CMS Manual System	Department of Health & Human Services
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services
Transmittal 1819	Date: September 25, 2009
	Change Request 6405

Transmittal 1778, dated July 24, 2009, is being rescinded and replaced to provide technical clarification replacing the word, reject to deny, in business requirements 6405.1.9, 6405.1.10, and 6405.2.6. Additionally, business requirement 6405.1.9 has been added to X-Ref Requirement Number.

The manual revision to section 230, originally released by this change request has been removed. Refer to Transmittal 1816, Change Request 6634, dated September 17, 2009, for the most current manual policy.

SUBJECT: Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient

I. SUMMARY OF CHANGES: Effective January 15, 2009, CMS will not cover a particular surgical or other invasive procedure to treat a particular medical condition when the practitioner erroneously performs: 1) a different procedure altogether; 2) the correct procedure but on the wrong body part; or 3) the correct procedure but on the wrong patient. Medicare will also not cover hospitalizations and other services related to these non-covered procedures as defined in the Medicare Benefit Policy Manual (BPM), chapter 1, sections 10 and 120 and chapter 16, section 180.

NEW / REVISED MATERIAL
EFFECTIVE DATE: JANUARY 15, 2009
IMPLEMENTATION DATE: JULY 6, 2009, FOR B MACS AND CARRIERS
OCTOBER 5, 2009, FOR A MACS, FIS, AND FISS

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

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: 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.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1819	Date: September 25, 2009	Change Request: 6405

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The manual revision to section 230, originally released by this change request has been removed. Refer to Transmittal 1816, Change Request 6634, dated September 17, 2009, for the most current manual policy.

SUBJECT: Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient

EFFECTIVE DATE: JANUARY 15, 2009
IMPLEMENTATION DATE: JULY 6, 2009, FOR B MACS AND CARRIERS
OCTOBER 5, 2009, FOR A MACS, FIS, AND FISS

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) internally generated a request for three national coverage analyses (NCAs) to establish national coverage determinations (NCDs) addressing Medicare coverage of 1) Wrong Surgical or Other Invasive Procedure Performed on a Patient; 2) Surgical or Other Invasive Procedure Performed on the Wrong Body Part; and 3) Surgical or Other Invasive Procedure Performed on the Wrong Patient.

In 2002, the National Quality Forum (NQF) published *Serious Reportable Events in Healthcare: A Consensus Report*[1], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list are the surgical errors listed above. Similar to any other patient population, Medicare beneficiaries may experience serious injury and/or death if they undergo erroneous surgical or other invasive procedures and may require additional healthcare in order to correct adverse outcomes that may result from such errors.

In order to address and reduce the occurrence of these surgeries, CMS internally generated three NCAs. There are no current NCDs that address coverage for these three surgical errors.

B. Policy: Effective January 15, 2009, CMS will not cover a particular surgical or other invasive procedure to treat a particular medical condition when the practitioner erroneously performs: 1) a different procedure altogether; 2) the correct procedure but on the wrong body part; or 3) the correct procedure but on the wrong patient. Medicare will also not cover hospitalizations and other services related to these non-covered procedures

[1] http://www.qualityforum.org/pdf/reports/sre.pdf

as defined in the Medicare Benefit Policy Manual (BPM) Chapter 1, sections 10 and 120 and Chapter 16, section 180.

Related Services

- Related services are defined in the Medicare BPM as discussed above. Related services do not include performance of the correct procedure.
- All services provided in the operating room when an error occurs are considered related and therefore not covered.
- All providers in the operating room when the error occurs, who could bill individually for their services, are not eligible for payment.
- All related services provided during the same hospitalization in which the error occurred are not covered.
- Following hospital discharge, any reasonable and necessary services are covered regardless of whether they are or are not related to the surgical error.

Definitions

1. Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

2. A surgical or other invasive procedure is considered to be the wrong procedure if it is not consistent with the correctly documented informed consent for that patient.

3. A surgical or other invasive procedure is considered to have been performed on the wrong body part if it is not consistent with the correctly documented informed consent for that patient including surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), or at the wrong level (spine).

NOTE: Emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent are not considered erroneous under this decision. Also, the event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

4. A surgical or other invasive procedure is considered to have been performed on the wrong patient if that procedure is not consistent with the correctly documented informed consent for that patient.

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), chapter 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, chapter 30 §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, chapter 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 follow-up care for the non-covered surgical error that would not be considered a related service to the non-covered surgical error as defined in the Medicare BPM, chapter 1, sections 10 and 120 and chapter 16, section 180.

New Modifiers: Three new HCPCS modifiers are available to use for processing claims related to this policy. They appear in the July 2009 IOCE effective for claims with dates of service on or after January 15, 2009, synonymous with the effective date of this policy, to be implemented July 6, 2009, for B MACs and carriers, and October 5, 2009, for A MACs, FIs, and FISS.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement.

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
Inpatient Claims											
6405.1	Effective for inpatient discharges on or after January 15, 2009, contractors shall educate hospitals to separate a hospital stay into two claims where 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). • Both the covered and non-covered claim shall have a matching Statement Covers Period.	X		X							
6405.1.1	Contractors shall educate hospitals to submit the non-covered TOB 110, clearly indicating in Remarks one of the applicable 2-digit surgical error codes (entered exactly as specified): • For a wrong surgery on patient, enter the following: **MX**	X		X							

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	• For a surgery on a wrong body part, enter the following: **MY** • For a surgery on wrong patient, enter the following: **MZ**										
6405.1.2	For inpatient claims, FISS shall create a bypass on duplicate edits for claims with duplicate dates of service when either a processed or suspended claim is a TOB 110 with one of the above stated surgical errors reported in Remarks.						X				
6405.1.3	FISS shall read the Remarks (located on the UB-04, Form Locator 80 or on the 837i at Loop 2300, Billing Note NTE01=ADD, NTE02) to initiate the bypass when one of the surgical errors listed above are noted in Remarks.						X				
6405.1.4	FISS shall suspend TOBs 110 or a no pay adjustment when received with one of the surgical errors (listed above) notated in Remarks.						X				
6405.1.5	Contractors shall create and maintain a list that includes the beneficiary HIC # and the surgical error date(s) of service.	X		X							
6405.1.6	Each time a contractor adds a surgical error occurrence to their list, they shall implement a Medical Policy Parameter (MPP) event as appropriate to suspend all claims for the beneficiary received for the date(s) of the surgical error claim.	X		X							
6405.1.7	Once the claim data is added to the surgical errors list, contractors shall append one of the following applicable surgical error (payer- only) condition codes to the claim related to the surgical error. • MX: Wrong Surgery on Patient • MY: Surgery Wrong Body Part • MZ: Surgery Wrong Patient	X		X							
6405.1.8	Once the applicable surgical error (payer-only) condition code is added to the claim, contractors shall continue to process the claim.	X		X							
6405.1.9	Contractors shall deny claims submitted for surgical errors, identified by one of the payer-only condition codes listed in 6405.1.7.	X		X							
6405.1.10	Contractors shall deny claims/lines using the following: Medicare Summary Notice:	X		X			X				MSN Work-Group

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	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: **50** – These are non-covered services because this is not deemed a 'medical necessity" by the payer. Group Code: **CO** – Contractual Obligation										
Practitioner, Ambulatory Surgical Centers (ASCs), Hospital Outpatient, and Other Appropriate TOBs											
6405.2	For hospital outpatient, ASCs, practitioner, and all appropriate TOBs for claims with dates of service on or after January 15, 2009, contractors shall educate providers to append one of the following applicable HCPCS modifiers to all lines related to the surgical error. • PA: Surgery Wrong Body Part • PB: Surgery Wrong Patient • PC: Wrong Surgery on Patient	X		X	X						
6405.2.1	Contractors, Shared System Maintainers (SSMs), and the IOCE shall be able to accept the aforementioned HCPCS modifiers, effective for dates of service on or after January 15, 2009.	X		X	X		X				IOCE COBC
6405.2.2	Contractors shall suspend claims, for dates of service on or after January 15, 2009, with services submitted for surgical errors, identified by one of the above HCPCS modifiers for addition to the surgical error list.	X		X	X		X				
6405.2.3	Contractors shall create and maintain a list that includes the beneficiary HIC # and the surgical error date of service.	X		X	X						
6405.2.4	Each time a contractor adds a surgical error occurrence to their list, they shall implement a System Control Facility (SCF) rule or Medical Policy Parameter (MPP) event as appropriate to suspend all claims for the beneficiary received for the date(s) of the surgical error claim.	X		X	X						
6405.2.5	Once the claim data is added to the surgical errors list and rule/event has been appropriately established, contractors shall continue to process the claim	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	submitted for surgical errors, identified by one of the above HCPCS modifiers in 6405.2.										
6405.2.6	Contractors shall line-item deny all services with one of the above HCPCS modifiers in 6405.2.	X		X	X						
6405.2.7	Contractors shall deny claims/lines 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: **50** – These are non-covered services because this is not deemed a 'medical necessity" by the payer. Group Code: **CO** – Contractual Obligation	X		X	X		X				MSN Work-Group
Establishing Surgical Error Point of Contacts											
6405.3	By the implementation date of this CR, contractors shall each designate a Point of Contact (POC) at their organization to do the following: 1) Send all information in Attachment 1 to Valeri Ritter at valeri.ritter@cms.hhs.gov for CMS to identify all contacts and distribute the compilation amongst all contacts; and 2) Send all future listings to Valeri Ritter.	X		X	X						
6405.3.1	Each identified contact at the contractors shall receive the compilation of these contacts from CMS within a week from the implementation date of this CR.										CMS
6405.3.2	Each time a contractor adds an occurrence to their list, they shall forward this information on a weekly basis by mail or fax to all POCs.	X		X	X						
Reviewing Claims for Coverage											
6405.4	Within 5 business days of receiving a claim for a surgical error, contractors shall begin to review	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	beneficiary history for related claims as appropriate per chapter 1, sections 10 and 120, and chapter 16, section 180 of the Medicare Benefits Policy Manual, Pub. 100-02.										
6405.4.1	Should contractors determine that related services should not have been covered and paid, they shall take appropriate steps to deny the services and recover any overpayment.	X		X	X						
6405.4.2	Every 30 days for an 18-month period from the date of the surgical error, contractors shall continue to review beneficiary history for any claims related to the surgical error and take appropriate action to deny and recover any overpayments as necessary.	X		X	X						
6405.4.3	Contractors shall not purge any records from the list until 3 years have passed from the surgical error claim's date of discharge/service (to allow for the time period to elapse in regard to timely filing limitations for any claims related to the surgical error).	X		X	X						
6405.4.4	Contractors shall review any claims applied to SCF rules and MPP events (specified in 6405.1.6 and 6405.2.4) to identify incoming claims that have the potential to be related to a previously identified surgical error claim.	X		X	X						
6405.4.5	Effective for claims with dates of service between January 15, 2009, and July 6, 2009 (for B MACs & carriers), and October 5, 2009 (for A MACs and FIs), contractors shall not go back and search for erroneously processed claims but shall adjust any claims brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6405.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of	X		X	X						

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

IV. SUPPORTING INFORMATION

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

X-Ref Requirement Number	Recommendations or other supporting information:
6405.1.2	Multiple TOBs should be accounted for situations in where claims are separated into the following: • A covered claim (11X excluding 110), • A non-covered claim (110 with a 'N' no pay code), • A benefits exhaust claim (110 with a 'B' no pay code), and/or • A covered Part B of A claim (121).
6405.4 6405.4.1 6405.4.2 6405.4.4 6405.4.5	Funding for these activities shall utilize Program Management Funds.
6405.1.9	Contractors shall utilize a MPP and/or ECPS to deny claims.

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s):

Institutional Claims Processing:
Joe Bryson at 410-786-2986 or joseph.bryson@cms.hhs.gov
Valeri Ritter at 410-786-8652 or valeri.ritter@cms.hhs.gov

Practitioner Claims Processing:
Leslie Trazzi at 410-786-7544 or leslie.trazzi@cms.hhs.gov
Tom Dorsey at 410-786-7434 or thomas.dorsey@cms.hhs.gov

Coverage Policy:
Sarah McClain at 410-786-2994 or sarah.mcclain@cms.hhs.gov
Pat Brocato-Simons at 410-786-0261 or patricia.brocatosimons@cms.hhs.gov

Post-Implementation Contact(s): Regional office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers,* use only one of the following statements:

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

Section B: *For Medicare Administrative Contractors (MACs)*, include the following statement:

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.

Attachment

Attachment

Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient

1) Contractor Name

2) Contractor #

3) Primary Contact Name

4) Primary Contact Phone #

5) Primary Contact Fax #

6) Primary Contact Email

7) Primary Contact Street Address

8) Secondary Contact Name

9) Secondary Contact Phone #

10) Secondary Contact Fax #

11) Secondary Contact Email

12) Secondary Contact Street Address