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s):

Coverage: Sarah McClain at sarah.mcclain@cms.hhs.gov or 410-786-2994
Institutional Claims Processing: Joe Bryson at joseph.bryson@cms.hhs.gov or 410-786-2986
Practitioner Claims Processing: Vera Dillard at vera.dillard@cms.hhs.gov or 410-786-6149

Post-Implementation Contact(s): Regional office

VI. FUNDING

A. TITLE XVIII Contractors:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

B. Medicare Administrative Contractors:

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.1147, 01-05-07)

67 – No Cost Items

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

On occasion, providers may receive an item (such as a device or drug) that is offered by a manufacturer/supplier free of charge. Such items, for purposes of these instructions, are considered "no cost items." Providers are not to seek reimbursement for no cost items as noted in Section 1862(a)(2) of the Social Security Act.

67.1 – Practitioner Billing for No Cost Items

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

Practitioner providers should not bill for no cost items as there is no "Non-Covered" charges field on the claim and there are also no system edits in place to require providers to do so.

67.2 – Institutional Billing for No Cost Items

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

In some instances, providers do not have to report the usage of a no cost device. However, in most cases, providers are required to bill a no cost item due to system edits that will ensure that an item (received at no cost or not) is billed along with an associated service (e.g., a device/drug must be reported along with an implantation/administration). To report a no cost item, institutional providers must place a token charge in the "Non-Covered" charge field for the no cost item. By doing so, the provider is accomplishing four things:

1) Communicating to the contractor that the provider is not seeking reimbursement for the no cost item; and

2) Reflecting, with completeness and accuracy, all services provided to the patient; and

3) Preventing the line item or claim from being rejected/denied by system edits that require an item to be billed in conjunction with an associative procedure (such as implants or administrations); and

4) Assuring that the patient and provider are not held liable for any charges for the no cost item.

The beneficiary should not be held liable for the non-covered charge. The claims processing system is set to default to provider liability unless a specific indicator of beneficiary liability is present.

For more information on billing no-cost items under The Outpatient Prospective Payment System (OPPS), refer to Pub. 100-04, The Medicare Claims Processing Manual, chapter 1, sections 20.6.9 and 61.3.

67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample
(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

Currently, institutional providers that use the Healthcare Common Procedural Coding System (HCPCS), bill the device HCPCS with a token charge to bypass device and device insertion procedure edits. Effective January 1, 2006, modifier -FB will be used to indicate that a device used in a procedure was furnished without cost to the provider and; therefore, it is not being charged to Medicare or the beneficiary. More information on the billing HCPCS modifier –FB can be located in Section 20.6.9 of the Medicare Claims Processing Manual, Chapter 4.

Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes will be used to identify and track medical devices that are provided by a manufacturer at no cost. The no-cost device may be provided due to warranty, replacement, recall or defect issues.

Table 1: New Condition Codes and Descriptions

Condition Code		***Description***
49	*Product Replacement within Product Lifecycle*	*A medical device is replaced before "end-of-life" because there is an indication that the device is not functioning properly. (This is a warranty situation.)*
50	*Product Replacement for Known Recall of a Product*	*A medical device is replaced because of a manufacturer or FDA recall.*

- *Providers must use the codes to identify medical devices that are provided by a manufacturer at no cost. These condition codes will be used to track no-cost recalled or replacement devices.*
- *Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no-cost device when conditions of replacement or recall are met.*

NOTE: *Outpatient hospitals billing "no cost" devices must append the -FB modifier to the procedure code for implanting the "no cost" device, along with the appropriate condition code (in Table 1 above). The modifier will identify the procedure code line for the "no cost" device, while the condition code will explain the reason why the device was provided free of cost.*

68 – Investigational Device Exemption (IDE)
(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

68.1 – General
(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

The CMS determines Medicare device coverage based on which category the FDA assigns the device. Devices are either designated as a Category A IDE or a Category B IDE.

NOTE: *For purposes of these instructions, IDEs will be referred to as "studies" instead of "trials" to help distinguish clinical trial instructions from IDE study instructions.*

Category A Devices

Category A devices are considered experimental. Therefore, the Category A device is not eligible for payment, and should not be billed to Medicare. Nonetheless, effective January 1, 2005, routine costs (as described in The National Coverage Determinations Manual, Section 310.1) of clinical trials involving a Category A IDE devices are covered when the Medicare contractors determine that the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

Category B Devices

Unlike Category A devices, Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved. Category B devices may be covered under Medicare as long as it meets the billing requirements listed in Section 68.2 below. If the device is billed under a Category B IDE study, and it meets the billing requirements for IDEs, the device itself and the routine costs associated with its use are eligible for payment (Reimbursement for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

More information regarding these two categories of IDEs can be located in The Benefit Policy Manual, Chapter 14.

68.2 – Notifying Contractors of an IDE Device Trial
(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare contractor. The following information must be furnished prior to submission of a claim for payment:

- *A copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number must be on the letter*
- *The name of the device (both trade, common or usual, and classification name)*
- *Any action taken to conform to any applicable IDE special controls*
- *A narrative description of the device sufficient to make a payment determination*

- *A statement indicating how the device is similar to and/or different from other comparable products*
- *Indication of whether the device will be billed on an inpatient or outpatient claim*
- *A brief summary of the study design or a copy of the actual trial protocol*
- *The provider's protocol for obtaining informed consents for beneficiaries participating in the clinical trial.*

NOTE: *Potential Medicare coverage of Category B IDE devices is predicated, in part, on the device's status with the FDA. If a sponsor loses its Category B status for the device or violates relevant IDE requirements necessitating the FDA's withdrawal approval, all payment will cease. Providers must notify their contractor within 30 days of any change in status for an IDE. By billing for an IDE, whether it is for a Category B device or for the routine costs of clinical trials involving a Category A device, the provider attests that the device was approved at the time the services were rendered.*

68.3 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of clinical trials involving a Category A device, as listed in Section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the contractor determines that the device does, in fact, meet the requirements of coverage, then the provider may begin billing the routine costs of a clinical trial involving a Category A device.

Providers shall submit claims for the routine costs of a clinical trial involving a Category A IDE by billing according to the clinical trial billing instructions found in Section 69.7 (Qualifying Clinical Trials) of this chapter.

In addition to billing the routine costs, providers must identify the line for which the Category A IDE device is being billed. Institutional providers must bill the device involved with the clinical trial by placing the Category A IDE Number on a 0624 (IDE) revenue code line, with the charges for the device placed in the "Non-covered" charges field. Practitioner providers must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device. The 0624 revenue code and the QV modifier alert contractors that the Category A IDE is billed on that line.

68.4 – Billing Requirements for Providers Billing Category B IDEs

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDEs. Once the contractor

notifies the provider that all required information for the IDE has been furnished, the provider may bill claims for the particular Category B IDE.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. Institutional providers must bill the Category B IDE Number on a 0624 revenue code line with charges in the covered charges field (providers receiving the device free of charge must bill the IDE charges as non-covered). Practitioner providers must bill the Category B IDE on a line with a QA modifier (FDA IDE).

The following table shows the designated field locations to report the IDE Number on institutional and practitioner claims:

Data	***CMS-1450***	***UB-92 (version 6)***	***CMS-1500***	***837i and 837p***
IDE #	*FL 43*	*RT 34*	*Item 23*	*Segment 2300, REF02, data element 127*

68.5 – Contractor Review of Category B IDEs

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

When reviewing Category B IDE claims, Medicare contractors determine payment on a case-by-case basis. That is, contractors make local coverage determinations based on whether or not certain criteria are met. In addition to other national and local coverage policies, the following criteria are used by Medicare contractors to determine Medicare payment for Category B IDE trials:

- *The use of the device must be part of an FDA-approved clinical trial*
- *The device must be assigned to Category B as described by FDA regulations*
- *The use of the device must be medically necessary for the patient for whom coverage is sought*
- *The amount, duration, and frequency of the use of the device must be medically appropriate*
- *The device must be used in a setting appropriate for the patient's medical needs and condition*

69.1 – General

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

The CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in *The National Coverage Determinations Manual, Section 310.1*.

69.5 - Billing Requirements – General

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

Instruct physicians, suppliers and hospitals to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free of charge by research sponsors may not be billed to be *paid by* Medicare*, and providers are not required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free of charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as non-covered at the time of entry, while also assuring that the beneficiary is not held liable. This instruction applies to all hospitals including hospitals located in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC).*

69.6 - Billing Requirements for *Clinical Trials (Effective January 1, 2002)*

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

Routine Costs Submitted by Practitioners:

For services furnished to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying clinical trials, are to be coded/billed in the following manner:

- The "QV" procedure code modifier is reported at the line item level.
- Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the primary diagnosis

If the QV modifier is billed and diagnosis code V70.7 is submitted *by practitioners* as a secondary rather than the primary diagnosis, do not consider the service as having been furnished to a healthy, control group, diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Routine Costs Submitted by Institutional Providers:

For services furnished to Medicare beneficiaries, who are healthy, control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed on the in the following manner:

- Condition code 30 (qualifying clinical trial) is reported at the *claim* level
- Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the secondary diagnosis
- "QV" procedure code modifier (only for outpatient claims submitted *by institutional providers*) *is reported at the line item level*

Fiscal intermediary	**Carrier**

Condition code 30 (for all types of service)	**QV modifier**
ICD-9 diagnosis code V70.7 (as secondary diagnosis for all types of service)	**ICD-9 diagnosis code V70.7** (as primary diagnosis)
QV modifier (outpatient services only)	

NOTE: *The QV modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV modifier. When billed in conjunction with the V70.7 diagnosis code, the QV modifier will serve as the provider's attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).*

161 - Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting

(Rev.1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

A. Background

In the past, PTA to treat obstructive lesions of the cerebral arteries was non-covered by Medicare because the safety and efficacy of the procedure had not been established. This national coverage determination (NCD) meant that the procedure was also non-covered for beneficiaries participating in Food and Drug Administration (FDA)-approved investigational device exemption (IDE) clinical trials.

B. Policy

On February 9, 2006, a request for reconsideration of this NCD initiated a national coverage analysis. CMS reviewed the evidence and determined that intracranial PTA with stenting is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act for the treatment of cerebral vessels (as specified in The National Coverage Determinations Manual, chapter 1, part 1, section 20.7) only when furnished in accordance with FDA-

approved protocols governing Category B IDE clinical trials. All other indications for intracranial PTA with stenting remain non-covered.

C. Billing

Providers of covered intracranial PTA with stenting shall use Category B IDE billing requirements, as listed above in section 68.4. In addition to these requirements, providers must bill the appropriate procedure and diagnosis codes to receive payment. That is, under Part A, providers must bill intracranial PTA using procedure codes 00.62 and 00.65, along with a diagnosis code of 437.0. Under Part B, providers must bill procedure code 37799 along with a diagnosis code of 437.0.

NOTE: *ICD-9CM codes are subject to modification. Providers must always ensure they are using the latest and most appropriate codes.*