



Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgery or Other Invasive Procedure Performed on the Wrong Body Part; and Surgical or Other Invasive Procedure Performed on the Wrong Patient – JA6405

Note: MLN Matters® article MM6405 was revised to correct the references to the *Medicare Benefit Policy Manual*. The reference for the revised manual should have stated Chapter 1, Sections 10 and 120, and Chapter 16, Section 180. All other information is unchanged.

Additional information on the use of the PA, PB, and PC modifiers discussed below is available in the MLN Matters® article at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6718.pdf> on the CMS website.

Related CR Release Date: September 25, 2009 **Revised**

Date Job Aid Revised: January 22, 2010

Effective Date: January 15, 2009

Implementation Date: July 6, 2009, for those billing carriers and Part B MACs; October 5, 2009, for FIs and Part A MACs

Key Words	MM6405, CR6405, R1819CP, R102NCD, MM6634, CR6634, MM6718, CR6718, Surgical, Invasive
Contractors Affected	<ul style="list-style-type: none"> • Medicare Carriers • Fiscal Intermediaries (FIs) • Part A/B Medicare Administrative Contractors (A/B MACs)
Provider Types Affected	Physicians, other practitioners, and providers billing Medicare Carriers, FIs or A/B MACs for services provided to Medicare beneficiaries



Effective January 15, 2009, the Centers for Medicare & Medicaid Services (CMS) does 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.

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- 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:
 - A different procedure altogether;
 - The correct procedure but on the wrong body part; or
 - 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.
 - 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.
 - **Providers should note that related services do not include performance of the correct procedure.**

Definitions

Provider Needs to Know...

- **Surgical and other invasive procedures** are defined as operative procedures in which skin, 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.
- 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.
- 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).

- 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.

Beneficiary Liability

- Generally, a beneficiary liability notice such as 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/service that the provider reasonably believes Medicare will not cover on the basis of Section 1862(a)(1) of the Social Security Act.
- An ABN must include all of the elements described in the *Medicare Claims Processing Manual*, Chapter 30, Section 50.6.3, in order to be considered valid. For example, the ABN must specifically describe the item/service expected to be denied (e.g., a left leg amputation) and must include a cost estimate for the non-covered item/service.
- Similarly, HINNs must specifically describe the item/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 *Medicare Claims Processing Manual*, Chapter 30, Section 200.
- Therefore, 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 Chapter 30, Sections 50.6.3 and 200, respectively, of the *Medicare Claims Processing Manual*.
- 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 (see Chapter 1, Sections 10 and 120, and Chapter 16, Section 180, of the *Benefit Policy Manual*).

Inpatient Claims

- Effective for inpatient discharges on or after January 15, 2009, hospitals are required to submit a no-pay claim (Type of Bill (TOB) 110) when the erroneous surgery related to the NCD is reported. If there are covered services/procedures provided during the same stay as the erroneous surgery, hospitals are then required to submit two claims:
 - One claim with covered service(s)/procedure(s) unrelated to the erroneous surgery(s) on a 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 must have a matching Statement Covers Period.
- **For discharges on or after January 15, 2008, and before October 1, 2009**, the non-covered TOB 110 will be required to be submitted via the UB-04 (hard copy) claim form, clearly indicating in Form Locator (FL) 80 (Remarks), or the 837i (electronic) claim form, Loop 2300, one of the applicable 2-digit surgical error codes as follows:
 - MX: For a wrong surgery on patient;
 - MY: For surgery on the wrong body part; or
 - MZ: For surgery on the wrong patient.
- For discharges on or after October 1, 2009, hospitals should refer to MM6634 for how to submit an erroneous surgery claim. MM6634 can be found at <http://www.cms.hhs.gov/MLN MattersArticles/downloads/MM6634.pdf> on the CMS website.
- The claim for the non-covered services will be denied using:
 - **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.

Outpatient, Ambulatory Surgical Centers (ASCs), Other Appropriate Bill Types and Practitioner Claims

- Hospital outpatient departments, ASCs, practitioners, and those submitting other appropriate TOBs are required to append one of the following applicable NCD modifiers to all lines related to the erroneous surgery(s) with dates of service on or after January 15, 2009:
 - PA: Surgery Wrong Body Part
 - PB: Surgery Wrong Patient
 - PC: Wrong Surgery on Patient
- Contractors will suspend claims with dates of service on and after January 15, 2009, with surgical errors identified by one of the above Healthcare Common Procedure Coding System (HCPCS) modifiers.
- Contractors will create/maintain a list that includes the beneficiary health information code and the surgical error date of service. Each new surgical error occurrence will be added to the list, and a Medicare Premium Payment (MPP) program event or a system control facility (SCF) rule will be implemented so that all claims for that beneficiary for that date of service will be suspended. Contractors will then continue to process the claim.
- Claim lines submitted with one of the above HCPCS modifiers will be line-item denied using the following:
 - **CARC 50** – "These are non-covered services because this is not deemed a

'medical necessity" by the payer."

- **Group Code - CO** – Contractual Obligation.

Related Claims

- Within 5 days of receiving a claim for a surgical error, contractors will begin to review beneficiary history for related claims as appropriate (both claims already received and processed and those received subsequent to the notification of the surgical error).
- In addition, contractors will review any claims applied to SCF rules and MPP events to identify incoming claims that have the potential to be related.
- When Medicare identifies such claims, it will take appropriate action to deny such claims and to recover any overpayments on claims already processed.
- Every 30 days for an 18-month period from the date of the surgical error, contractors will continue to review beneficiary history for related claims and take appropriate action as necessary.

Background

- In 2002, the National Quality Forum published *Serious Reportable Events in Healthcare: A Consensus Report*, 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 that currently contains 28 items.
- In order to address and reduce the occurrence of these surgeries, CR6405 establishes three new NCDs that nationally non-cover the three surgical errors and sets billing policy to implement appropriate claims processing.

Operational Impact

N/A

Reference Materials

The related MLN Matters® article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6405.pdf> on the CMS website.

The official instruction (CR6405) issued regarding this change may be found in two transmittals. The first transmittal presents the NCD related to this issue and that transmittal is at <http://www.cms.hhs.gov/Transmittals/downloads/R102NCD.pdf> on the CMS website.

The other transmittal presents the *Medicare Claims Processing Manual* revision and instructions. That transmittal is at <http://www.cms.hhs.gov/Transmittals/downloads/R1819CP.pdf> on the CMS website.

The *Medicare Claims Processing Manual* is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp> on the CMS website.

In addition, for the revisions to the *Medicare Claims Processing Manual*, providers should see the article related to CR6634 at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6634.pdf> on the CMS website.
