CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2998	**Date: July 25, 2014**
	Change Request 8693

SUBJECT: Update to Pub. 100-04, Chapter 32 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

I. SUMMARY OF CHANGES: This Change Request (CR) contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 32. Additionally, references to CMS contractor types have been replaced with Medicare Administrative Contractors (MACs) in the sections that are updated by this transmittal. There are no new coverage policies, payment policies, or codes introduced in this transmittal. There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

EFFECTIVE DATE: Upon implementation of ICD-10; January 1, 2012 - ASC X12
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 25, 2014 - ASC X12; Upon Implementation of ICD-10

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/ Table of Contents
R	32/10.1/ Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements
R	32/11.2/ Electromagnetic Therapy
R	32/11.3.2/ Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding
R	32/11.3.6/ Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs), and Group Codes
R	32/12.2/ A/B MAC (B) Billing Requirements
R	32/12.3/ A/B MAC (A) Billing Requirements
R	32/12.4/ Remittance Advice (RA) Notices
R	32/20.2/ Healthcare Common Procedure Coding System (HCPCS) Procedure Codes and Applicable Diagnosis Codes
R	32/20.3/ Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes (CARCs)
R	32/30.1/ Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities
R	32/40.2.2/ Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595)
R	32/40.3/ Bill Types
R	32/50.4.1/ Allowable Covered Diagnosis Codes
R	32/50.4.2/ Allowable Covered Procedure Codes
R	32/50.7/ Remittance Advice Notice for A/B MACs (A)
R	32/60.4.1/ Allowable Covered Diagnosis Codes
R	32/60.5.2/ Applicable Diagnosis Codes for A/B MACs (B)
R	32/60.8.1/ Remittance Advice Notices
R	32/68.3/ Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE
R	32/68.4/ Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE
R	32/69.2/ Payment for Qualifying Clinical Trial Services
R	32/69.6/ Requirements for Billing Routine Costs of Clinical Trials
R	32/70.4/ Special Billing and Payment Requirements for A/B MACs (A)
R	32/80.3/ Diagnosis Codes
R	32/80.6/ Editing Instructions for A/B MACs (A)

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/90/ Stem Cell Transplantation
R	32/90.2/ HCPCS and Diagnosis Coding - ICD-9-CM Applicable
N	32/90.2.1/- HCPCS and Diagnosis Coding for Stem Cell Transplantation - ICD-10-CM Applicable
R	32/90.3/ Non-Covered Conditions
R	32/90.4/ Edits
R	32/90.6/ Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)
R	32/100.1.2/ Special Billing Requirements for A/B MACs (A) for Inpatient Billing
R	32/160.2.1/ Carotid Artery Stenting (CAS) Post-Approval Extension Studies
R	32/161/ Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting
R	32/170.3/ A/B MAC (A) Billing Requirements
R	32/180.2/ Billing Requirements
R	32/190.2/ Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code
R	32/200.2/ Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)
R	32/230/ Billing Wrong Surgical or Other Invasive Procedures Performed on a Patient, Surgical or Other Invasive Procedures Performed on the Wrong Body Part, and Surgical or Other Invasive Procedures Performed on the Wrong Patient
R	32/250.3/ Payment Requirements
R	32/260.2.1/ Hospital Billing Instructions
R	32/260.2.2/ Practitioner Billing Instructions
R	32/270.1/ Coding Requirements for Implantable Automatic Defibrillators
R	32/270.2/ Billing Requirements for Patients Enrolled in a Data Collection System

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted 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.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-04	Transmittal: 2998	Date: July 25, 2014	Change Request: 8693

SUBJECT: Update to Pub. 100-04, Chapter 32 to Provide Language-Only Changes for Updating ICD-10 and ASC X12

EFFECTIVE DATE: Upon implementation of ICD-10; January 1, 2012 - ASC X12
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: Upon Implementation of ICD-10; August 25, 2014 - ASC X12

I. GENERAL INFORMATION

A. Background: This CR contains language-only changes for updating ICD-10 and ASC X12 language in Pub 100-04, Chapter 32.

B. Policy: There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements have been announced previously in various communications.

Certain codes have not been issued to the shared system for systems change yet but will be issued in a future CR. MACs are to be aware of all of the changes, including the changes planned, which are not effective until October 1, 2014. These codes are: E08.40, E09.40, E11.610, E13.41, E13.43, E13.44, and E13.610.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8693.1	A/B MACs shall be aware of the updated language for ICD-10 and for ASC X12 in Pub. 100 - 04, Chapter 32.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Not Applicable, 123-456-7890.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted 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.

ATTACHMENTS: 0

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev. 2998, 07-25-14)

10.1 - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A. Coding Applicable to *A/B MACs (A and B)*

Effective April 1, 2002, a National Coverage Decision was made to allow for Medicare coverage of ABPM for those beneficiaries with suspected "white coat hypertension" (WCH). ABPM involves the use of a non-invasive device, which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by a physician. Suspected "WCH" is defined as: (1) Clinic/office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; (2) At least two documented separate blood pressure measurements taken outside the clinic/office which are < 140/90 mm Hg; and (3) No evidence of end-organ damage. ABPM is not covered for any other uses. Coverage policy can be found in Medicare National Coverage Determinations Manual, Chapter 1, *Part 1,* §20.19. (*http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp*).

The ABPM must be performed for at least 24 hours to meet coverage criteria. Payment is not allowed for institutionalized beneficiaries, such as those receiving Medicare covered skilled nursing in a facility. In the rare circumstance that ABPM needs to be performed more than once for a beneficiary, the qualifying criteria described above must be met for each subsequent ABPM test.

Effective dates for applicable Common Procedure Coding System (HCPCS) codes for ABPM for suspected WCH and their covered effective dates are as follows:

HCPCS	Definition	Effective Date
93784	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report.	04/01/2002
93786	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.	04/01/2002
93788	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.	01/01/2004
93790	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; physician review with interpretation and report.	04/01/2002

In addition, *one of* the following diagnosis code*s* must be present:

	Diagnosis Code	Description
If ICD-9-CM is applicable	796.2	Elevated blood pressure reading without diagnosis of hypertension.
If ICD-10-CM is applicable	*R03.0*	*Elevated blood pressure reading without diagnosis of hypertension*

B. *A/B MAC (A)* Billing Instructions

The applicable types of bills acceptable when billing for ABPM services are 13X, 23X, 71X, 73X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to *A/B MACs (A)*. The *A/B MACs (A)* pay for hospital outpatient ABPM services billed on a 13X type of bill with HCPCS 93786 and/or 93788 as follows: (1) Outpatient Prospective Payment System (OPPS) hospitals pay based on the Ambulatory Payment Classification (APC); (2) non-OPPS hospitals (Indian Health Services Hospitals, Hospitals that provide Part B services only, and hospitals located in American Samoa, Guam, Saipan and the Virgin Islands) pay based on reasonable cost, except for Maryland Hospitals which are paid based on a percentage of cost. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for ABPM.

The *A/B MACs (A)* pay for comprehensive outpatient rehabilitation facility (CORF) ABPM services billed on a 75x type of bill with HCPCS code 93786 and/or 93788 based on the Medicare Physician Fee Schedule (MPFS) amount for that HCPCS code.

The *A/B MACs (A)* pay for ABPM services for critical access hospitals (CAHs) billed on a 85x type of bill as follows: (1) for CAHs that elected the Standard Method and billed HCPCS code 93786 and/or 93788, pay based on reasonable cost for that HCPCS code; and (2) for CAHs that elected the Optional Method and billed any combination of HCPCS codes 93786, 93788 and 93790 pay based on reasonable cost for HCPCS 93786 and 93788 and pay 115% of the MPFS amount for HCPCS 93790.

The *A/B MACs (A)* pay for ABPM services for skilled nursing facility (SNF) outpatients billed on a 23x type of bill with HCPCS code 93786 and/or 93788, based on the MPFS.

The *A/B MACs (A)* accept independent and provider-based rural health clinic (RHC) bills for visits under the all-inclusive rate when the RHC bills on a 71x type of bill with revenue code 052x for providing the professional component of ABPM services. The *A/B MACs (A)* should not make a separate payment to a RHC for the professional component of ABPM services in addition to the all-inclusive rate. RHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The *A/B MACs (A)* accept free-standing and provider-based federally qualified health center (FQHC) bills for visits under the all-inclusive rate when the FQHC bills on a 73x type of bill with revenue code 052x for providing the professional component of ABPM services.

The *A/B MACs (A)* should not make a separate payment to a FQHC for the professional component of ABPM services in addition to the all-inclusive rate. FQHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The *A/B MACs (A)* pay provider-based RHCs/FQHCs for the technical component of ABPM services when billed under the base provider's number using the above requirements for that particular base provider type, i.e., a OPPS hospital based RHC would be paid for the ABPM technical component services under the OPPS using the APC for code 93786 and/or 93788 when billed on a 13x type of bill.

Independent and free-standing RHC/FQHC practitioners are only paid for providing the technical component of ABPM services when billed to the *A/B MAC (B)* following the *MAC's* instructions.

C. *A/B MAC (B)* Claims

A/B MACs (B) pay for ABPM services billed with *ICD-9-CM* diagnosis code 796.2 *(if ICD-9 is applicable) or, if ICD-10 is applicable, ICD-10-CM diagnosis code R03.0* and HCPCS codes 93784 or for any combination of 93786, 93788 and 93790, based on the MPFS for the specific HCPCS code billed.

D. Coinsurance and Deductible

The *A/B MACs (A and B)* shall apply coinsurance and deductible to payments for ABPM services except for services billed to the *A/B MAC (A)* by FQHCs. For FQHCs only co-insurance applies.

11.2 - Electromagnetic Therapy

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A. HCPCS Coding Applicable to *A/B MACs (A and B)*

Effective July 1, 2004, a National Coverage Decision was made to allow for Medicare coverage of electromagnetic therapy for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electromagnetic therapy for the treatment of wounds are not covered by Medicare. Electromagnetic therapy will not be covered as an initial treatment modality.

The use of electromagnetic therapy will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electromagnetic therapy is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days. Continued treatment with electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electromagnetic therapy must be discontinued when the wound demonstrates a 100% epithelialzed wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1 section 270.1. (*http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp*)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0329	ElectromagneticTherapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	07/01/2004

Medicare will not cover the device used for the electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered.

B. *A/B MAC (A)* Billing Instructions

The applicable types of bills acceptable when billing for electromagnetic therapy services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to *A/B MACs (A)*. *A/B MACs (A)* pay for electromagnetic therapy services under the Medicare Physician Fee Schedule for a hospital, CORF, ORF, and SNF.

Payment methodology for independent (RHC), provider-based RHCs, free-standing FQHC and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

Payment Methodology for a CAH is payment on a reasonable cost basis unless the CAH has elected the Optional Method and then the *A/B MAC (A)* pays pay 115% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.
In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	Description
420	Physical Therapy
430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *
977, 978	Critical Access Hospital- method II CAH professional services only

* **NOTE:** As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

C. *A/B MAC (B)* Claims

A/B MACs (B) pay for Electromagnetic Therapy services billed with HCPCS codes G0329 based on the MPFS. Claims for electromagnetic therapy services must be billed *using the ASC X12 837 professional claim format or* Form CMS-1500 following instructions in chapter 12 of this manual (*www.cms.hhs.gov/manuals/104_claims/clm104index.asp*).

Payment information for HCPCS code G0329 will be added to the July 2004 update of the Medicare Physician Fee Schedule Database (MPFSD).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for electromagnetic therapy services except for services billed to the *A/B MAC (A)* by FQHCs. For FQHCs only co-insurance applies.

11.3.2 – Healthcare Common Procedure Coding System (HCPCS) Codes and Diagnosis Coding

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

HCPCS Code

Effective for claims with dates of service on or after August 2, 2012 Medicare providers shall report HCPCS code G0460 for PRP services.

If* ICD-9 Diagnosis coding *is applicable

For claims with dates of service on or after August 2, 2012, PRP, for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical study must be billed using the following ICD codes:

- V70.7
- ICD-9 code from the approved list of diagnosis codes maintained by the Medicare contractor.

If ICD-10 Diagnosis coding is applicable

For claims with dates of service on or after the implementation of ICD-10, ICD-10 CM diagnosis coding is applicable.

- *Z00.6*
- *ICD-10 code from the approved list of diagnosis codes maintained by the Medicare contractor.*

Additional billing requirement:

The following modifier and condition code shall be reported when billing for PRP services only in the context of an approved clinical study:

- Q0 modifier
- Condition code 30 (for institutional claims only)
- Value Code D4 with an 8-digit clinical trial number. NOTE: This is optional and only applies to Institutional claims.

11.3.6 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RARCs), Claim Adjustment Reason Codes (CARCs) and Group Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Contractors shall use the following messages when returning to provider/returning as unprocessable claims when required information is not included on claims for autologous platelet-rich plasma (PRP) for the treatment of chronic non-healing diabetic, venous and/or pressure wounds only in the context of an approved clinical study:

CARC 16 - Claim/service lacks information *or has submission/billing error(s)* which is *(are)* needed for adjudication. *At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.*

RARC MA130 – Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information.

Contractors shall deny claims for RPR services, HCPCS code G0460, when services are provided on other than TOBs 12X, 13X, 22X, 23X, 71X, 75X, 77X, and 85X using:

MSN 21.25: “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version: “El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones.”

CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. **NOTE:** Refer to the 832 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

RARC N428: “Service/procedure not covered when performed in this place of service.”

Group Code – CO (Contractual Obligation)

Contractors shall deny claims for PRP services for POS other than 11, 22, or 49 using the following:

MSN 21.25: “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version: “El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones.”

CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. **NOTE**; Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service payment Information REF), if present.

RARC N428: “Service/procedure not covered when performed in this place of service.”

Group Code – CO (Contractual Obligation)

12.2 - *A/B MAC (B)* Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A/B MACs (B) shall pay for counseling services billed with codes 99406 and 99407 for dates of service on or after January 1, 2008. *A/B MACs (B)* shall pay for counseling services billed with codes G0375 and G0376 for dates of service performed on and after March 22, 2005 through Dec. 31, 2007. The type of service (TOS) for each of the new codes is 1.

A/B MACs (B) pay for counseling services billed based on the Medicare Physician Fee Schedule (MPFS). Deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge, which means that charges to the beneficiary may be no more than 115 percent of the allowed amount.

Physicians or qualified non-physician practitioners shall bill the *A/B MAC (B)* for smoking and tobacco-use cessation counseling services *using the ASC X12 837 professional claim format or* the Form CMS-1500.

12.3 - *A/B MAC (A)* Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The *A/B MACs (A)* shall pay for Smoking and Tobacco-Use Cessation Counseling services with codes 99406 and 99407 for dates of service on or after January 1, 2008. *A/B MACs (A)* shall pay for counseling services billed with codes G0375 and G0376 for dates of service performed on or after March 22, 2005 through December 31, 2007.

A. Claims for Smoking and Tobacco-Use Cessation Counseling Services should be submitted *using the ASC X12 837 institutional claim format or* Form CMS-1450.

The applicable bill types are 12X, 13X, 22X, 23X, 34X, 71X, 73X, 83X, and 85X. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for Smoking and Tobacco-Use Cessation Counseling services.

Applicable revenue codes are as follows:

Provider Type	**Revenue Code**
Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs)	052X
Indian Health Services (IHS)	0510
Critical Access Hospitals (CAHs) Method II	096X, 097X, 098X
All Other Providers	0942

NOTE: When these services are provided by a clinical nurse specialist in the RHC/FQHC setting, they are considered "incident to" and do not constitute a billable visit.

Payment for outpatient services is as follows:

Type of Facility	Method of Payment
Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs)	All-inclusive rate (AIR) for the encounter
Indian Health Service (IHS)/Tribally owned or operated hospitals and hospital- based facilities	All-inclusive rate (AIR)
IHS/Tribally owned or operated non-hospital-based facilities	Medicare Physician Fee Schedule (MPFS)
IHS/Tribally owned or operated Critical Access Hospitals (CAHs)	Facility Specific Visit Rate
Hospitals subject to the Outpatient Prospective Payment System (OPPS)	Ambulatory Payment Classification (APC)
Hospitals not subject to OPPS	Payment is made under current methodologies
Skilled Nursing Facilities (SNFs) **NOTE:** Included in Part A PPS for skilled patients.	Medicare Physician Fee Schedule (MPFS)
Home Health Agencies (HHAs)	Medicare Physician Fee Schedule (MPFS)
Critical Access Hospitals (CAHs)	Method I: Technical services are paid at 101% of reasonable cost. Method II: technical services are paid at 101% of reasonable cost, and Professional services are paid at 115% of the MMPFS Data Base
Maryland Hospitals	Payment is based according to the Health Services Cost Review Commission (HSCRC). That is 94% of submitted charges subject to any unmet deductible, coinsurance, and non-covered charges policies.

NOTE: Inpatient claims submitted with Smoking and Tobacco-Use Cessation Counseling Services are processed under the current payment methodologies.

12.4 - Remittance Advice (RA) Notices

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Contractors shall use the appropriate claim RA(s) when denying payment for smoking and tobacco-use cessation counseling services.

The following messages are used where applicable:

- If the counseling services were furnished before March 22, 2005, use an appropriate RA claim adjustment reason code, such as, 26, "Expenses incurred prior to coverage."

- If the claim for counseling services is being denied because the coverage criteria are not met, use an appropriate *claim adjustment* reason code, such as, B5, "Payment adjusted because coverage/program guidelines were not met or were exceeded."

- If the claim for counseling services is being denied because the maximum benefit has been reached, use an appropriate RA claim adjustment reason code, such as, 119, "Benefit maximum for this time period or occurrence has been reached."

20.2 - Healthcare Common Procedure Coding System (HCPCS) Procedure Codes and Applicable Diagnosis Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Effective for services performed on and after January 1, 2010, the following new HCPCS codes have been created for KDE services when provided to patients with stage IV CKD.

- G0420: Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour

- G0421: Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour

When billing for KDE services *the applicable ICD diagnosis code shall be used*:

- *If ICD-9-CM is applicable, ICD-9-CM -* 585.4 (chronic kidney disease, Stage IV (severe)), or

- *If ICD-9-CM is applicable, ICD-10-CM – N18.4 (Chronic Kidney Disease, stage 4*.

NOTE: Claims with HCPCS codes G0420 or G0421 and ICD-9 code 585.4*, if applicable, or, if ICD -10 is applicable, ICD-10 code N18.4* that are billed for KDE services are not allowed on a professional and institutional claim on the same service date.

20.3 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes (CARCs)

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The following messages are used by Medicare contractors when denying non-covered services associated with KDE services when provided to patients with stage IV CKD:

When denying claims for KDE services billed without diagnosis code 585.4 contractors shall use:

- MSN 16.10 - Medicare does not pay for this item or service.

- CARC 167 - This (these) diagnosis(es) is (are) not covered. *NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.*

When denying claims for KDE services when submitted for more than 6 sessions contractors shall use:

- MSN 15.22 - The information provided does not support the need for this many services or items in this period of time so Medicare will not pay for this item or service.

- CARC 119 - Benefit maximum for this time period or occurrence has been reached.

When denying claims for KDE services when two claims are billed (professional and institutional) on the same service date, contractors shall use:

- MSN 15.5 – The information provided does not support the need for similar services by more than one doctor during the same time period.

- CARC 18 – *Exact duplicate claim/service (Use only with Group Code OA except where state workers' compensation regulations requires CO).*

A/B MACs (A) shall deny KDE services when rendered in an urban area unless:

- The provider is a hospital on the section 401 list or

- The claim is submitted on TOB 85X.

A/B MACs (A) shall deny payment for KDE services when submitted on TOB 72X.
Use the following messages:

- MSN 21.6 – This item or service is not covered when performed, referred or ordered by this provider.

- CARC 170 – Payment is denied when performed/billed by this type of provider *in this type of facility. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.*

30.1 - Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Hyperbaric Oxygen Therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Effective April 1, 2003, a National Coverage Decision expanded the use of HBO therapy to include coverage for the treatment of diabetic wounds of the lower extremities. For specific coverage criteria for HBO Therapy, refer to the National Coverage Determinations Manual, Chapter 1, section 20.29.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

I. Billing Requirements for *A/B MACs (A)*

Claims for HBO therapy should be submitted *using the ASC X12 837 institutional claim format or, in rare cases,* on Form CMS-1450.

a. Applicable Bill Types

The applicable hospital bill types are 11X, 13X and 85X.

b. Procedural Coding

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.

- C1300 – Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.

NOTE: Code C1300 is not available for use other than in a hospital outpatient department. In skilled nursing facilities (SNFs), HBO therapy is part of the SNF PPS payment for beneficiaries in covered Part A stays.

For hospital inpatients and critical access hospitals (CAHs) not electing Method I, HBO therapy is reported under revenue code 940 without any HCPCS code. For inpatient services*, if ICD-9-is applicable,* show ICD-9-CM procedure code 93.59. *If ICD-10 is applicable, show ICD-10-PCS code 5A05121.*

For CAHs electing Method I, HBO therapy is reported under revenue code 940 along with HCPCS code 99183.

c. Payment Requirements for *A/B MACs (A)*

Payment is as follows:

A/B MAC (A) payment is allowed for HBO therapy for diabetic wounds of the lower extremities when performed as a physician service in a hospital outpatient setting and for inpatients. Payment is allowed for claims with valid *diagnosis* codes as shown above with dates of service on or after April 1, 2003. Those claims with invalid codes should be denied as not medically necessary.

For hospitals, payment will be based upon the Ambulatory Payment Classification (APC) or the inpatient Diagnosis Related Group (DRG). Deductible and coinsurance apply.

Payment to Critical Access Hospitals (electing Method I) is made under cost reimbursement. For Critical Access Hospitals electing Method II, the technical component is paid under cost reimbursement and the professional component is paid under the Physician Fee Schedule.

II. *A/B MAC (B)* Billing Requirements

Claims for this service should be submitted *using the ASC X12 837 professional claim format or* Form CMS-1500.

The following HCPCS code applies:

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.

a. Payment Requirements for *A/B MACs (B)*

Payment and pricing information will occur through updates to the Medicare Physician Fee Schedule Database (MPFSDB). Pay for this service on the basis of the MPFSDB. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken, are subject to the Medicare limiting charge.

III. Medicare Summary Notices (MSNs)

Use the following MSN Messages where appropriate:

In situations where the claim is being denied on the basis that the condition does not meet our coverage requirements, use one of the following MSN Messages:

> "Medicare does not pay for this item or service for this condition." (MSN Message 16.48)

The Spanish version of the MSN message should read:

"Medicare no paga por este articulo o servicio para esta afeccion."

In situations where, based on the above utilization policy, medical review of the claim results in a determination that the service is not medically necessary, use the following MSN message:

"The information provided does not support the need for this service or item." (MSN Message 15.4)

The Spanish version of the MSN message should read:

"La informacion proporcionada no confirma la necesidad para este servicio o articulo."

IV. Remittance Advice Notices

Use appropriate existing remittance advice *remark codes* and *claim adjustment* reason codes at the line level to express the specific reason if you deny payment for HBO therapy for the treatment of diabetic wounds of lower extremities.

40.2.2 – Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595)

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Payment is as follows:

- Hospital outpatient departments – OPPS
- Critical access hospital (CAH) - Reasonable cost
- Comprehensive outpatient rehabilitation facility - Medicare physician fee schedule (MPFS)
- Rural health clinics/federally qualified health centers (RHCs/FQHCs) - All inclusive rate, professional component only. The technical component is outside the scope of the RHC/FQHC benefit. Therefore, the provider of that technical service bills their *A/B MAC (B) using the ASC X12 837 professional claim format or* Form CMS-1500 and payment is made under the MPFS. For provider-based RHCs/FQHCs payment for the technical component is made as indicated above based on the type of provider the RHC/FQHC is based with.

Deductible and coinsurance apply.

40.3 – Bill Types

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The applicable bill types for test stimulation procedures are 13X, 71X, 73X, 75X and 85X.

The RHCs and FQHCs bill you under bill type 71X and 73X for the professional component. The technical component is outside the scope of the RHC/FQHC benefit. The provider of that technical service bills their *A/B MAC (B) using the ASC X12 837 professional claim format or the* Form CMS-1500.

The technical component for a provider-based RHC/FQHC is typically furnished by the provider. The provider of that service bills you under bill type 13X, or 85X as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services.) Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for test stimulation procedures.

The applicable bill types for implantation procedures and devices are 11X, 13X, and 85X.

50.4.1 – Allowable Covered Diagnosis Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Deep Brain Stimulation is covered for the following diagnosis codes:

If ICD-9-CM is applicable:

- *ICD-9-CM* 332.0 - Parkinson's disease, with paralysis agitans
- *ICD-9-CM* 333.1 - Essential and other specified forms of tremor

If ICD-10-CM is applicable:

- *ICD-10-CM G20 - Parkinson's Disease*
- *ICD-10-CM G25.0 - Essential tremor*
- *ICD-10-CM G25.2 - Other specified form of tremor*

50.4.2 – Allowable Covered Procedure Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The following procedure codes may be present:

If ICD-9-CM is applicable:

ICD-9-CM 02.93 – Implantation of intracranial neurostimulator, encompasses the component parts of the surgery that include tunneling to protect the wiring and the initial creation of a pocket for the insertion of the electrical unit into the chest wall

ICD-9-CM 86.09 – Other incision of skin and subcutaneous tissue, to reflect the creation of a pocket for the battery device

ICD-9-CM 86.99 – Other operations on skin and subcutaneous tissue, for the tunneling of the wire connectors

IF ICD-10-PCS is applicable:

ICD-10-PCS Code	***Code Description***
00H03MZ	*Insertion of Neurostimulator Lead into Brain, Percutaneous Approach*
00H04MZ	*Insertion of Neurostimulator Lead into Brain, Percutaneous Endoscopic Approach*
00H60MZ	*Insertion of Neurostimulator Lead into Cerebral Ventricle, Open Approach*
00H63MZ	*Insertion of Neurostimulator Lead into Cerebral Ventricle, Percutaneous Approach*
00H64MZ	*Insertion of Neurostimulator Lead into Cerebral Ventricle, Percutaneous Endoscopic Approach*
0H85XZZ	*Division of Chest Skin, External Approach*
0JWT3MZ	*Revision of Stimulator Generator in Trunk Subcutaneous Tissue and*

ICD-10-PCS Code	*Code Description*
	Fascia, Percutaneous Approach
0JWT0MZ	*Revision of Stimulator Generator in Trunk Subcutaneous Tissue and Fascia, Open Approach*
0JQ60ZZ	*Repair Chest Subcutaneous Tissue and Fascia, Open Approach*
0JQ63ZZ	*Repair Chest Subcutaneous Tissue and Fascia, Percutaneous Approach*

Coverage policy may be found in the National Coverage Determinations Manual in Chapter 1, section 160.24: Deep Brain Stimulation, using the following link: (*http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp).*

50.7 – Remittance Advice Notice for *A/B MACs (A)*

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason if you deny payment for DBS. If denying services as furnished before April 1, 2003, use existing *ASC* X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

60.4.1 – Allowable Covered Diagnosis Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

For services furnished on or after July 1, 2002, the applicable ICD-9-CM diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:

- V43.3 (organ or tissue replaced by other means; heart valve),
- 289.81 (primary hypercoagulable state),
- 451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis),
- 453.0-453.3 (other venous embolism & thrombosis),
- 453.40-453.49 (includes 453.40-453.42, *453.6,* 453.8-453.9) (venous embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites),
- 415.11-415.12, 415.19 (pulmonary embolism & infarction), or,
- 427.31 (atrial fibrillation (established) (paroxysmal)).

For services furnished on or after the implementation of ICD-10 the applicable ICD-10-CM diagnosis codes for this benefit are:

Heart Valve Replacement

- *Z95.2 - Presence of prosthetic heart valve*

Primary Hypercoagulable State

ICD-10-CM Code	*Code Description*

ICD-10-CM Code	Code Description
D68.51	Activated protein C resistance
D68.52	Prothrombin gene mutation
D68.59	Other primary thrombophilia
D68.61	Antiphospholipid syndrome
D68.62	Lupus anticoagulant syndrome

Phlebitis & Thrombophlebitis

ICD-10-CM Code	Code Description
I80.00	Phlebitis and thrombophlebitis of superficial vessels of unspecified lower extremity
I80.01	Phlebitis and thrombophlebitis of superficial vessels of right lower extremity
I80.02	Phlebitis and thrombophlebitis of superficial vessels of left lower extremity
I80.03	Phlebitis and thrombophlebitis of superficial vessels of lower extremities, bilateral
I80.10	Phlebitis and thrombophlebitis of unspecified femoral vein
I80.11	Phlebitis and thrombophlebitis of right femoral vein
I80.12	Phlebitis and thrombophlebitis of left femoral vein
I80.13	Phlebitis and thrombophlebitis of femoral vein, bilateral
I80.201	Phlebitis and thrombophlebitis of unspecified deep vessels of right lower extremity
I80.202	Phlebitis and thrombophlebitis of unspecified deep vessels of left lower extremity
I80.203	Phlebitis and thrombophlebitis of unspecified deep vessels of lower extremities, bilateral
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity
I80.221	Phlebitis and thrombophlebitis of right popliteal vein
I80.222	Phlebitis and thrombophlebitis of left popliteal vein
I80.223	Phlebitis and thrombophlebitis of popliteal vein, bilateral
I80.229	Phlebitis and thrombophlebitis of unspecified popliteal vein
I80.231	Phlebitis and thrombophlebitis of right tibial vein
I80.232	Phlebitis and thrombophlebitis of left tibial vein
I80.233	Phlebitis and thrombophlebitis of tibial vein, bilateral
I80.239	Phlebitis and thrombophlebitis of unspecified tibial vein
I80.291	Phlebitis and thrombophlebitis of other deep vessels of right lower extremity
I80.292	Phlebitis and thrombophlebitis of other deep vessels of left lower extremity
I80.293	Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral
I80.299	Phlebitis and thrombophlebitis of other deep vessels of unspecified lower extremity
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified
I80.211	Phlebitis and thrombophlebitis of right iliac vein
I80.212	Phlebitis and thrombophlebitis of left iliac vein
I80.213	Phlebitis and thrombophlebitis of iliac vein, bilateral
I80.219	Phlebitis and thrombophlebitis of unspecified iliac vein
I80.8	Phlebitis and thrombophlebitis of other sites
I80.9	Phlebitis and thrombophlebitis of unspecified site

Other Venous Embolism & Thrombosis

ICD-10-CM Code	***Code Description***
I82.0	*Budd- Chiari syndrome*
I82.1	*Thrombophlebitis migrans*
I82.211	*Chronic embolism and thrombosis of superior vena cava*
I82.220	*Acute embolism and thrombosis of inferior vena cava*
I82.221	*Chronic embolism and thrombosis of inferior vena cava*
I82.291	*Chronic embolism and thrombosis of other thoracic veins*
I82.3	*Embolism and thrombosis of renal vein*

Venous Embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites

ICD-10-CM Code	***Code Description***
I82.401	*Acute embolism and thrombosis of unspecified deep veins of right lower extremity*
I82.402	*Acute embolism and thrombosis of unspecified deep veins of left lower extremity*
I82.403	*Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral*
I82.409	*Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity*
I82.411	*Acute embolism and thrombosis of right femoral vein*
I82.412	*Acute embolism and thrombosis of left femoral vein*
I82.413	*Acute embolism and thrombosis of femoral vein, bilateral*
I82.419	*Acute embolism and thrombosis of unspecified femoral vein*
I82.421	*Acute embolism and thrombosis of right iliac vein*
I82.422	*Acute embolism and thrombosis of left iliac vein*
I82.423	*Acute embolism and thrombosis of iliac vein, bilateral*
I82.429	*Acute embolism and thrombosis of unspecified iliac vein*
I82.431	*Acute embolism and thrombosis of right popliteal vein*
I82.432	*Acute embolism and thrombosis of left popliteal vein*
I82.433	*Acute embolism and thrombosis of popliteal vein, bilateral*
I82.439	*Acute embolism and thrombosis of unspecified popliteal vein*
I82.4Y1	*Acute embolism and thrombosis of unspecified deep veins of right proximal lower extremity*
I82.4Y2	*Acute embolism and thrombosis of unspecified deep veins of left proximal lower extremity*
I82.4Y3	*Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral*
I82.4Y9	*Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity*
I82.441	*Acute embolism and thrombosis of right tibial vein*
I82.442	*Acute embolism and thrombosis of left tibial vein*
I82.443	*Acute embolism and thrombosis of tibial vein, bilateral*
I82.449	*Acute embolism and thrombosis of unspecified tibial vein*
I82.491	*Acute embolism and thrombosis of other specified deep vein of right lower extremity*
I82.492	*Acute embolism and thrombosis of other specified deep vein of left lower extremity*

ICD-10-CM Code	Code Description
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.4Z1	Acute embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.4Z2	Acute embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.4Z3	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
I82.501	Chronic embolism and thrombosis of unspecified deep veins of right lower extremity
I82.502	Chronic embolism and thrombosis of unspecified deep veins of left lower extremity
I82.503	Chronic embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I82.509	Chronic embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.591	Chronic embolism and thrombosis of other specified deep vein of right lower extremity
I82.592	Chronic embolism and thrombosis of other specified deep vein of left lower extremity
I82.593	Chronic embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.599	Chronic embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.511	Chronic embolism and thrombosis of right femoral vein
I82.512	Chronic embolism and thrombosis of left femoral vein
I82.513	Chronic embolism and thrombosis of femoral vein, bilateral
I82.519	Chronic embolism and thrombosis of unspecified femoral vein
I82.521	Chronic embolism and thrombosis of right iliac vein
I82.522	Chronic embolism and thrombosis of left iliac vein
I82.523	Chronic embolism and thrombosis of iliac vein, bilateral
I82.529	Chronic embolism and thrombosis of unspecified iliac vein
I82.531	Chronic embolism and thrombosis of right popliteal vein
I82.532	Chronic embolism and thrombosis of left popliteal vein
I82.533	Chronic embolism and thrombosis of popliteal vein, bilateral
I82.539	Chronic embolism and thrombosis of unspecified popliteal vein
I82.5Y1	Chronic embolism and thrombosis of unspecified deep veins of right proximal lower extremity
I82.5Y2	Chronic embolism and thrombosis of unspecified deep veins of left proximal lower extremity
I82.5Y3	Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral
I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
I82.541	Chronic embolism and thrombosis of right tibial vein
I82.542	Chronic embolism and thrombosis of left tibial vein

ICD-10-CM Code	Code Description
I82.543	Chronic embolism and thrombosis of tibial vein, bilateral
I82.549	Chronic embolism and thrombosis of unspecified tibial vein
I82.5Z1	Chronic embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.5Z2	Chronic embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.5Z3	Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
I82.611	Acute embolism and thrombosis of superficial veins of right upper extremity
I82.612	Acute embolism and thrombosis of superficial veins of left upper extremity
I82.613	Acute embolism and thrombosis of superficial veins of upper extremity, bilateral
I82.619	Acute embolism and thrombosis of superficial veins of unspecified upper extremity
I82.621	Acute embolism and thrombosis of deep veins of right upper extremity
I82.622	Acute embolism and thrombosis of deep veins of left upper extremity
I82.623	Acute embolism and thrombosis of deep veins of upper extremity, bilateral
I82.629	Acute embolism and thrombosis of deep veins of unspecified upper extremity
I82.601	Acute embolism and thrombosis of unspecified veins of right upper extremity
I82.602	Acute embolism and thrombosis of unspecified veins of left upper extremity
I82.603	Acute embolism and thrombosis of unspecified veins of upper extremity, bilateral
I82.609	Acute embolism and thrombosis of unspecified veins of unspecified upper extremity
I82.A11	Acute embolism and thrombosis of right axillary vein
I82.A12	Acute embolism and thrombosis of left axillary vein
I82.A13	Acute embolism and thrombosis of axillary vein, bilateral
I82.A19	Acute embolism and thrombosis of unspecified axillary vein
I82.A21	Chronic embolism and thrombosis of right axillary vein
I82.A22	Chronic embolism and thrombosis of left axillary vein
I82.A23	Chronic embolism and thrombosis of axillary vein, bilateral
I82.A29	Chronic embolism and thrombosis of unspecified axillary vein
I82.B11	Acute embolism and thrombosis of right subclavian vein
I82.B12	Acute embolism and thrombosis of left subclavian vein
I82.B13	Acute embolism and thrombosis of subclavian vein, bilateral
I82.B19	Acute embolism and thrombosis of unspecified subclavian vein
I82.B21	Chronic embolism and thrombosis of right subclavian vein
I82.B22	Chronic embolism and thrombosis of left subclavian vein
I82.B23	Chronic embolism and thrombosis of subclavian vein, bilateral
I82.B29	Chronic embolism and thrombosis of unspecified subclavian vein
I82.C11	Acute embolism and thrombosis of right internal jugular vein
I82.C12	Acute embolism and thrombosis of left internal jugular vein
I82.C13	Acute embolism and thrombosis of internal jugular vein, bilateral
I82.C19	Acute embolism and thrombosis of unspecified internal jugular vein
I82.C21	Chronic embolism and thrombosis of right internal jugular vein
I82.C22	Chronic embolism and thrombosis of left internal jugular vein

ICD-10-CM Code	Code Description
I82.C23	Chronic embolism and thrombosis of internal jugular vein, bilateral
I82.C29	Chronic embolism and thrombosis of unspecified internal jugular vein
I82.210	Acute embolism and thrombosis of superior vena cava
I82.290	Acute embolism and thrombosis of other thoracic veins
I82.701	Chronic embolism and thrombosis of unspecified veins of right upper extremity
I82.702	Chronic embolism and thrombosis of unspecified veins of left upper extremity
I82.703	Chronic embolism and thrombosis of unspecified veins of upper extremity, bilateral
I82.709	Chronic embolism and thrombosis of unspecified veins of unspecified upper extremity
I82.711	Chronic embolism and thrombosis of superficial veins of right upper extremity
I82.712	Chronic embolism and thrombosis of superficial veins of left upper extremity
I82.713	Chronic embolism and thrombosis of superficial veins of upper extremity, bilateral
I82.719	Chronic embolism and thrombosis of superficial veins of unspecified upper extremity
I82.721	Chronic embolism and thrombosis of deep veins of right upper extremity
I82.722	Chronic embolism and thrombosis of deep veins of left upper extremity
I82.723	Chronic embolism and thrombosis of deep veins of upper extremity, bilateral
I82.729	Chronic embolism and thrombosis of deep veins of unspecified upper extremity
I82.811	Embolism and thrombosis of superficial veins of right lower extremities
I82.812	Embolism and thrombosis of superficial veins of left lower extremities
I82.813	Embolism and thrombosis of superficial veins of lower extremities, bilateral
I82.819	Embolism and thrombosis of superficial veins of unspecified lower extremities
I82.890	Acute embolism and thrombosis of other specified veins
I82.891	Chronic embolism and thrombosis of other specified veins
I82.90	Acute embolism and thrombosis of unspecified vein
I82.91	Chronic embolism and thrombosis of unspecified vein

Pulmonary Embolism & Infarction

ICD-10-CM Code	Code Description
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale

Atrial Fibrillation

ICD-10-CM Code	Code Description
I48.0	Paroxysmal atrial fibrillation
I48.2	Chronic atrial fibrillation
I48	-91 Unspecified atrial fibrillation Other
I23.6	Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction

ICD-10-CM Code	*Code Description*
I27.82	*Chronic pulmonary embolism*
I67.6	*Nonpyogenic thrombosis of intracranial venous system*
O22.50	*Cerebral venous thrombosis in pregnancy, unspecified trimester*
O22.51	*Cerebral venous thrombosis in pregnancy, first trimester*
O22.52	*Cerebral venous thrombosis in pregnancy, second trimester*
O22.53	*Cerebral venous thrombosis in pregnancy, third trimester*
O87.3	*Cerebral venous thrombosis in the puerperium*
Z79.01	*Long term (current) use of anticoagulants*

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, section 190.11 PT/INR. (*http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp*

60.5.2 – Applicable Diagnosis Codes for *A/B MACs (B)*

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

For services furnished on or after July 1, 2002, the applicable ICD-9-CM diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:

- V43.3 (organ or tissue replaced by other means; heart valve),
- 289.81 (primary hypercoagulable state),
- 451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis),
- 453.0-453.3 (other venous embolism & thrombosis),
- 453.40-453.49 (includes 453.40-453.42, 453.8-453.9) (venous embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites)
- 415.11-415.12, 415.19 (pulmonary embolism & infarction) or,
- 427.31 (atrial fibrillation (established) (paroxysmal)).

For services furnished on or after implementation of ICD-10 the applicable ICD-10-CM diagnosis codes for this benefit are:

Heart Valve Replacement

- *Z95.2 - Presence of prosthetic heart valve*

Primary Hypercoagulable State

ICD-10-CM Code	*Code Description*
D68.51	*Activated protein C resistance*
D68.52	*Prothrombin gene mutation*
D68.59	*Other primary thrombophilia*

ICD-10-CM Code	Code Description
D68.61	Antiphospholipid syndrome
D68.62	Lupus anticoagulant syndrome

Phlebitis & Thrombophlebitis

ICD-10-CM Code	Code Description
I80.00	Phlebitis and thrombophlebitis of superficial vessels of unspecified lower extremity
I80.01	Phlebitis and thrombophlebitis of superficial vessels of right lower extremity
I80.02	Phlebitis and thrombophlebitis of superficial vessels of left lower extremity
I80.03	Phlebitis and thrombophlebitis of superficial vessels of lower extremities, bilateral
I80.10	Phlebitis and thrombophlebitis of unspecified femoral vein
I80.11	Phlebitis and thrombophlebitis of right femoral vein
I80.12	Phlebitis and thrombophlebitis of left femoral vein
I80.13	Phlebitis and thrombophlebitis of femoral vein, bilateral
I80.201	Phlebitis and thrombophlebitis of unspecified deep vessels of right lower extremity
I80.202	Phlebitis and thrombophlebitis of unspecified deep vessels of left lower extremity
I80.203	Phlebitis and thrombophlebitis of unspecified deep vessels of lower extremities, bilateral
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity
I80.221	Phlebitis and thrombophlebitis of right popliteal vein
I80.222	Phlebitis and thrombophlebitis of left popliteal vein
I80.223	Phlebitis and thrombophlebitis of popliteal vein, bilateral
I80.229	Phlebitis and thrombophlebitis of unspecified popliteal vein
I80.231	Phlebitis and thrombophlebitis of right tibial vein
I80.232	Phlebitis and thrombophlebitis of left tibial vein
I80.233	Phlebitis and thrombophlebitis of tibial vein, bilateral
I80.239	Phlebitis and thrombophlebitis of unspecified tibial vein
I80.291	Phlebitis and thrombophlebitis of other deep vessels of right lower extremity
I80.292	Phlebitis and thrombophlebitis of other deep vessels of left lower extremity
I80.293	Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral
I80.299	Phlebitis and thrombophlebitis of other deep vessels of unspecified lower extremity
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified
I80.211	Phlebitis and thrombophlebitis of right iliac vein
I80.212	Phlebitis and thrombophlebitis of left iliac vein
I80.213	Phlebitis and thrombophlebitis of iliac vein, bilateral
I80.219	Phlebitis and thrombophlebitis of unspecified iliac vein
I80.8	Phlebitis and thrombophlebitis of other sites
I80.9	Phlebitis and thrombophlebitis of unspecified site

Other Venous Embolism & Thrombosis

ICD-10-CM Code	***Code Description***
I82.0	*Budd- Chiari syndrome*
I82.1	*Thrombophlebitis migrans*
I82.211	*Chronic embolism and thrombosis of superior vena cava*
I82220	*Acute embolism and thrombosis of inferior vena cava*
I82.221	*Chronic embolism and thrombosis of inferior vena cava*
I82.291	*Chronic embolism and thrombosis of other thoracic veins*
I82.3	*Embolism and thrombosis of renal vein*

Venous Embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites

ICD-10-CM Code	***Code Description***
I82.401	*Acute embolism and thrombosis of unspecified deep veins of right lower extremity*
I82.402	*Acute embolism and thrombosis of unspecified deep veins of left lower extremity*
I82.403	*Acute embolism and thrombosis of unspecified deep veins of lower extremity, bilateral*
I82. 409	*Acute embolism and thrombosis of unspecified deep veins of unspecified lower extremity*
I82.411	*Acute embolism and thrombosis of right femoral vein*
I82.412	*Acute embolism and thrombosis of left femoral vein*
I82.413	*Acute embolism and thrombosis of femoral vein, bilateral*
I82.419	*Acute embolism and thrombosis of unspecified femoral vein*
I82.421	*Acute embolism and thrombosis of right iliac vein*
I82.422	*Acute embolism and thrombosis of left iliac vein*
I82.423	*Acute embolism and thrombosis of iliac vein, bilateral*
I82.429	*Acute embolism and thrombosis of unspecified iliac vein*
I82.431	*Acute embolism and thrombosis of right popliteal vein*
I82.432	*Acute embolism and thrombosis of left popliteal vein*
I82.433	*Acute embolism and thrombosis of popliteal vein, bilateral*
I82.439	*Acute embolism and thrombosis of unspecified popliteal vein*
I82.4Y1	*Acute embolism and thrombosis of unspecified deep veins of right proximal lower extremity*
I82.4Y2	*Acute embolism and thrombosis of unspecified deep veins of left proximal lower extremity*
I82.4Y3	*Acute embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral*
I82.4Y9	*Acute embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity*
I82.441	*Acute embolism and thrombosis of right tibial vein*
I82.442	*Acute embolism and thrombosis of left tibial vein*
I82.443	*Acute embolism and thrombosis of tibial vein, bilateral*
I82.449	*Acute embolism and thrombosis of unspecified tibial vein*
I82.491	*Acute embolism and thrombosis of other specified deep vein of right lower extremity*

ICD-10-CM Code	Code Description
I82.492	Acute embolism and thrombosis of other specified deep vein of left lower extremity
I82.493	Acute embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.499	Acute embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.4Z1	Acute embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.4Z2	Acute embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.4Z3	Acute embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I82.4Z9	Acute embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
I82.501	Chronic embolism and thrombosis of unspecified deep veins of right lower extremity
I82.502	Chronic embolism and thrombosis of unspecified deep veins of left lower extremity
I82.503	Chronic embolism and thrombosis of unspecified deep veins of lower extremity, bilateral
I82.509	Chronic embolism and thrombosis of unspecified deep veins of unspecified lower extremity
I82.591	Chronic embolism and thrombosis of other specified deep vein of right lower extremity
I82.592	Chronic embolism and thrombosis of other specified deep vein of left lower extremity
I82.593	Chronic embolism and thrombosis of other specified deep vein of lower extremity, bilateral
I82.599	Chronic embolism and thrombosis of other specified deep vein of unspecified lower extremity
I82.511	Chronic embolism and thrombosis of right femoral vein
I82.512	Chronic embolism and thrombosis of left femoral vein
I82.513	Chronic embolism and thrombosis of femoral vein, bilateral
I82.519	Chronic embolism and thrombosis of unspecified femoral vein
I82.521	Chronic embolism and thrombosis of right iliac vein
I82.522	Chronic embolism and thrombosis of left iliac vein
I82.523	Chronic embolism and thrombosis of iliac vein, bilateral
I82.529	Chronic embolism and thrombosis of unspecified iliac vein
I82.531	Chronic embolism and thrombosis of right popliteal vein
I82.532	Chronic embolism and thrombosis of left popliteal vein
I82.533	Chronic embolism and thrombosis of popliteal vein, bilateral
I82.539	Chronic embolism and thrombosis of unspecified popliteal vein
I82.5Y1	Chronic embolism and thrombosis of unspecified deep veins of right proximal lower extremity
I82.5Y2	Chronic embolism and thrombosis of unspecified deep veins of left proximal lower extremity
I82.5Y3	Chronic embolism and thrombosis of unspecified deep veins of proximal lower extremity, bilateral
I82.5Y9	Chronic embolism and thrombosis of unspecified deep veins of unspecified proximal lower extremity
I82.541	Chronic embolism and thrombosis of right tibial vein

ICD-10-CM Code	Code Description
I82.42	Chronic embolism and thrombosis of left tibial vein
I82.543	Chronic embolism and thrombosis of tibial vein, bilateral
I82.549	Chronic embolism and thrombosis of unspecified tibial vein
I82.5Z1	Chronic embolism and thrombosis of unspecified deep veins of right distal lower extremity
I82.5Z2	Chronic embolism and thrombosis of unspecified deep veins of left distal lower extremity
I82.5Z3	Chronic embolism and thrombosis of unspecified deep veins of distal lower extremity, bilateral
I82.5Z9	Chronic embolism and thrombosis of unspecified deep veins of unspecified distal lower extremity
I82.611	Acute embolism and thrombosis of superficial veins of right upper extremity
I82.612	Acute embolism and thrombosis of superficial veins of left upper extremity
I82.613	Acute embolism and thrombosis of superficial veins of upper extremity, bilateral
I82.619	Acute embolism and thrombosis of superficial veins of unspecified upper extremity
I82.621	Acute embolism and thrombosis of deep veins of right upper extremity
I82.622	Acute embolism and thrombosis of deep veins of left upper extremity
I82.623	Acute embolism and thrombosis of deep veins of upper extremity, bilateral
I82.629	Acute embolism and thrombosis of deep veins of unspecified upper extremity
I82.601	Acute embolism and thrombosis of unspecified veins of right upper extremity
I82.602	Acute embolism and thrombosis of unspecified veins of left upper extremity
I82.603	Acute embolism and thrombosis of unspecified veins of upper extremity, bilateral
I82.609	Acute embolism and thrombosis of unspecified veins of unspecified upper extremity
I82.A11	Acute embolism and thrombosis of right axillary vein
I82.A12	Acute embolism and thrombosis of left axillary vein
I82.A13	Acute embolism and thrombosis of axillary vein, bilateral
I82.A19	Acute embolism and thrombosis of unspecified axillary vein
I82.A21	Chronic embolism and thrombosis of right axillary vein
I82.A22	Chronic embolism and thrombosis of left axillary vein
I82.A23	Chronic embolism and thrombosis of axillary vein, bilateral
I82.A29	Chronic embolism and thrombosis of unspecified axillary vein
I82.B11	Acute embolism and thrombosis of right subclavian vein
I82.B12	Acute embolism and thrombosis of left subclavian vein
I82.B13	Acute embolism and thrombosis of subclavian vein, bilateral
I82.B19	Acute embolism and thrombosis of unspecified subclavian vein
I82.B21	Chronic embolism and thrombosis of right subclavian vein
I82.B22	Chronic embolism and thrombosis of left subclavian vein
I82.B23	Chronic embolism and thrombosis of subclavian vein, bilateral
I82.B29	Chronic embolism and thrombosis of unspecified subclavian vein
I82.C11	Acute embolism and thrombosis of right internal jugular vein
I82.C12	Acute embolism and thrombosis of left internal jugular vein
I82.C13	Acute embolism and thrombosis of internal jugular vein, bilateral
I82.C19	Acute embolism and thrombosis of unspecified internal jugular vein
I82.C21	Chronic embolism and thrombosis of right internal jugular vein

ICD-10-CM Code	Code Description
I82.C22	Chronic embolism and thrombosis of left internal jugular vein
I82.C23	Chronic embolism and thrombosis of internal jugular vein, bilateral
I82.C29	Chronic embolism and thrombosis of unspecified internal jugular vein
I82.210	Acute embolism and thrombosis of superior vena cava
I82.290	Acute embolism and thrombosis of other thoracic veins
I82.701	Chronic embolism and thrombosis of unspecified veins of right upper extremity
I82.702	Chronic embolism and thrombosis of unspecified veins of left upper extremity
I82.703	Chronic embolism and thrombosis of unspecified veins of upper extremity, bilateral
I82.709	Chronic embolism and thrombosis of unspecified veins of unspecified upper extremity
I82.711	Chronic embolism and thrombosis of superficial veins of right upper extremity
I82.712	Chronic embolism and thrombosis of superficial veins of left upper extremity
I82.713	Chronic embolism and thrombosis of superficial veins of upper extremity, bilateral
I82.719	Chronic embolism and thrombosis of superficial veins of unspecified upper extremity
I82.721	Chronic embolism and thrombosis of deep veins of right upper extremity
I82.722	Chronic embolism and thrombosis of deep veins of left upper extremity
I82.723	Chronic embolism and thrombosis of deep veins of upper extremity, bilateral
I82.729	Chronic embolism and thrombosis of deep veins of unspecified upper extremity
I82.811	Embolism and thrombosis of superficial veins of right lower extremities
I82.812	Embolism and thrombosis of superficial veins of left lower extremities
I82.813	Embolism and thrombosis of superficial veins of lower extremities, bilateral
I82.819	Embolism and thrombosis of superficial veins of unspecified lower extremities
I82.890	Acute embolism and thrombosis of other specified veins
I82.891	Chronic embolism and thrombosis of other specified veins
I82.90	Acute embolism and thrombosis of unspecified vein
I82.91	Chronic embolism and thrombosis of unspecified vein

Pulmonary Embolism & Infarction

ICD-10-CM Code	Code Description
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale

Atrial Fibrillation

ICD-10-CM Code	Code Description
I48.0	Paroxysmal atrial fibrillation
I48.2	Chronic atrial fibrillation
I48.	-91 Unspecified atrial fibrillation Other

ICD-10-CM Code	***Code Description***
I23.6	*Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction*
I27.82	*Chronic pulmonary embolism*
I67.6	*Nonpyogenic thrombosis of intracranial venous system*
O22.50	*Cerebral venous thrombosis in pregnancy, unspecified trimester*
O22.51	*Cerebral venous thrombosis in pregnancy, first trimester*
O22.52	*Cerebral venous thrombosis in pregnancy, second trimester*
O22.53	*Cerebral venous thrombosis in pregnancy, third trimester*
O87.3	*Cerebral venous thrombosis in the puerperium*
Z79.01	*Long term (current) use of anticoagulants*
Z86.718	*Personal history of other venous thrombosis and embolism*
Z95.4	*Presence of other heart*

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, section 190.11 PT/INR. (*http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp*

60.8.1 – Remittance Advice Notices

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason for denying payment for PT/INR:

Remittance Advice Remark Code N386, "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have Web access, you may contact the contractor to request a copy of the NCD."

If denying services furnished after July 1, 2002, use *ASC* X 12-835 claim adjustment reason code 50, "These are non-covered services because this is not deemed a 'medical necessity' by the payer."

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

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of the Category A IDE device trial, as listed in section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A IDE 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 IDE device.

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category A Device

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under coverage with evidence development (CED). This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Web site when a new study appears in the NLM Clinical Trials data base. This number is

listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry web site at: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html. Providers report the 8-digit number on the following claims locat*ions*:

- *837 professional claim format (do not use 'CT' on the electronic claim); or*
- CMS-1500 paper form-place in Field 19 (preceded by 'CT').

In addition to the clinical trial number, claims shall include:

- *If ICD-9 is applicable,* ICD-9 diagnosis code V70.7
- *If ICD-10 is applicable,* ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)
- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

Claim Adjustment Reason Code (CARC) 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT)."

Remittance Advice Remark Code (RARC) MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code - Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device along with the IDE number.

Effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter O) modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category A IDE number on practitioner claims:

Data	**CMS-1500**	**837 institutional claim format and 837professional claim format**
IDE #	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category A device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: “Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services.”

CARC 16: “Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT).”

68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

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 IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE device and the routine costs associated with its use are eligible for payment under Medicare. (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved.)

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- Appropriate HCPCS modifier:
    - Q0 or Q1 as appropriate for claims with dates of service on or after January 1, 2014; or
    - Q0 (numeral 0 versus the letter O) modifier for claims with dates of service on or after January 1, 2008; or

- QA modifier for claims with dates of service prior to January 1, 2008.

- Category B IDE number

- Charges for the device billed as covered charges

NOTE: If the Category B IDE device is provided at no cost, outpatient prospective payment system (OPPS) providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing 'no cost items' under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:

- *837 professional claim format (do not use 'CT' on the electronic claim) or,*

- CMS-1500 paper form-place in Field 19 (preceded by 'CT').

In addition to the clinical trial number, claims shall include (in either the primary/secondary positions):

- *If ICD-9-CM is applicable,* ICD-9 diagnosis code V70.7

- *If ICD-10-CM is applicable,* ICD-10 diagnosis code Z00.6

- HCPCS modifier Q0 or Q1 as appropriate

Claims submitted without a clinical trial number shall be returned as unprocessable reporting the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter O) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

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

Data	**CMS-1450**	**CMS-1500**	**837 *institutional claim format* and 837 *professional claim format***
IDE #	*Revenue Code Description field*	Item 23	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider using the following messages:

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services."

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT."

69.2 - Payment for Qualifying Clinical Trial Services

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, durable medical equipment fee schedule, reasonable charge, etc.). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

NOTE: Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Web site when a new study appears in the NLM Clinical Trials data base. This number is listed prominently on each specific study's page and is always preceded by the letters "NCT." Contractors verify the validity of a trial/study/registry by consulting CMS's clinical trials/registry web site at: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html.

NOTE: Contractors shall ensure value code 'D4'/amount data from their internal claims processing is mapped/populated to the 837 *institutional claim format* for a coordination of benefits 837 *institutional claim.*

69.6 - Requirements for Billing Routine Costs of Clinical Trials

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Routine Costs Submitted by Practitioners/Suppliers

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier ‘Q1’ (numeral 1 instead of the letter i) ; and,

- *If ICD-9-CM is applicable,* ICD-9 diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis (effective September 19, 2000, diagnosis code V70.7 can be reported as either primary or secondary).

- *If ICD-10-CM is applicable, ICD-10 diagnosis code Z00.6*

CMS covers costs of healthy volunteers in a qualified clinical trial if it meets the following conditions:

- The trial is not designed exclusively to test toxicity or disease pathophysiology.

- The trial must have therapeutic intent.

- If the trial has therapeutic interventions, it must enroll patients with diagnosed disease rather than healthy volunteers.

- If the trial is studying diagnostic interventions, it may enroll healthy patients in order to have a proper control group.

Effective for claims processed after September 28, 2009, with dates of service on or after January 1, 2008, claims submitted with modifier Q1 shall be returned as unprocessable if ICD-9-CM code V70.7 *(if ICD-9 is applicable) or ICD-10-CM code Z00.6 (if ICD-10-CM is applicable)* is not submitted on the claim.

Contractors shall return the following messages:

Claims adjustment Reason Code 16*:* “Claim/service lacks information which is needed for adjudication. As least one Remark Code must be provided (may be comprised of either the Remittance Advice Code or NCPDP Reject Reason Code).”

Remittance Advice Remark Code M76: “Missing/incomplete/invalid diagnosis or condition.”

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** through December 31, 2013. Refer to change request (CR) 5790 for more information regarding the 8-digit number.

Effective for claims with dates of service on or after January 1, 2014 it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Providers report the 8-digit number on the following claims locators:

- *837 professional claim format*-Loop 2300 *REF02 (REF01=P4) (do not use ‘CT’ on the electronic claim); or*

- CMS-1500 paper form-place in Field 19 (preceded by ‘CT’).

In addition to the clinical trial number, claims should include:

- *If ICD-9-CM is applicable,* ICD-9 diagnosis code V70.7

- *If ICD-10-CM is applicable,* ICD-10 diagnosis code Z00.6 (in either the primary/secondary positions)

- HCPCS modifier Q0 or Q1 as appropriate

Practitioner claims submitted without a clinical trial number shall be returned as unprocessable using the following messages:

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: "Missing/incomplete/invalid Investigational Device Exemption number for FDA-approved clinical trial services."

RARC MA130: "Your claim contains incomplete and/or invalid information, and no appeal rights are afforded because the claim is unprocessable. Please submit a new claim with the complete/correct information."

Group Code-Contractual Obligation (CO)

Routine Costs Submitted by Institutional Providers

All Institutional Clinical Trial Claims

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** thru December 31, 2013. Refer to CR 5790 for more information regarding the 8-digit number. To bill the 8-digit clinical trial number, institutional providers shall code value code 'D4'---where the value code amount equals the 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- 837 *institutional claim format*-Loop 2300 *REF02 (REF01=P4)*
- Paper CMS-1450 *value code* 'D4'

NOTE: Effective for claims with dates of service on or after January 1, 2014, it is **mandatory** to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under CED. Institutional claims submitted without a clinical trial number shall be return to providers.

NOTE: The Q1 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 Q1 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 Q1 modifier. When billed in conjunction with the V70.7*/Z00.6* diagnosis code, the Q1 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).

Inpatient Clinical Trial Claims

Institutional providers billing clinical trial service(s) must report ICD-9 diagnosis code V70.7 *if ICD-9 is applicable or, if ICD-10-CM is applicable,* ICD-10 diagnosis code Z006 in either the primary or secondary position and a condition code 30 regardless of whether all services are related to the clinical trial or not.

NOTE: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., Q0/Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

Outpatient Clinical Trial Claims

On all outpatient clinical trial claims, providers need to do the following:

- Report condition code 30,
- Report ICD-9 diagnosis code V70.7*, if ICD-9-CM is applicable,* in the primary or secondary position;
- *Report* ICD-10 diagnosis code Z00.6*, if ICD-10-CM is applicable, in the primary or secondary position;* and
- Identify all lines that contain an investigational item/service with a HCPCS modifier of:
    - Q0 for dates of service on or after 1/1/08
- Identify all lines that contain a routine service with a HCPCS modifier of:
    - Q1 for dates of service on or after 1/1/08.

For clinical trial billing requirements for patients enrolled in a managed care plan, please refer to Section 69.9 of this chapter.

70.4 - Special Billing and Payment Requirements for *A/B MACs (A)*

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

If ICD-9-CM is applicable, this procedure (ICD-9-CM procedure code 52.85-*allotransplantation* of *cells of Islets of Langerhans*) is covered for the clinical trial in an inpatient hospital setting. *If ICD-10 is applicable, ICD-10-PCS codes for the clinical trial are:*

ICD-10-PCS Code	***Code Description***
3E030U1	*Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach*
3E033U1	*Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach*
3E0J3U1	*Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Percutaneous Approach*
3E0J7U1	*Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening*
3E0J8U1	*Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening Endoscopic*

The applicable TOB is 11X. A secondary diagnoses (diagnoses positions 2 – 9) of *ICD-9-CM code* V70.7 (examination of participant or control in clinical research) must be present along with condition code 30 (qualifying clinical trial) *if ICD-9 is applicable*. *If ICD-10-CM is applicable, the ICD-10-CM secondary diagnosis code of Z00.6 (examination of participant or control in clinical research) must be present along with condition code 30 (qualifying clinical trial).* V70.7 *or Z00.6* and condition code 30 alerts the claims

processing system that this is a clinical trial. The procedure is paid under inpatient prospective payment system for hospitals with patients in the trial. Deductible and coinsurance apply for fee-for-service beneficiaries.

Inpatient hospitals participating in this trial are entitled to an add-on payment of $18,848.00 for islet isolation services. This amount is in addition to the final IPPS payment made to the hospital. Should two infusions occur during the same hospital stay, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay.

Inpatient hospitals shall report charges for organ acquisition in Revenue Code 0810, 0811, 0812, 0813, or 0819. This includes charges for the pre-transplant items and services related to the acquisition and delivery of the pancreatic islet cell transplants. As is Medicare's policy with other organ transplants, Medicare contractors deduct acquisition charges prior to processing through the IPPS Pricer. Pancreata procured for islet cell transplant are not included in the prospective payment. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation follow up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

All other normal inpatient billing practices apply.

80.3 - Diagnosis Codes

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Diagnosis Codes.--Providers should report one of the following diagnosis codes in conjunction with this benefit:

- *If ICD-9-CM is applicable* - 250.60, 250.61, 250.62, 250.63, and 357.2.

- *If ICD-10-CM is applicable - E08.40, E0.842, E09.40, E09.42, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.610, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.610, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.610*

Coverage policy can be found *in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, section 70.2.1 Diabetic neuropathy w/ LOPs.*
(*http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp*

80.6 - Editing Instructions for *A/B MACs (A)*

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Edit 1 - Implement diagnosis to procedure code edits to allow payment only for the LOPS codes, G0245, G0246, and G0247 when submitted with one of the *following* diagnosis codes

- *If ICD-9-CM is applicable:* 250.60, 250.61, 250.62, 250.63, or 357.2.

- *If ICD-10-CM is applicable: E08.40, E08.42, E09.40, E09.42, E10.40, E10.41, E10.42, E10.43, E10.44, E10.49, E10.610, E11.40, E11.41, E11.42, E11.43, E11.44, E11.49, E11.610, E13.40, E13.41, E13.42, E13.43, E13.44, E13.49, E13.610*

Deny these services when submitted without one of the appropriate diagnoses.

Use the same messages you currently use for procedure to diagnosis code denials.

Edit 2 – Deny G0247 if it is not submitted on the same claim as G0245 or G0246.

Use MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.
Use RA claim adjustment reason code 107 - *The related or qualifying claim/service was not identified on this claim. NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.*

90 - Stem Cell Transplantation

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplantation (AuSCT) must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. See Pub. 100-03, National Coverage Determinations Manual, section 110.8.1, for a complete description of covered and noncovered conditions. For Part A hospital inpatient claims processing instructions, refer to Pub. 100-04, Chapter 3, section 90.3. The following sections contain claims processing instructions for *all other* claims.

90.2 - HCPCS and Diagnosis Coding – *ICD-9-CM Applicable*

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Allogeneic Stem Cell Transplantation

- Effective for services performed on or after August 1, 1978:
    - For the treatment of leukemia or leukemia in remission, providers shall use ICD-9-CM codes 204.00 through 208.91 and HCPCS code 38240.
    - For the treatment of aplastic anemia, providers shall use ICD-9-CM codes 284.0 through 284.9 and HCPCS code 38240.
- Effective for services performed on or after June 3, 1985:
    - For the treatment of severe combined immunodeficiency disease, providers shall use ICD-9-CM code 279.2 and HCPCS code 38240.
    - For the treatment of Wiskott-Aldrich syndrome, providers shall use ICD-9-CM code 279.12 and HCPCS code 38240.
- Effective for services performed on or after May 24, 1996:

- Allogeneic stem cell transplantation, HCPCS code 38240 is not covered as treatment for the diagnosis of multiple myeloma ICD-9-CM codes 203.00 or 203.01.

Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services performed on or after April 28, 1989:

- For the treatment of patients with acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA) matched, providers shall use ICD-9-CM code 204.01 lymphoid; ICD-9-CM code 205.01 myeloid; ICD-9-CM code 206.01 monocytic; or ICD-9-CM code 207.01 acute erythremia and erythroleukemia; or ICD-9-CM code 208.01 unspecified cell type and HCPCS code 38241.

- For the treatment of resistant non-Hodgkin's lymphomas for those patients presenting with poor prognostic features following an initial response, providers shall use ICD-9-CM codes 200.00 - 200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88 or 202.90-202.98 and HCPCS code 38241.

- For the treatment of recurrent or refractory neuroblastoma, providers shall use ICD-9-CM codes Neoplasm by site, malignant, the appropriate HCPCS code and HCPCS code 38241.

- For the treatment of advanced Hodgkin's disease for patients who have failed conventional therapy and have no HLA-matched donor, providers shall use ICD-9-CM codes 201.00 - 201.98 and HCPCS code **38241.**

Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services furnished on or after October 1, 2000:

- For the treatment of multiple myeloma (only for beneficiaries who are less than age 78, have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma, and have adequate cardiac, renal, pulmonary and hepatic functioning), providers shall use ICD- 9-CM code 203.00 or 238.6 and HCPCS code 38241.

- For the treatment of recurrent or refractory neuroblastoma, providers shall use appropriate code (see ICD-9-CM neoplasm by site, malignant) and HCPCS code 38241.

- Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan (HDM) together with autologous stem cell transplantation (HDM/AuSCT) is reasonable and necessary for Medicare beneficiaries of any age group for the treatment of primary amyloid light chain (AL) amyloidosis, ICD-9-CM code 277.3 who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and,

- Cardiac left ventricular ejection fraction (EF) greater than 45%.

90.2.1 - HCPCS and Diagnosis Coding for Stem Cell Transplantation - ICD-10-CM Applicable

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

ICD-10 is applicable to services on and after the implementation of ICD-.

For services provided use the appropriate code from the ICD-10 CM codes in the table below.. See §90.2 for a list of covered conditions

ICD-10	***Description***
C91.01	*Acute lymphoblastic leukemia, in remission*
C91.11	*Chronic lymphocytic leukemia of B-cell type in remission*
C91.31	*Prolymphocytic leukemia of B-cell type, in remission*
C91.51	*Adult T-cell lymphoma/leukemia (HTLV-1-associated), in remission*
C91.61	*Prolymphocytic leukemia of T-cell type, in remission*
C91.91	*Lymphoid leukemia, unspecified, in remission*
C91.A1	*Mature B-cell leukemia Burkitt-type, in remission*
C91.Z1	*Other lymphoid leukemia, in remission*
C92.01	*Acute myeloblastic leukemia, in remission*
C92.11	*Chronic myeloid leukemia, BCR/ABL-positive, in remission*
C92.21	*Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission*
C92.31	*Myeloid sarcoma, in remission*
C92.41	*Acute promyelocytic leukemia, in remission*
C92.51	*Acute myelomonocytic leukemia, in remission*
C92.61	*Acute myeloid leukemia with 11q23-abnormality in remission*
C92.91	*Myeloid leukemia, unspecified in remission*
C92.A1	*Acute myeloid leukemia with multilineage dysplasia, in remission*
C92.Z1	*Other myeloid leukemia, in remission*
C93.01	*Acute monoblastic/monocytic leukemia, in remission*
C93.11	*Chronic myelomonocytic leukemia, in remission*
C93.31	*Juvenile myelomonocytic leukemia, in remission*
C93.91	*Monocytic leukemia, unspecified in remission*
C93.91	*Monocytic leukemia, unspecified in remission*
C93.Z1	*Other monocytic leukemia, in remission*
C94.01	*Acute erythroid leukemia, in remission*
C94.21	*Acute megakaryoblastic leukemia, in remission*
C94.31	*Mast cell leukemia, in remission*
C94.81	*Other specified leukemias, in remission*
C95.01	*Acute leukemia of unspecified cell type, in remission*
C95.11	*Chronic leukemia of unspecified cell type, in remission*
C95.91	*Leukemia, unspecified, in remission*
D45	*Polycythemia vera*
D61.01	*Constitutional (pure) red blood cell aplasia*
D61.09	*Other constitutional aplastic anemia*
D82.0	*Wiskott-Aldrich syndrome*
D81.0	*Severe combined immunodeficiency [SCID] with reticular dysgenesis*
D81.1	*Severe combined immunodeficiency [SCID] with low T- and B-cell numbers*
D81.2	*Severe combined immunodeficiency [SCID] with low or normal B-cell numbers*
D81.6	*Major histocompatibility complex class I deficiency*

ICD-10	***Description***
D81.7	*Major histocompatibility complex class II deficiency*
D81.89	*Other combined immunodeficiencies*
D81.9	*Combined immunodeficiency, unspecified*
D81.2	*Severe combined immunodeficiency [SCID] with low or normal B-cell numbers*
D81.6	*Major histocompatibility complex class I deficiency*
D60.0	*Chronic acquired pure red cell aplasia*
D60.1	*Transient acquired pure red cell aplasia*
D60.8	*Other acquired pure red cell aplasias*
D60.9	*Acquired pure red cell aplasia, unspecified*
D61.01	*Constitutional (pure) red blood cell aplasia*
D61.09	*Other constitutional aplastic anemia*
D61.1	*Drug-induced aplastic anemia*
D61.2	*Aplastic anemia due to other external agents*
D61.3	*Idiopathic aplastic anemia*
D61.810	*Antineoplastic chemotherapy induced pancytopenia*
D61.811	*Other drug-induced pancytopenia*
D61.818	*Other pancytopenia*
D61.82	*Myelophthisis*
D61.89	*Other specified aplastic anemias and other bone marrow failure syndromes*
D61.9	*Aplastic anemia, unspecified*

If ICD-10-CM is applicable, the following ranges of ICD-10-CM codes are also covered for AuSCT:

- *Resistant non-Hodgkin's lymphomas, ICD-10-CM diagnosis codes C82.00-C85.29, C85.80-C86.6, C96.4, and C96.Z-C96.9.*

- *Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma, ICD-10-CM codes C90.00 and D47.Z9*

***NOTE**: The following conditions are not covered:*
- *Acute leukemia not in remission*
- *Chronic granulocytic leukemia*
- *Solid tumors (other than neuroblastoma)*
- *Multiple myeloma*
- *For Medicare beneficiaries age 64 or older, all forms of amyloidosis, primary and non-primary*
- *Non-primary amyloidosis*

Also coverage for conditions other than those specifically designated as covered in §90.2 or specifically designated as non-covered in this section or in §90.3will be at the discretion of the individual contractor.

90.3 - Non-Covered Conditions

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Autologous stem cell transplantation is not covered for the following conditions:

- Acute leukemia not in remission (*If ICD-9-CM is applicable,* ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00) *or (If ICD-10-CM is applicable, ICD-10-CM codes C91.00, C92.00, C93.00, C94.00, and C95.00)*

- Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11 *if ICD-9-CM is applicable*) *or (if ICD-10-CM is applicable, ICD-10-CM codes C92.10 and C92.11);*

- Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0 through 199.1 *if ICD-9-CM is applicable or if ICD-10-CM is applicable, ICD-10-CM codes C00.0 – C80.2 and D00.0 – D09.9.)*

- Effective for services rendered on or after May 24, 1996 through September 30, 2000, multiple myeloma (ICD-9-CM code 203.00 and 203.01 *if ICD-9-CM is applicable or if ICD-10-CM is applicable, ICD-10-CM codes C90.00 and D47.Z9);*

- Effective for services on or after October 1, 2000, through March 14, 2005, for Medicare beneficiaries age 64 or older, all forms of amyloidosis, primary and non-primary

- Effective for services on or after 10/01/00, for all Medicare beneficiaries, non-primary amyloidosis

ICD-9-CM codes	***Description***	***ICD-10-CM codes***	***Description***
277.30	*Amyloidosis, unspecified*	*E85.9*	*Amyloidosis, unspecified*
277.31	*Familial Mediterranean fever*	*E85.0*	*Non-neuropathic heredofamilial amyloidosis*
277.39	*Other amyloidosis*	*E85.1*	*Neuropathic heredofamilial amyloidosis*
277.39	*Other amyloidosis*	*E85.2*	*Heredofamilial amyloidosis, unspecified*
277.39	*Other amyloidosis*	*E85.3*	*Secondary systemic amyloidosis*
277.39	*Other amyloidosis*	*E85.4*	*Organ-limited amyloidosis*
277.39	*Other amyloidosis*	*E85.8*	*Other amyloidosis*

NOTE: Coverage for conditions other than those specifically designated as covered in 90.2 *or 90.2.1* or specifically designated as non-covered in this section will be at the discretion of the individual *A/B MAC (B)*.

90.4 - Edits

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

NOTE: Coverage for conditions other than those specifically designated as covered in 80.2 or specifically designated as non-covered in this section will be at the discretion of the individual *A/B MAC (B)*.

Appropriate diagnosis to procedure code edits should be implemented for the *non*-covered conditions and services in 90.2 *90.2.1, and 90.3 as applicable*

As the ICD-9-CM code 277.3 for amyloidosis does not differentiate between primary and non-primary, *A/B MACs (B)* should perform prepay reviews on all claims with a diagnosis of ICD-9-CM code 277.3 and a HCPCS procedure code of 38241 to determine whether payment is appropriate.

If ICD-10-CM is applicable, the applicable ICD-10 CM codes are: E85.0, E85.1, E85.2, E85.3, E85.4, E85.8, and E85.9.

90.6 - Clinical Trials for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A. Background

Myelodysplastic Syndrome (MDS) refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and cytogenetics.

On August 4, 2010, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination (NCD) stating that CMS believes that the evidence does not demonstrate that the use of allogeneic hematopoietic stem cell transplantation (HSCT) improves health outcomes in Medicare beneficiaries with MDS. Therefore, allogeneic HSCT for MDS is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act). However, allogeneic HSCT for MDS is reasonable and necessary under §1862(a)(1)(E) of the Act and therefore covered by Medicare ONLY if provided pursuant to a Medicare-approved clinical study under Coverage with Evidence Development (CED). Refer to Pub.100-03, NCD Manual, Chapter 1, section 110.8.1, for more information about this policy, and Pub. 100-04, MCP Manual, Chapter 3, section 90.3.1, for information on CED.

B. Adjudication Requirements

Payable Conditions. For claims with dates of service on and after August 4, 2010, contractors shall pay for claims for HSCT for MDS when the service was provided pursuant to a Medicare-approved clinical study under CED; these services are paid only in the inpatient setting (Type of Bill (TOB) 11X), as outpatient Part B (TOB 13X), and in Method II critical access hospitals (TOB 85X). Contractors shall require the following coding in order to pay for these claims:

- Existing Medicare-approved clinical trial coding conventions, as required in Pub. 100-04, MCP Manual, Chapter 32, section 69, and inpatient billing requirements regarding acquisition of stem cells in Pub. 100-04, MCP Manual, Chapter 3, section 90.3.3.

- *If ICD-9-CM is applicable, for* Inpatient Hospital Claims: ICD-9-CM procedure codes 41.02, 41.03, 41.05, and 41.08 *or,*

- *If ICD-10-CM is applicable, ICD-10-PCS, procedure codes 30230G1, 30230Y1, 3023G1, 30233Y1, 30240G1, 30240Y1, 30243G1, 30243Y1, 30250G1,30250Y1, 30253G1, 30253Y1, 30260G1, 30260Y1, 30263G1, and 30263Y1*

- *If* Outpatient Hospital or Professional Claims: *HCPCS* procedure code 38240

- *If ICD-9-CM is applicable,* ICD-9-CM diagnosis code 238.75 *or*

- *If ICD-10-CM is applicable, ICD-10-CM diagnosis codes D46.9, D46.Z, or Z00.6*

- *Professional claims only: place of service codes 21 or 22.*

Denials. Contractors shall deny claims failing to meet any of the above criteria. In addition, contractors shall apply the following requirements:

- Providers shall issue a hospital issued notice of non-coverage (HINN) or advance beneficiary notice (ABN) to the beneficiary if the services performed are not provided in accordance with CED.

- Contractors shall deny claims that do not meet the criteria for coverage with the following messages:

CARC 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer.

NOTE: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.

Group Code – Patient Responsibility (PR) if HINN/ABN issued, otherwise Contractual Obligation (CO)

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

100.1.2 – Special Billing Requirements for *A/B MACs (A)* for Inpatient Billing

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

- The second or subsequent diagnosis code must be *(ICD-9CM)* V70.7 (examination of participant or control in clinical research) *if ICD-9-CM is applicable, or, if ICD-10-CM is applicable, (ICD-10-CM) Z00.6 (Encounter for exam for normal comparison and control in clinical research program). These diagnoses* alert the claims processing system that this is a clinical trial.

For inpatient Part B and outpatient bills:

- For patients in an approved clinical trial with hearing test scores greater than 40% to less than or equal to 60% hearing, the QR modifier must be reported with the cochlear implantation device and all other related costs or; (see note below)

- For patients in an approved clinical trial under the clinical trial policy with hearing test scores greater than 60% hearing, the QV modifier must be billed for routine costs.

NOTE: The QR or QV modifier does not need to be applied to HCPCS 92601-92604 or any applicable audiology codes.

160.2.1 – Carotid Artery Stenting (CAS) Post-Approval Extension Studies

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A. Background

As the post-approval studies began to end, CMS received requests to extend coverage for the post-approval studies. CMS has reviewed the extension requests and has determined that patients participating in post-approval extension studies are also included in the currently covered population of patients participating in FDA-approved post-approval studies.

B. Policy

To grant approval for post-approval studies, the FDA reviews each study protocol. Once approval is granted, the FDA issues a formal approval letter to the study sponsor. Extensions of post-approval studies are not

subject to approval by the FDA because they surpass the post-approval study requirements identified in the conditions of approval for post-approval studies. Since the FDA cannot approve these extension studies, individual Post-Market Approval (PMA) numbers cannot be issued to separately identify each study. Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study.

CMS has determined that all extension studies must be reviewed by the FDA. The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since an individual PMA number cannot be assigned by the FDA to each extension study, these studies will use the PMA number assigned to the original FDA-approved post-approval study (i.e., CAPTURE 2 shall use the PMA number assigned to CAPTURE 1).

C. Billing

In order to receive Medicare coverage for patients participating in post-approval extension studies, providers shall submit both the FDA acknowledgement letter and the CMS letter providing coverage for the extension study to their contractor. Additionally, providers shall submit any other materials contractors would require for FDA-approved post-approval studies.

In response, contractors will issue a letter assigning an effective date for each facility's participation in the extension study. Providers may bill for procedures performed in the extension study for dates of service on and after the assigned effective date. Providers billing *A/B MACs (A)* must bill using the most current ICD-9 CM *if ICD-9-CM is applicable, or, if ICD-10-CM is applicable, ICD-10-PCS codes 037G34Z, 037G3DZ, 037G3ZZ, 037G44Z, 037G4DZ, 037G4ZZ, 03CG3ZZ, 057L3DZ, 057L4DZ & 05CL3ZZ* procedure codes *may be used.*

161 - Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

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 *for the date of service* to receive payment. *That is,* under Part A, providers must bill intracranial PTA using *ICD-9-CM* procedure codes 00.62 and 00.65*, if ICD-9-CM is applicable, or, if ICD-10-PCS is applicable, ICD-10-PCS procedure codes 037G34Z, 037G3DZ, 037G3ZZ, 037G44Z, 037G4DZ,*

037G4ZZ, 03CG3ZZ, 057L3DZ, 057L4DZ and 05CL3ZZ. ICD-9-CM diagnosis code 437.0 or ICD-10-CM diagnosis code 167.2applies, depending on the date of service.

Under Part B, providers must bill HCPCS procedure code 37799. *If ICD-9-CM is applicable ,ICD-9-CM diagnosis code 437.0 or if ICD-10-CM is applicable,ICD-10-CM diagnosis code 167.2applies.*

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

170.3 - *A/B MAC (A)* Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The A/B MAC *(A)* will pay for LADR when approved under the IDE/clinical trial criteria only when submitted with ICD-9-CM procedure code 84.65 *if ICD-9 is applicable,* with condition code 30 and *if ICD-9-CM is applicable,* ICD-9-CM diagnosis code V70.7 when submitted on type of bill (TOB) 11X from May 16, 2006 through August 13, 2007.

Special Billing instructions:

For services performed on TOB 11X in critical access hospitals (CAH), the payment will be 101% of reasonable cost.

For services performed on TOB 11X Indian Health Services (IHS) inpatient hospitals will pay under the inpatient prospective payment system (IPPS) based on the DRG.

For services performed on TOB 11X, IHS CAHs will pay under 101% facility specific per diem rate.

NOTE: *The* ICD-9-CM procedure code 84.65 is *not* payable for beneficiaries over 60 years of age, with the Charite™ lumbar artificial disc, which is the only one that is FDA approved for any diagnosis. If a different manufacture's disc is used in *an* approved clinical trials or is an approved IDE, then condition code 30 and *ICD-9-CM* diagnosis code V70.7 must be on the claim for it to be payable.

Effective for discharges on or after August 14, 2007, CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age as identified *in* section 150.10, of Pub.100-03, the NCD Manual. A/B MACS *(A)* shall deny claims with ICD-9-CM procedure code 84.65 for Medicare beneficiaries over 60 years of age.

For Medicare beneficiaries 60 years of age and younger, there is no NCD, leaving such determinations to continue to be made by the local contractors.

180.2 - Billing Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Claims for cryosurgery for the prostate gland are to be submitted on the ASC X12 837, or, in exceptional circumstances, on a hard copy Form CMS – 1450. This procedure can be rendered in an inpatient or outpatient hospital setting (types of bill (TOBs) 11x 13x, 83x, and 85x).

The *A/B MAC (A)* will look for the following when processing claims with cryosurgery services:

- *If ICD-9-CM is applicable, ICD-9 CM d*iagnosis code 185 *or*
- *If ICD-10-CM is applicable, ICD-10 CM diagnosis code C61* must be on all cryosurgical claims;

- For outpatient claims HCPCS 55873 and revenue codes 0360, 0361, or 0369 Cryosurgery ablation of localized prostate cancer, stages T1- T3 (includes ultrasonic guidance for interstitial cryosurgery probe placement, postoperative irrigations and aspiration of sloughing tissue included) must be on all outpatient claims; and

- For inpatient claims *correct procedure codes are:*

    - *If ICD-9-CM is applicable,* ICD-9-CM procedure code 60.62 (perineal prostatectomy- the definition includes cryoablation of prostate, cryostatectomy of prostate, and radical cryosurgical ablation of prostate)

    - *If ICD-10 is applicable,ICD-10-PCS procedure code 0V500ZZ (Destruction of Prostate, Open Approach), or 0V503ZZ (Destruction of Prostate, Percutaneous Approach), or 0V504ZZ (Destruction of Prostate, Percutaneous Endoscopic Approach).*

190.2 – Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The following HCPCS procedure code is used for billing extracorporeal photopheresis

- 36522 - Photopheresis, extracorporeal

The following are the applicable *ICD-9-CM* diagnosis codes for the new expanded coverage:

- 996.83 - Complications of transplanted heart, or

- 996.85 - Complications of transplanted bone marrow

Effective for services for BOS following lung allograft transplantation the following is a list of applicable ICD-9-CM diagnosis codes:

- 996.84 - Complications of transplanted lung
- 491.9 - Unspecified chronic bronchitis
- 491.20 - Obstructive chronic bronchitis without exacerbation
- 491.21 - Obstructive chronic bronchitis with (acute) exacerbation
- 496 - Chronic airway obstruction, not elsewhere classified

The following is the applicable *ICD-9-CM* procedure code for the new expanded coverage:

- 99.88 - Therapeutic photopheresis.

If ICD-10 is applicable, use the ICD-10-CM diagnosis codes

ICD-9-CM CODE	LONG DESCRIPTION	ICD-10-CM CODE	LONG DESCRIPTION
491.20	Obstructive chronic bronchitis without exacerbation	J44.9	Chronic obstructive pulmonary disease, unspecified
491.21	Obstructive chronic bronchitis with (acute) exacerbation	J44.	Chronic obstructive pulmonary disease with (acute) exacerbation
491.9	Unspecified chronic bronchitis	J42	Unspecified chronic bronchitis

496	Chronic airway obstruction, not elsewhere classified	J44.9	Chronic obstructive pulmonary disease, unspecified
996.84	Complications of transplanted lung	T86.810	Lung transplant rejection
996.84	Complications of transplanted lung	T86.811	Lung transplant failure
996.84	Complications of transplanted lung	T86.812	Lung transplant infection (not recommended for ECP coverage)
ICD-9-CM CODE	LONG DESCRIPTION	ICD-10-CM CODE	LONG DESCRIPTION
996.84	Complications of transplanted lung	T86.818	Other complications of lung transplant
996.84	Complications of transplanted lung	T86.819	Unspecified complication of lung transplant
V70.7	Examination of participant in clinical trial	Z00.6	Encounter for examination for normal comparison and control in clinical research program (needed for CED)

NOTE: Contractors shall edit for an appropriate oncological and autoimmune disorder diagnosis for payment of extracorporeal photopheresis according to the National Coverage Determination

Effective for claims with dates of service on or after April 30, 2012, in addition to HCPCS 36522, the following ICD-*9*-CM/ICD-10-*CM* codes are applicable for extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation only with ECP is provided under a clinical research study as outlined in Section 190 above:

A reference listing of ICD-9 CM and ICD-10-*CM diagnosis* coding and descriptions is listed *above.*

Providers must also report modifier Q0 - (Investigational clinical service provided in a clinical research study that is in an approved research study) on these claims. *Providers* must use *ICD-9-CM* diagnosis code V70.7 *if ICD-9 is applicable* and condition code 30 (*A/B MACs (A)* only) for these claims. *If ICD-10 is applicable, providers must use ICD-10-CM diagnosis code Z00.6*

200.2 - Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

One of the following diagnosis codes must be reported, as appropriate, when billing for Vagus Nerve Stimulation:

If ICD-9-CM is applicable:

- 345.41 Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures with intractable epilepsy, *or,*

- 345.51 Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures with intractable epilepsy

If ICD-10-CM is applicable:

- *G40.011 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, with status epileptic*
- *G40.019 Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable, without status epilepticus*
- *G40.111 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, with status epilepticus*
- *G40.119 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable, without status epilepticus*
- *G40.211 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, with status epilepticus*
- *G40.219 Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable, without status epilepticus*

230 – Billing Wrong Surgical or Other Invasive Procedures Performed on a Patient, Surgical or Other Invasive Procedures Performed on the Wrong Body Part, and Surgical or Other Invasive Procedures Performed on the Wrong Patient

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The Centers for Medicare & Medicaid Services (CMS) internally generated a request for a national coverage analysis (NCA) to establish national coverage determinations (NCDs) addressing Medicare coverage of Wrong Surgical or Other Invasive Procedures Performed on a Patient, Surgical or Other Invasive Procedures Performed on the Wrong Body Part, and Surgical or Other Invasive Procedures Performed on the Wrong Patient. Information regarding these NCDs can be found in Publication (Pub.) 100-03, Chapter 1, sections 140.6, 140.7, and 140.8, respectively.

Inpatient Claims

Hospitals are required to bill two claims when a surgical error is reported and a covered service is also being reported:

- One claim with covered service(s)/procedure(s) unrelated to the erroneous surgery(s) on a Type of Bill (TOB) 11X (with the exception of 110), and
- The other claim with the non-covered service(s)/procedure(s) related to the erroneous surgery(s) on a TOB 110 (no-pay claim)

NOTE: Both the covered and non-covered claim shall have a matching Statement Covers Period.

For discharges prior to October 1, 2009, the non-covered TOB 110 must indicate on the 837 *institutional claim format*, *or* in *the Remarks field* of the *Form* CMS1450 one of the applicable erroneous surgery(s) two-digit codes (entered exactly as specified below):

- For a wrong surgery on patient, enter the following: **MX**
- For a surgery on a wrong body part, enter the following: **MY**
- For a surgery on wrong patient, enter the following: **MZ**

For discharges on or after October 1, 2009, the non-covered TOB 110 must have one of the following diagnosis code*s* reported in diagnosis position 2-9, instead of billing the aforementioned two-digit codes in Remarks:

If ICD-9-CM Is Applicable

- **E876.5** - Performance of wrong operation (procedure) on correct patient (existing code)
- **E876.6** - Performance of operation (procedure) on patient not scheduled for surgery
- **E876.7**- Performance of correct operation (procedure) on wrong side/body part

NOTE: The above codes shall not be reported in the External Cause of Injury (E-code) field.

If ICD-10-CM Is Applicable

- *Y65.51 Performance of wrong procedure (operation) on correct patient*
- *Y65.52 Performance of procedure (operation) on patient not scheduled for surgery*
- *Y65.53 Performance of correct procedure (operation) on wrong side of body parts*

Outpatient, Ambulatory Surgical Centers, and Practitioner Claims

Providers are required to append one of the following applicable HCPCS modifiers to all lines related to the erroneous surgery(s):

- PA: Surgery Wrong Body Part
- PB: Surgery Wrong Patient
- PC: Wrong Surgery on Patient

All claims

Claim/Lines submitted with a surgical error will be denied/line-item denied using the following:

Medicare Summary Notice
23.17 – Medicare won't cover these services because they are not considered medically necessary."
23.17 – Medicare no cubrirá estos servicios porque no son considerados necesarios por razones médicas.

Claim Adjustment Reason Code
CARC 50 – These are non-covered services because this is not deemed a 'medical necessity" by the payer.

Group Code
CO – Contractual Obligation

Beneficiary Liability

Generally, beneficiary liability notices such an Advance Beneficiary Notice of Non-coverage (ABN) or a Hospital Issued Notice of Non-coverage (HINN) is appropriate when a provider is furnishing an item or service that the provider reasonably believes Medicare will not cover on the basis of §1862(a)(1). An ABN must include all of the elements described in Pub. 100-04, Claims Processing Manual (CPM), Ch. 30, §50.6.3, in order to be considered valid. For example, the ABN must specifically describe the item or service expected to be denied (e.g. a left leg amputation) and must include a cost estimate for the non-covered item or service. Similarly, HINNs must specifically describe the item or service expected to be denied (e.g. a left leg amputation) and must include all of the elements described in the instructions found in the CPM Ch. 3,0 §200. Thus, a provider cannot shift financial liability for the non-covered services to the beneficiary, unless the ABN or the HINN satisfies all of the applicable requirements in the CPM Ch. 30, §50.6.3 and §200, respectively. Given these requirements, CMS cannot envision a scenario in which HINNs or ABNs could be validly delivered in these NCD cases. However, an ABN or a HINN could be validly delivered prior to furnishing services related to the follow-up care for the non-covered surgical error that would not be considered a related service to the non-covered surgical error.

250.3 – Payment Requirements

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Beginning April 5, 2010, for claims with dates of service on and after August 3, 2009, the Medicare Shared System will track the number of times a beneficiary receives pharmacogenomic testing for warfarin response. When a claim is received for pharmacogenomic testing for warfarin response, and the shared system has determined that the beneficiary has already received the test in his/her lifetime, it will generate a Medicare line-item denial and the Medicare contractor will provide the following messages to enforce the one-time limitation for the test:

Claim Adjustment Reason Code (CARC) 50 – These are non-covered services because this is not deemed a 'medical necessity' by the payer. This change to be effective April 1, 2010: These are non-covered services because this is not deemed a 'medical necessity' by the payer.

NOTE: Refer to the 835 Healthcare Policy Identification Segment, if present.

Remittance Advice Remark Code (RARC) N362 – The number of Days or Units of Service exceeds our acceptable maximum.

Group Code CO – Contractual Obligation

Medicare Summary Notice (MSN) 16.76 – This service/item was not covered because you have exceeded the lifetime limit for getting this service/item. (Este servicio/artículo no fue cubierto porque usted ya se ha pasado del límite permitido de por vida, para recibirlo.).

The Medicare shared system and the *A/B MACs (B)* will also ensure that pharmacogenomic testing for warfarin response is billed in accordance with clinical trial reporting requirements. In other words, the shared system and the *A/B MACs (B)* will return to provider/return as unprocessable lines for pharmacogenomic testing for warfarin response when said line is not billed with HCPCS modifier Q0 and ICD-9 CM diagnosis code V70.7 *(if ICD-9 is applicable) or if ICD-9-CM is applicable, ICD-10-CM Z00.6* is not present as a secondary diagnosis. When the system or the *A/B MAC (B)* initiates the line-item return to provider or returns the claim as unprocessable, the Medicare contractor will respond with the following messages:

For a missing QO modifier:
CARC 4 - The procedure code is inconsistent with the modifier used or a required modifier is missing.

For a missing V70.7 *or Z00.6* diagnosis code when a HCPCS Q0 modifier is reported with HCPCS G9143:
CARC 16 - Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)

Remark Code 64 - Missing/incomplete/invalid other diagnosis.

For either a missing Q0 modifier and/or a missing V70.7 *or ICD-10-CM Z00.6* diagnosis code:

- Group Code CO- Contractual Obligation

MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)

260.2.1 – Hospital Billing Instructions

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

A - Hospital Outpatient Claims

For hospital outpatient claims, hospitals must bill covered dermal injections for treatment of facial LDS by having all of the required elements on the claim:

- A line with HCPCS codes Q2026 or Q2027 with a Line Item Date of service (LIDOS) on or after March 23, 2010,
- A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,
- *If ICD-9-CM is applicable,* ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy) *or,*
- *If ICD-10-CM is applicable, ICD-10-CM diagnosis codes B20 Human Immunodeficiency Virus (HIV) disease and E88.1 Lipodystrophy, not elsewhere classified*

The applicable NCD is 250.5 Facial Lipodystrophy.

B - Outpatient Prospective Payment System (OPPS) Hospitals or Ambulatory Surgical Centers (ASCs):

For line item dates of service on or after March 23, 2010, and until HCPCS codes Q2026 and Q2027 are billable, facial LDS claims shall contain a temporary HCPCS code C9800, instead of HCPCS G0429 and HCPCS Q2026/Q2027, as shown above.

C - Hospital Inpatient Claims

*H*ospitals must bill covered dermal injections for treatment of facial LDS by having all of the required elements on the claim:

- Discharge date on or after March 23, 2010,
- ***If ICD-9-CM is applicable,***
    - ICD-9-CM procedure code 86.99 (other operations on skin and subcutaneous tissue, i.e., injection of filler material*), or*
    - ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy)
- ***If ICD-10-PCS is applicable,***
    - *ICD-10-PCS procedure code 3E00XGC Introduction of Other Therapeutic Substance into Skin and Mucous Membrances, External Approach, or*
    - *ICD-10-CM diagnosis codes B20 Human Immundodeficiency Virus [HIV] disease and E88.1 Lipodystrophy not elsewhere classified.*

A diagnosis code for a comorbidity of depression may also be required for coverage on an outpatient and/or inpatient basis as determined by the individual Medicare contractor's policy.

260.2.2 – Practitioner Billing Instructions

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Practitioners must bill covered claims for dermal injections for treatment of facial LDS by having all of the required elements on the claim:

Performed in a non-facility setting:

- A line with HCPCS codes Q2026 or Q2027 with a LIDOS on or after March 23, 2010,
- A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,
- *If* ICD-9-CM *applies,* diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy) *or,*
- *If ICD-10-CM applies, diagnosis codes B20 Human Immunodeficiency Virus (HIV) disease and E88.1 (Lipodystrophy not elsewhere classified).*

NOTE: A diagnosis code for a comorbidity of depression may also be required for coverage based on the individual Medicare contractor's policy.

Performed in a facility setting:

- A line with HCPCS code G0429 with a LIDOS on or after March 23, 2010,
- *If ICD-9 applies,* ICD-9-CM diagnosis codes 042 (HIV) and 272.6 (Lipodystrophy) *or*
- *If ICD-10 applies, ICD-10-CM diagnosis codes B20 Human Immundodeficiency Virus (HIV) disease and E88.1 (Lipodystrophy not elsewhere classified).*

NOTE: A diagnosis code for a comorbidity of depression may also be required for coverage based on the individual Medicare contractor's policy.

270.1 – Coding Requirements for Implantable Automatic Defibrillators

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

The following are the applicable *HCPCS* procedure codes for implantable automatic defibrillators:

33240- (Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator)
33241(Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator)
33243 (Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy)
33244 (Removal of single or dual chamber pacing cardioverter-defibrillator electrodes by transvenous extraction)
33249- (Insertion or repositioning of electrode leads(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator)

For inpatient hospitals claims, *if* ICD-9 CM *is applicable use* procedure code 37.94. *If* ICD-10-PCS *is applicable the following applies.*

More than one ICD-10-PCS code (a cluster) is required. There are two possible clusters:

FIRST CLUSTER: Use 1 code from the first list and one code from the second list.

Cluster 1 first list:

0JH608Z Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach

0JH638Z Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0JH808Z Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0JH838Z Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

Cluster 1 second list:

02H60KZ Insertion of Defibrillator Lead into Right Atrium, Open Approach

02H63KZ Insertion of Defibrillator Lead into Right Atrium, Percutaneous Approach

02H64KZ Insertion of Defibrillator Lead into Right Atrium, Percutaneous Endoscopic Approach

02H70KZ Insertion of Defibrillator Lead into Left Atrium, Open Approach

02H73KZ Insertion of Defibrillator Lead into Left Atrium, Percutaneous Approach

02H74KZ Insertion of Defibrillator Lead into Left Atrium, Percutaneous Endoscopic Approach

02HK0KZ Insertion of Defibrillator Lead into Right Ventricle, Open Approach

02HK3KZ Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Approach

02HK4KZ Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Endoscopic Approach

02HL0KZ Insertion of Defibrillator Lead into Left Ventricle, Open Approach

02HL3KZ Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach

02HL4KZ Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Endoscopic Approach

SECOND CLUSTER:

Use 1 code from 1st list & 1 code from the 4th list; also add one code from each of the 2nd & 3rd lists if doing a replacement instead of initial insertion.

Cluster 2 first list:

0JH608Z Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Open Approach

0JH638Z Insertion of Defibrillator Generator into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0JH808Z Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0JH838Z Insertion of Defibrillator Generator into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

Cluster 2 second list:

0JPT0PZ Removal of Cardiac Rhythm Related Device from Trunk Subcutaneous Tissue and Fascia, Open Approach

0JPT3PZ Removal of Cardiac Rhythm Related Device from Trunk Subcutaneous Tissue and Fascia, Percutaneous Approach

Cluster 2 third list:

02PA0MZ Removal of Cardiac Lead from Heart, Open Approach

02PA3MZ Removal of Cardiac Lead from Heart, Percutaneous Approach

02PA4MZ Removal of Cardiac Lead from Heart, Percutaneous Endoscopic Approach

02PAXMZ Removal of Cardiac Lead from Heart, External Approach

Cluster 2 fourth list:

02H60KZ Insertion of Defibrillator Lead into Right Atrium, Open Approach

02H63KZ Insertion of Defibrillator Lead into Right Atrium, Percutaneous Approach

02H64KZ Insertion of Defibrillator Lead into Right Atrium, Percutaneous Endoscopic Approach

02H70KZ Insertion of Defibrillator Lead into Left Atrium, Open Approach

02H73KZ Insertion of Defibrillator Lead into Left Atrium, Percutaneous Approach

02H74KZ Insertion of Defibrillator Lead into Left Atrium, Percutaneous Endoscopic Approach

02HK0KZ Insertion of Defibrillator Lead into Right Ventricle, Open Approach

02HK3KZ Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Approach

02HK4KZ Insertion of Defibrillator Lead into Right Ventricle, Percutaneous Endoscopic Approach

02HL0KZ Insertion of Defibrillator Lead into Left Ventricle, Open Approach

02HL3KZ Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Approach

02HL4KZ Insertion of Defibrillator Lead into Left Ventricle, Percutaneous Endoscopic Approach

270.2 – Billing Requirements for Patients Enrolled in a Data Collection System

(Rev. 2998, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01-12 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10)

Effective for dates of service on or after April 1, 2005, Medicare required that patients receiving a defibrillator for the primary prevention of sudden cardiac arrest be enrolled in a qualifying data collection system. Providers shall use modifier Q0 to identify patients whose data is being submitted to a data collection system.

The following diagnosis codes identify non-primary prevention (secondary prevention) patient or replacement implantations (e.g. due to recalled devices):

If ICD-9-CM is applicable, select from the following diagnosis codes:

427.1 Ventricular tachycardia

427.41 Ventricular fibrillation

427.42 Ventricular flutter

427.5 Cardiac arrest

427.9 Cardiac dysrhythmia, unspecified

V12.53 Personal history of sudden cardiac arrest

996.04 Mechanical complication of cardiac device, implant, and graft, due to automatic implantable cardiac defibrillator

V53.32 Fitting and adjustment of other device, automatic implantable cardiac defibrillator

If ICD-10-CM is applicable, select from the following list:

I47.0 Re-entry Ventricular Arrhythmia

I47.2 Ventricular Tachycardiaselect

I49.3 Ventricular Premature depolarization

I49.01 Ventricular Fibrillation

I49.02 Ventricular Flutter

I46.2 Cardiac arrest due to underlying cardiac condition

I46.8 Cardiac arrest due to other underlying condition

I46.9 Cardiac arrest, cause unspecified

I49.9 Cardiac arrhythmia, unspecified

T82.110A Breakdown (mechanical) of cardiac electrode, initial encounter

T82.111A Breakdown (mechanical) of cardiac pulse generator (battery), initial encounter

T82.118A Breakdown (mechanical) of other cardiac electronic device, initial encounter

T82.119A Breakdown (mechanical) of unspecified cardiac electronic device, initial encounter

T82.120A Displacement of cardiac electrode, initial encounter

T82.121A Displacement of cardiac pulse generator (battery), initial encounter

T82.128A Displacement of other cardiac electronic device, initial encounter

T82.129A Displacement of unspecified cardiac electronic device, initial encounter

T82.190A Other mechanical complication of cardiac electrode, initial encounter

T82.191A Other mechanical complication of cardiac pulse generator (battery), initial encounter

T82.198A Other mechanical complication of other cardiac electronic device, initial encounter

T82.199A Other mechanical complication of unspecified cardiac device, initial encounter

Z86.74 Personal history of sudden cardiac arrest

Z45.02 Encounter for adjustment and management of automatic implantable cardiac defibrillator

When any of the above codes appear on a claim, the Q0 modifier is not required. The Q0 modifier may be appended to claims for secondary prevention indications when data is being entered into a qualifying data collection system.