

Decision Memo for Surgery on the Wrong Body Part (CAG-00402N)

Decision Memo

TO: Administrative File: CAG-00402N
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SUBJECT: Coverage Decision Memorandum for Surgical or Other Invasive Procedure Performed on the Wrong Body Part

DATE: January 15, 2009

I. Decision

The Centers for Medicare and Medicaid Services (CMS) has determined that when a Medicare beneficiary requires a particular surgical or other invasive procedure to treat a particular medical condition and the practitioner erroneously performs that procedure on the wrong body part, Medicare will not cover that particular surgical or other invasive 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 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). 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.

II. Background

Rising concern about the monetary costs and physical harms to patients from medical errors led to a number of publications about the problem in the late 1990s. The Institute of Medicine report, *To Err Is Human*¹, published in 1999, called attention to statistics from the American Hospital Association that indicated that the death rate from medical errors could range from 44,000 to 98,000 per year with costs estimated in the tens of billions of dollars. It became clear that there needed to be a method for accurately identifying and reporting errors, tracking their consequences and establishing processes to prevent their occurrence.

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."

Medicare beneficiaries are not immune from these events. They experience serious injury and/or death if surgeries are performed on the wrong body part and require additional healthcare in order to correct adverse outcomes resulting from these errors. In order to address and reduce the occurrence of these surgeries CMS internally generated a request for an NCD to determine whether performing surgery on the wrong body part is reasonable and necessary under the Medicare program.

Coverage of and payment for services related to a noncovered service are addressed in the Medicare Benefit Policy Manual in Chapter 1, section 10; Chapter 1, section 120; and Chapter 16, section 180. These policies would be applicable to a surgical or other invasive procedure performed on the wrong body part after this national coverage analysis is finalized.

III. History of Medicare Coverage

Medicare has not previously developed NCDs that address coverage for surgical or other invasive procedures performed on the wrong body part.

Benefit Category Determination

For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories in the Social Security Act. Surgeries performed on a patient, at a minimum, fall under the benefit categories set forth in section 1861(b) (inpatient hospital services), a part A benefit under 1812(a)(1) and 1861(s)(1) (physicians services), a part B benefit; 1861(j) (skilled nursing facility); 1861(m) (home health services); 1861(s)(2)(A) (services incident to a physicians professional service) 1861(s)(2)(B) (outpatient hospitals); 1861(s)(2)(E) (rural health clinic services and Federally qualified health center services); 1861(s)(3) (diagnostic tests); and 1861(b)(3) (inpatient diagnostic services).

This may not be an exhaustive list of all applicable Medicare benefit categories for these services.

IV. Timeline of Recent Activities

July 31, 2008	CMS opened an internally generated NCD addressing coverage for wrong surgery performed on patients. Initial 30-day public comment period began.
August 30, 2008	Initial 30-day public comment period closed.
December 2, 2008	Proposed decision memorandum posted; 30-day public comment period begins.
January 15, 2009	Final decision memorandum posted. NCD becomes effective.

V. Assessment

Assessment Questions

- What is the definition of “surgery performed on the wrong body part?”
- What is the scope of surgical procedures that are included in the event “surgery performed on the wrong body part?”
- Is surgery performed on the wrong body part ever reasonable and necessary?

In general, we determine something to be reasonable and necessary if we find evidence that demonstrates that an item or service improves health outcomes. However, in this instance, an evidentiary review is unnecessary to determine that performing a surgical or other invasive procedure on the wrong body part will not improve health outcomes but harms the patient. We will discuss below the consensus in the healthcare community on the lack of benefit of these procedures.

1. Evidence

CMS examined various reports and reviews that address performing a surgical or other invasive procedure on the wrong body part. Many of the articles written about surgical errors group errors relating to erroneous site, wrong procedure performed and wrong patient into “wrong site surgery.”

Estimating rates of erroneous surgery is limited because of a lack of reporting requirements. A 2006 study by Kwaan et al., reviewing 10 years of data from a large malpractice insurer encompassing 2.8 million procedures, reported an incidence of 1 in 112994 operations of non-spine wrong site operations (Kwaan et al. 2006). This study is widely quoted and cited in a discussion of the study in a 2007 article in the *Annals of Surgery* which raises the point that the incidence of a “devastating outcome of a wrong site surgery” is not known, but might be expected to occur “once each year in a 300-bed hospital” and “surgeons who work on symmetrical structures may have a 1 in 4 chance to be involved in a wrong-site error during their careers” (Clarke et al. 2007).

Although accurate estimates of the numbers of erroneous surgeries are not available because of lack of uniform reporting, an AHRQ supported study published in the April 2006 issue of *Archives of Surgery* reported that the three

types of “wrong site surgeries” are extremely rare and major injury from them is even rarer. This study concluded that two-thirds of the errors studied could have been prevented by existing site verification protocols. However, many of the protocols “involve considerable complexity without clear added benefit” (Clarke et al. 2006). The 2009 safety goals (see below) are a step toward solving this problem. A number of specialty groups including orthopedic surgery and interventional radiology and states including Florida, Oregon and Minnesota, among others, are putting special emphasis on tracking, reporting and preventing these surgical errors.

2. Professional Society Position Statements

NQF has defined each of the serious reportable events on its current list. For this event, NQF has the following definition:

Surgery performed on the wrong body part is defined as any surgery performed on a body part that is not consistent with the correctly documented informed consent for that patient. It includes surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), level (spine). It excludes emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent. 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) (NQF 2006 Update).

In developing its list of serious reportable events, NQF defined the scope of surgical procedures that it recommended for inclusion in the reportable adverse surgical events:

Surgery is defined as an invasive operative procedure in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Surgeries 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 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 procedures such as drawing blood (NQF 2006 Update).

NQF also recommended that organizations further refine this as needed for their particular needs.

In July 2003, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) approved the “Universal Protocol for Preventing Wrong Site, Wrong Procedure and Wrong Person Surgery™,”³ which was designed to help prevent such errors. The document’s introduction states: “Wrong site, wrong procedure, wrong person surgery can be prevented. This universal protocol is intended to achieve that goal. It is based on the consensus of experts from the relevant clinical specialties and professional disciplines and is endorsed by more than 40 professional medical associations and organizations.” The principal components of the Universal Protocol include:

- A pre-procedure verification process
- Marking of the procedure site.
- A “time out” immediately before the start of the procedure.
- Adaptation of these steps to non-operating room settings for procedures performed in other places, such as at bedside.

The protocol became effective for all JCAHO accredited hospitals, ambulatory care and office-based surgery facilities on July 1, 2004. At the Wrong Site Surgery Summit in 2007 co-convened by JCAHO, the universal protocol was revised to include new performance elements and changes to improve consistency which became effective January 1, 2009. Summit participants included surgeons, physicians, nurses, risk managers and partner organizations whose purpose was to clarify and improve the protocol to enable better compliance. The changes are also part of JCAHO’s 2009 National Patient Safety Goals. Also new for 2009 are specific Office-Based Surgery National Patient Safety Goals. The changes may be viewed on the JCAHO website.^{4,5,6}

3. Public Comments

During the 30-day public comment period following the release of the proposed decision memorandum (PDM), CMS received comments from 17 individuals and groups. The majority of comments collectively address the three national coverage analyses (NCAs) for surgical errors. In the paragraphs below, general questions and concerns are summarized followed by CMS responses in italics. Separate comments submitted by various interest groups are summarized and

similarly followed by italicized responses. In some instances, similar public comments from interest groups are grouped together and subsequently addressed as a whole by the Agency.

General Questions and Concerns

One commenter contends that CMS should establish an appeals process for medically necessary procedures that are performed but do not exactly match the informed consent. This commenter also questions whether a hospital is responsible for covering a patient's life long care (i.e. dialysis due to the removal of the wrong kidney); when the noncovered services end and medically necessary services begin; and if the NCD only covers the specific episode of care.

Details based on the three types of surgical errors noncovered in these NCDs may be challenged using the same appeals processes as any other noncovered item or service. Details regarding the appeals processes are available at 42 C.F.R. Part 405, Subpart I; 42 C.F.R. Part 426 and <http://www.cms.hhs.gov/OrgMedFFSAppeals/>. Claims processing instructions specific to the three surgical error NCDs will be prepared and released by CMS following the posting of the NCDs. In addition, coverage of and payment for services related to a noncovered service are addressed in the Medicare Benefit Policy Manual (BPM) Chapter 1, sections 10 and 120 and Chapter 16, section 180.

One commenter questions whether CMS intends to apply payment penalties for wrong site surgeries in a punitive manner and if a hospital or individual physician would be found liable for the error and future care.

This NCD does not address payment policy, which is outside the scope of the NCD process. See section 1869(f)(1)(B).

CMS intends for the NCDs to limit Medicare coverage as required by section 1862(a)(1)(A) of the Medicare statute.

The NCDs are not intended to reward or punish. Similarly, issues of State liability are beyond the scope of an NCD.

One commenter asks if the remaining Hospital Acquired Conditions (HACs) and Never Events will be addressed via NCDs.

At this time CMS does not plan to address the remaining HACs and Never Events through national coverage determinations.

One commenter questions how services related to a noncovered surgical error would be identified on a claims form.

As noted above, coverage of and payment for services related to a noncovered service are addressed in the Medicare BPM in Chapter 1, sections 10 and 120, and Chapter 16, section 180, and these policies would apply to a noncovered surgical or other invasive procedure performed on the wrong body part. In addition, claims processing instructions specific to the surgical error NCDs will be prepared and released by CMS following the posting of the NCDs.

One commenter warns that by establishing noncoverage for these types of surgical errors and related care, CMS may place beneficiaries in an "unfortunate situation" in which physicians may avoid involvement in surgical error cases.

This commenter contends that CMS must ensure "that those who are innocent in these situations (the subsequent surgeons, hospitals, surgery centers, anesthesiologists) are still paid for these services."

Nonpayment of services related to the noncovered service (e.g., the surgical error) will continue as previously established in the Medicare BPM Chapter 1, sections 10 and 120 and Chapter 16, section 180. These provisions identify the services that are or are not reimbursable when related to a noncovered service.

Interest Group Comments

National Business Group on Health

The Business Group agrees that costs for and associated with hospitalizations for wrong site surgeries should not be reimbursed. They urge Medicare to take additional steps to establish policies that move "toward paying only for effective and efficient care in order to sustain the program and improve the safety and quality of health care delivery for all Americans." The Business Group recommends that the three surgical errors should be added as measures to Medicare's Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program.

The Business Group notes the need for these NCDs due to increased costs to payers resulting from these types of surgical errors. The Business Group also notes that the NCDs, which establish nonpayment for these surgical errors, take necessary additional steps in addressing payment for "Never Events" beyond the HAC provisions in the Inpatient Prospective Payment System (IPPS).

America's Health Insurance Plans (AHIP)

AHIP states that it "strongly supports" the proposed decisions and states that establishing these NCDs "is a necessary step towards reducing the number of avoidable complications, serious injuries and/or deaths due to these surgical errors." AHIP also agrees with CMS' proposed definition of "surgery."

CMS agrees that the establishment of these NCDs will likely encourage providers, physicians, and other health care practitioners to take additional steps to protect Medicare beneficiaries' health and safety and reduce inappropriate costs to beneficiaries and the Medicare program as a whole.

Wellpoint

Wellpoint supports the proposed NCDs and asserts "that a payer and its members should not pay for services related to a preventable adverse event." Wellpoint also agrees with CMS' definition of "surgery" but requests that CMS provide a clear definition of the types of procedures that fall under the NCDs.

CMS believes that the definition and examples set forth above accurately and sufficiently identify the procedures that may fall under these NCDs. We further note that this definition is based largely on language developed by the NQF.

Comments Relating to the Appeals Process

Premier Healthcare Alliance

Premier Healthcare Alliance agrees with the three proposed decisions as well as with the proposed definition of surgical and other invasive procedures that would be subject to non-coverage. Premier contends that the definition language “based on language from the National Quality Forum is sufficiently clear to implement this policy.” Premier asserts that an appeals process must be proactively established to allow providers to request a case review when “1) the error that led to the inappropriate procedure was clearly not the fault of the hospital; 2) an unnecessary or unscheduled procedure is performed but the correct surgery is also preformed and there has been no harm to the patient; and 3) code edits erroneously identify a case.” Premier also requests that CMS identify whether hospitals should bill Medicare and receive no payment for the errors or should not bill Medicare at all for the three surgical errors.

American College of Cardiology (ACC)

The ACC contends that CMS should establish an appeals process to allow physicians and other providers to gain recourse against any inappropriately made agency noncoverage decisions.

Cleveland Clinic

Cleveland Clinic asserts that the proposed policies are too broad and need further clarification of criteria for decision making by carriers, intermediaries and providers.

Federation of American Hospitals (FAH)

The FAH requests that CMS provide a detailed plan for the implementation of these NCD and more clarity regarding the documentation of these surgical errors. In particular, FAH requests that CMS develop and make public for comment a procedure detailing how providers are to capture information not generally included in a claims form (i.e. informed consent) as well as a process for addressing complexities in care (i.e. transferring a patient to a second hospital), provide guidelines addressing accountability and what payments will be withheld, and develop an appeals process.

American Society of Anesthesiologists (ASA)

The ASA requests that CMS provide clarification regarding “how it intends to address the scenario in which a separate team of physicians assumes care of the patient after one of” the three surgical errors occurs. The ASA recommends considering a method similar to the Present on Admission (POA) process.

Denials based on the three types of surgical errors noncovered in these NCDs may be challenged using the existing claims appeals process. Details regarding the appeals processes are available at 42 C.F.R. Part 405, Subpart I; 42 C.F.R. Part 426. See also, <http://www.cms.hhs.gov/OrgMedFFSAppeals/>. Information regarding coverage of related services is available in the Medicare BPM Chapter 1, sections 10 and 120 and Chapter 16, section 180.

Claims processing instructions specific to the surgical error NCDs will be prepared and released by CMS following the posting of the NCDs. These instructions will provide the requested detailed implementation plans and administrative guidance.

Cleveland Clinic

Cleveland Clinic requests that the NCDs be delayed until “necessary administrative guidance” is complete and additional public comments are accepted and that if the proposed NCDs are finalized, their effective dates should be one year after posting to allow for administration of changes.

The effective date of the NCDs will be the date on which they are published consistent with statutory time limits in section 1862(l) of the Act. The implementation date of the instructions for Medicare contractors will be a later date (to be determined) to allow time for necessary administrative changes.

Astellas Pharma US

Astellas Pharma requests that CMS extend the public comment period and delay adoption of final NCDs due to their perceived complexity and confusion regarding the statutory authority under which the NCDs would be implemented. Astellas contends that CMS is inappropriately using the rationale underlying section 1886(d)(4)(D) of the Social Security Act (the Act) (the IPPS HAC Program) to support noncoverage under an “entirely separate statutory provision[s],” section 1862(a)(1) of the Act (the “reasonable and necessary” standard for NCDs). Astellas asserts that CMS is establishing noncoverage NCDs to “encourage hospitals to adopt preventive measures that eliminate or substantially reduce such surgeries” and states that the HAC program “is designed to encourage hospitals to take measures that eliminate or substantially reduce conditions that are reasonably preventable – but not to penalize hospitals for admitting patients likely to acquire complications that cannot reasonably be prevented or to compromise hospitals’ ability to provide appropriate care to patients with serious conditions.”

The NCD process and the HAC program are two separate and distinct matters based on separate and distinct statutory authorities. As we explained in our proposed decision memoranda, these NCDs are based on section 1862(a)(1)(A) of the Social Security Act. The NCDs are not based on section 1886(d)(4)(D), that applies to payment for certain inpatient

hospital services. Under section 1862(a)(1)(A), CMS is able to make decisions with regard to whether particular items or services are reasonable and necessary, and thereby “covered” under the Medicare program. A decision to noncover a particular item or service may have many resulting consequences; however, the ultimate intended outcome is to formally provide no coverage for these three types of surgical errors and thereby provide no payment (not reduced payment) for these events. The three NCDs are intended to limit Medicare payment for items and services under both part A and part B, as required by section 1862(a)(1)(A). The ultimate intended outcome - noncoverage and nonpayment - may encourage providers, physicians, and other health care practitioners to take additional steps to reduce errors and provide better patient care. As stated earlier, CMS expects that these noncoverage NCDs will lead to reduced occurrences of such events; however, reduced occurrences are only part of the anticipated results of these NCDs.

Astellas also contends that the NCD language should be amended to noncover an error if it is “reasonably preventable” and that via the “reasonable and necessary” coverage authority, CMS should only deem a procedure “unreasonable” (and thereby noncovered) based on preventable adverse outcomes. They argue that CMS should only adopt noncoverage for healthcare associated conditions that “could reasonably have been prevented” and that CMS should not select any condition that does not meet the standards for inclusion in the HAC program. Astellas presents these recommendations based on their interpretation of the proposed NCDs that “CMS appears to depart from” the usual application of “reasonable and necessary” which is based on a prospective evaluation of likely benefits and risks and “proposes to non-cover the incorrect surgeries on the basis of an outcome-based description of the service itself.” As described above, CMS conducted the three NCAs pursuant to the statutory authority set forth at section 1862(a)(1)(A). CMS disagrees with Astellas’ recommendation to change the NCD language from “reasonable and necessary” to “reasonably preventable.” While most commenters and evidence in the record demonstrate that the surgical errors included in these NCDs are “reasonably prevented,” NCDs under the reasonable and necessary authority are frequently based on evidence of the expected health status of patients after a surgical intervention has been performed (e.g. bariatric surgery, surgery for diabetes, pancreas transplants). Because the NCDs are established under a different authority than the HACs, it would be inappropriate for CMS to limit noncoverage only to conditions that meet the standards for inclusion in the HAC program. The Secretary determined that these surgical errors are best addressed by NCDs. When patients undergo a wrong site surgery, the procedure results in outcomes that do not improve patients’ health and in many cases harm the patients. We have determined that these unimproved and/or harmful outcomes are not “reasonable and necessary” and therefore appropriately noncovered in these NCDs. Astellas also asserts that “CMS should clarify that Medicare will cover any care necessary to treat complications or other adverse events ‘related to’ incorrect surgeries that are non-covered pursuant to the final NCDs...” Nonpayment of services related to the noncovered service (e.g. the surgical error) will continue as previously established in the Medicare BPM Chapter 1, sections 10 and 120 and Chapter 16, section 180. These provisions identify the related services that are or are not reimbursable due to a noncovered service.

Comments Related to the Use of NCDs

American Medical Association (AMA)

The AMA states that it “is extremely disappointed that CMS is moving forward with the NCDs in this procedural manner.” The AMA contends that these issues require greater public discussion than the NCD process affords and thus many critical questions (e.g. definitions for surgical errors covered by the proposed NCDs, accountability and scope of non-payment) will go unanswered. The AMA asserts that “physicians and providers must have clear guidance on Medicare coverage and payment policy, but the NCD process in these instances is a complete obstacle to this goal.” The AMA contends that since “NCDs set national policy on whether Medicare will cover an item or service and under what conditions” it is inappropriate for CMS to use the NCD process to address surgical errors. Instead, a clear payment policy should be developed that outlines the circumstances under which surgery claims would not be reimbursable by Medicare. The AMA states that “the issue at question is not whether surgical procedures will be covered by the Medicare program, but rather under what circumstances the payment for covered surgical procedures will be denied or reduced.” The AMA also stresses the importance of establishing an appeals process for any inappropriately denied claims.

The AMA urges “CMS to withdraw these NCDs, and explore options for revising Medicare payment policies associated with these three surgical conditions.” The AMA supports this request by asserting that none of the three surgical conditions would usually be qualified for the development of an NCD, Medicare claims processing personnel lack the expertise to determine whether certain surgical procedures are performed correctly and beneficiaries will have coverage wrongly denied due to errors in judgment by Medicare contractors.

American College of Surgeons (ACS)

The ACS contends that the NCD process is not appropriate for addressing concerns regarding wrong site surgeries and that CMS should instead develop “a clear payment policy outlining circumstances under which surgery claims would not be payable by Medicare.” Like the AMA, the ACS asserts that “the issue at question is not whether surgical

procedures will be covered by the Medicare program, but rather under what circumstances the payment for covered surgical procedures will be denied or reduced.” The ACS states that a payment policy, as opposed to an NCD, would provide physicians and hospitals with an appeals process for procedures they considered inappropriately denied. The ACS also requests that CMS remove language addressing spine levels from the classification of “wrong body part.”

American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)

The AANS and CNS contend that the NCD process is not the most effective way to address concerns regarding “wrong” surgeries and “request that CMS instead consider the value of developing a clear payment policy outlining circumstances under which surgery claims would not be payable by Medicare.” They assert that under the NCD approach, providers would have no means for appealing a noncoverage determination, but a payment determination would allow for such an appeal. The AANS and CNS request that CMS amend the NCD language “not intended to capture changes in the surgical plan after surgical entry” to “made at anytime following anesthesia induction.” They also request that the statement be an explicit exclusion in the NCD policy. “The AANS and CNS strongly urge CMS to either exempt wrong spine levels from its NCD proposal or to include an additional statement that excludes exceptional circumstances from non-coverage determinations, such as situations where patient characteristics can impede identification of the precise location prior to surgical entry into the patient.”

While CMS understands that the three surgical errors described in the NCDs are not frequent occurrences, we are using the NCD process to make it clear that Medicare will not cover these particular surgical or other invasive procedures if they occur. The courts have repeatedly recognized that the Medicare statute enables the Secretary to make uniform national policies under section 1862(a)(1)(A). CMS believes that addressing surgical errors through NCDs is appropriate and that the NCD process has afforded the public and any interested party ample opportunity for submitting additional evidence as well as expressing comments and concerns.

As with all NCDs nuances regarding the administration of payment policies necessary to implement these policies will be addressed in the claims processing instructions, which will be prepared and released by CMS after the NCDs are finalized. Educational materials will be prepared and released in the form of Medicare Learning Network (MLN) Matters article(s).

CMS believes that the language addressing spine levels is appropriate to include and therefore has not removed it.

Ambulatory Surgery Center Association (ASC)

The ASC states that new NCDs are not needed to sustain the momentum of efforts currently made to track, report and raise awareness regarding wrong site surgery. The ASC notes that it’s “members already understand that claims should not be submitted and Medicare payment should not be made for wrong site surgery that provides no benefit to the patient.” The ASC expresses concern “that the issuance now of detailed and highly-publicized NCDs” will erroneously imply to the public “that billing for wrong site surgery is a major problem and that providers are not sufficiently focused on the issue.” The ASC agrees with the AMA that the NCD process is not appropriate for addressing wrong site surgery and also urges CMS to reconsider using the NCD approach.

While CMS understands that other efforts by non-Medicare entities have been taken to track, report and raise awareness regarding wrong site surgery, these NCDs establish clear noncoverage policies for wrong site surgeries. In order to ensure that these types of surgical errors are noncovered, finalizing these NCDs is necessary. With regard to billing and payment instructions, CMS will address those issues separately from the NCDs in the near future, but to be clear, CMS will require claims to be submitted for these types of surgical errors. As discussed in previous responses, CMS believes that the NCD process is appropriate for addressing Medicare coverage of wrong site surgeries.

VI. Analysis

1. Definition

The NQF identified a list of preventable, serious adverse events and developed definitions that would facilitate reporting of such occurrences. We did not locate any other similar nationally accepted method of reporting such events and are therefore adopting the definitions of the events at issue from that list:

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. It includes surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), 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).

2. Scope

The NQF has defined the scope of procedures included in this event and we agree with that scope. However, as recommended by NQF, we are proposing some changes to avoid confusion of terms within the Medicare program. The term “surgery” has been used regularly throughout the history of the Medicare program in statute, regulation and policy. To define that term as NQF has, has the potential to modify these policies. Thus, we propose, rather than defining “surgery,” to define “surgical and other invasive procedures” while still encompassing all procedures included within the NQF definition. We also propose to clarify for Medicare purposes that all CPT codes in the surgery section of the CPT manual are included as well as other invasive procedures such as angioplasty and catheterizations. Thus, we propose the following scope:

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.

3. Coverage

Evidence of harm or lack of evidence of benefit is not necessary to determine that performing a surgical procedure on the wrong body part of a Medicare beneficiary does not improve health care outcomes. We have included in the discussion above several prominent healthcare entities that agree with this conclusion. Thus, we are proposing that performing surgery on the wrong body part is not reasonable and necessary and thus not covered. In addition, as we discussed above, rather than using the term “surgery” we will substitute “surgical and other invasive procedures” to avoid conflict with other Medicare policies.

IX. Decision

The Centers for Medicare and Medicaid Services (CMS) has determined that when a Medicare beneficiary requires a particular surgical or other invasive procedure to treat a particular medical condition and the practitioner erroneously performs that procedure on the wrong body part, Medicare will not cover that particular surgical or other invasive 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 body part if it is not consistent with the correctly documented informed consent for that patient. It includes surgery on the right body part, but on the wrong location on the body; for example, left versus right (appendages and/or organs), 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.

¹ <http://www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf>

² <http://www.qualityforum.org/pdf/reports/sre.pdf>

³ <http://www.jointcommission.org/PatientSafety/UniversalProtocol/>

⁴ http://www.jointcommission.org/NewsRoom/NewsReleases/nr_npgs_gen.htm

⁵ http://www.jointcommission.org/NR/rdonlyres/40A7233C-C4F7-4680-9861-80CDFD5F62C6/0/09_NPSG_HAP_gp.pdf

⁶ http://www.jointcommission.org/NR/rdonlyres/89440B8D-6FCC-4372-B2FA-02DA564D022E/0/09_NPSG_OBS_gp.pdf

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