CMS Manual System	Department of Health & Human Services
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services
Transmittal 101	Date: JUNE 12, 2009
	Change Request 6405

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 180 and chapter 16, section 120.

These additions are national coverage determinations (NCDs). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD.

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
R	1/Table of Contents
N	1/140.6/Wrong Surgical or Other Procedure Performed on a Patient (Effective January 15, 2009)
N	1/140.7/Surgical or Other Invasive Procedure Performed on the Wrong Body Part (Effective January 15, 2009)
N	1/140.8/Surgical or Other Invasive Procedure Performed on the Wrong Patient (Effective January 15, 2009)

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. 100-03	Transmittal: 101	Date: June 12, 2009	Change Request: 6405

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 as defined in the Pub. 100-02, Benefit Policy Manual (BPM), chapter 1, sections 10 and 180 and chapter 16, section 120.

Related Services

- Related services are defined in the Pub. 100-02, 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.

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

- 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 Pub. 100-04, 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 Pub. 100-04, 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 Pub. 100-02, BPM, chapter 1, sections 10 and 180 and chapter 16, section 120.

New Modifiers

Three new HCPCS modifiers will be available to use for processing claims related to this policy. They will 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	
6405.1	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 Pub. 100-02, BPM, chapter 1, sections 10 and 180 and chapter 16, section 120. (See Pub. 100-04, CPM, chapter 32, section 230, the Pub. 100-03, NCD Manual, chapter 1, sections 140.6-140.8, and Pub. 100-04, CPM, business requirements, for detailed information relative to this CR.)	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	
6405.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this	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	
	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:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s):

Institutional Claims Processing: Valeri Ritter at 410-786-8652 or valeri.ritter@cms.hhs.gov
Joe Bryson at 410-786-2986 or joseph.bryson@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, 410-786-0261, 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.

Medicare National Coverage Determinations Manual

Chapter 1, Part 2 (Sections 90 – 160.26)

Coverage Determinations

Table of Contents
(Rev. 101, 06-12-09)

140.6 – Wrong Surgical or Other Invasive Procedure Performed on a Patient (Effective January 15, 2009)

(Rev. 101; Issued: 06-12-09; Effective Date: 01-15-09; Implementation Date: JULY 6, 2009 FOR B MACS AND CARRIERS OCTOBER 5, 2009, FOR A MACS, FIs, AND FISS)

A. General

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 is "Wrong surgical procedure performed on a patient." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs a different procedure on a Medicare beneficiary because that particular surgical or other invasive procedure is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

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. 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).

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

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

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.

D. Other

N/A

(NCD last reviewed January 2009.)

140.7 – Surgical or Other Invasive Procedure Performed on the Wrong Body Part (Effective January 15, 2009)

(Rev. 101; Issued: 06-12-09; Effective Date: 01-15-09; Implementation Date: JULY 6, 2009 FOR B MACS AND CARRIERS OCTOBER 5, 2009, FOR A MACS, FIs, AND FISS)

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report"[2], 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 is "Surgery performed on the wrong body part." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a

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

particular medical condition when a practitioner erroneously performs the procedure on the wrong body part because that particular surgical or other invasive procedure is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

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 of the body; for example, left versus right (appendages and/or organs), or at the wrong level (spine). 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).

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.

D. Other

N/A

(NCD last reviewed January 2009.)

140.8 – Surgical or Other Invasive Procedure Performed on the Wrong Patient (Effective January 15, 2009)

(Rev. 101; Issued: 06-12-09; Effective Date: 01-15-09; Implementation Date: JULY 6, 2009 FOR B MACS AND CARRIERS OCTOBER 5, 2009, FOR A MACS, FIs, AND FISS)

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report"[3], 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 is "Surgical procedure performed on the wrong patient." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs a procedure that was intended for a different patient on a Medicare beneficiary who does not need that procedure because it is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

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.

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.

D. Other

N/A

(NCD last reviewed January 2009.)

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