CIGNA REIMBURSEMENT POLICY

The following Reimbursement Policy applies to all plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Original Effective Date…….10/01/2008
Policy History/Updates
Reimbursement Policy Number R05

Subject **Never Events**

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Related policies:
R19 Hospital Acquired Conditions

INSTRUCTIONS FOR USE
*Reimbursement policies are intended to supplement certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of individual's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these reimbursement policies are based. For example, an individual's benefit plan document may contain a specific exclusion related to a topic addressed in a reimbursement policy. In the event of a conflict, an individual's benefit plan document **always supercedes** the information in a reimbursement policy.* *Proprietary information of CIGNA. Copyright ©2011 CIGNA*

Reimbursement Policy

CIGNA does not provide reimbursement for "never events" whether inpatient or outpatient as they are not medically necessary.

CIGNA will not provide reimbursement to any provider associated with a Never Event (i.e. surgeon, anesthesiologist and radiologist).

CIGNA will not provider reimbursement for any related services, defined as all services provided in the operating or procedure room when the error occurs.

This policy, along with provider contracting initiatives and provider transparency strategies, is intended to improve hospital reporting, help reduce the number of these events, assist the member in becoming more informed regarding hospital quality issues and to more closely align our practices with CMS (Centers for Medicare and Medicaid Services).

General Background

The Leapfrog Group, founded in 2000, is an employer-led group of more than 145 organizations "that sponsor health care benefits and support the use of their purchasing power to initiate breakthrough improvements in the safety, quality and affordability of health care". Based on the National Quality Forum (NQF) "never events" definition (which differs from CIGNA's definition), the Leapfrog Group encourages hospitals to adhere to the following initiatives:

- Apologize to the patient and/or family affected by the never event;
- Report the event to at least one of the following agencies: the Joint Commission, a state reporting program for medical errors; a Patient Safety Organization.
- Perform a root cause analysis consistent with instructions from the chosen reporting agency, and
- Waive all costs directly related to the serious reportable adverse event.

The National Quality Forum, a private organization whose members include the American Medical Association (AMA), defines "never events" as "errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility".

In order to be included in the NQF list of "never events", the following criteria must be met:

- "Unambiguous – clearly identifiable and measurable, and thus feasible to include in a reporting system;
- Usually preventable – recognizing that some events are not always avoidable, given the complexity of health care;
- Serious – resulting in the death or loss of a body part, disability, or more than transient loss of a body function, and
- Any of the following:
    - Adverse and/or
    - Indicative of a problem in the health care facility's safety systems and/or, important for public credibility or public accountability."

The NQF definition of "never events" encompasses both what CIGNA calls Never Events and Hospital Acquired Conditions. This policy addresses Never Events. Hospital Acquired Conditions are addressed in a separate policy.

Never Events

Procedures performed on the wrong side, wrong body part, wrong procedure or wrong person are referred to in this policy as "Never Events". These Never Events are not medically necessary[1] as they are not required to diagnose or treat an illness, injury, disease or its symptoms and are not consistent with generally accepted standards of medical practice. All Never Events involving a wrong procedure, or a procedure performed on the wrong side, wrong body part, or wrong person are considered not medically necessary, and no reimbursement is allowed for Never Events. Hospitals and health care professionals generally refrain from billing members for these Never Events. In addition, billing patients for these Never Events is not consistent with CMS guidelines, or the National Quality Forum Leapfrog Quality Initiatives.

Wrong-side, wrong-site, wrong-procedure, and wrong person adverse events (WSPEs) are devastating, unacceptable, and often result in litigation. WSPEs are likely more common than is generally realized. Beginning in July 2004, Joint Commission-accredited hospitals were required to adhere to the Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery by implementing time outs

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[1] A typical definition of medical necessity is as follows:
Medically Necessary Covered Services and Supplies are those determined by the Healthplan Medical Director to be:

- Required to diagnose or treat an illness, injury, disease or its symptoms; and
- In accordance with generally accepted standards of medical practice; and
- Clinically appropriate in terms of type, frequency, extent, site and duration; and
- Not primarily for the convenience of the patient, Physician, or other health care provider; and
- Rendered in the last intensive setting that is appropriate for the delivery of the services and supplies. Where applicable, the Healthplan Medical Director may compare the cost-effectiveness of alternative services, settings or supplies when determining the least intensive setting.

and site verifications for all invasive procedures (Norton E., 2007). Higher-level policies or programs have been implemented by the American Academy of Orthopaedic Surgery, Joint Commission on Accreditation of Healthcare Organizations, Veteran's Health Administration, Canadian Orthopaedic, and the North American Spine Society Associations to reduce wrong site surgery. (Michaels RK, et. al., 2006)

Seiden and Barah (2006) published an analysis of several databases that demonstrated that Never Events occur across all specialties, with high numbers noted in orthopedic and dental surgery. Databases analyzed included: (1) the National Practitioner Data Bank (NPDB), (2) the Florida Code 15 mandatory reporting system, (3) the American Society of Anesthesiologists (ASA) Closed Claims Project database, and (4) a novel Web-based system for collecting WSPE cases (http://www.wrong-side.org). Results showed that the NPDB recorded 5940 Never Events (2217 wrong-side surgical procedures and 3723 wrong-treatment/wrong-procedure errors) in 13 years. Florida Code 15 occurrences of WSPEs number 494 since 1991, averaging 75 events per year since 2000. The ASA Closed Claims Project has recorded 54 cases of WSPEs. Analysis of WSPE cases, including WSPE cases submitted to http://www.wrong-side.org, suggest several common causes of WSPEs and recurrent systemic failures. Based on these findings, they estimated that there are 1300 to 2700 WSPEs annually in the United States. Despite a significant number of cases, they noted that reporting of WSPEs is virtually nonexistent, with reports in the lay press far more common than reports in the medical literature. Research suggests clear factors that contribute to the occurrence of WSPEs, as well as ways to reduce them. They concluded that wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events, although rare, are more common than health care providers and patients appreciate. Prevention of WSPEs requires new and innovative technologies, reporting of case occurrence, and learning from successful safety initiatives (such as in transfusion medicine and other high-risk nonmedical industries), while reducing the shame associated with these events.

Kwaan MR et. al. (2006) published a case series and survey of wrong-site/procedure/person procedures. Data was obtained from hospitals and a malpractice liability insurer. All wrong-site surgery cases reported to a large malpractice insurer between 1985 and 2004 were reviewed. Incidence, characteristics, and causes of wrong-site surgery and characteristics of site-verification protocols were reviewed. Results showed that among 2,826,367 operations at insured institutions during the study period, 25 nonspine wrong-site operations were identified, producing an incidence of 1 in 112,994 operations (95% confidence interval, 1 in 76,336 to 1 in 174,825). Medical records were available for review in 13 cases. Among reviewed claims, patient injury was permanent-significant in 1, temporary-major in 2, and temporary-minor or temporary-insignificant in 10. Under optimal conditions, the Joint Commission on Accreditation of Healthcare Organizations Universal Protocol might have prevented 8 (62%) of the 13 cases. Hospital protocol design varied significantly. The protocols mandated 2 to 4 personnel to perform 12 separate operative-site checks on average (range, 5-20). Five protocols required site marking in cases that involved nonmidline organs or structures; 6 required it in all cases. The authors concluded that wrong-site surgery is unacceptable but exceedingly rare, and major injury from wrong-site surgery is even rarer. Current site-verification protocols could have prevented only two thirds of the examined cases.

Neily et al (2009) conducted a study based on incorrect surgical procedures reported from Veterans Health Administration (VHA) Medical Centers from 2001 to mid-2006 to provide solutions for preventing these types of events. They reviewed 242 reported events (212 adverse events and 130 close calls). They found that 108 adverse events (50.9%) occurred in the OR and 104 (49.1%) occurred elsewhere. They concluded that the most common root cause was communication (21.0%). They also concluded that incorrect surgical procedures presented a challenge for both inside and outside of the OR and that they support earlier communication based on crew resource management to prevent adverse events.

CMS has adopted a national payment policy that all Wrong Site/Procedure/Person procedures (E876.5, E876.6 and E876.7) are never reimbursed to facilities. In addition, related services, as defined in the Medicare Benefit Policy Manual (BPM) Chapter 1, sections 10 and 120 and Chapter 16, section 180 are not covered. They include:

- 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.

CIGNA has concluded that Never Events - procedures for the wrong site, wrong procedure or wrong person - are not medically necessary as they are not required to diagnose or treat an illness, injury, disease or its symptoms and/or are not within generally accepted standards of medical practice. All such Never Events will be denied for lack of medical necessity. All related services, defined as all services provided in the operating room when the error occurs are considered not medically necessary and therefore will not be covered.

Case Example #1: A patient is taken to the operating room for an operative procedure on the left knee. Through an error, the physician operates on the normal right knee and discovers the mistake only when he determines during the surgery that the anatomy of the knee is perfectly normal. The physician terminates the procedure and orders the patient to the recovery room. After the patient has recovered from the anesthesia, the physician explains to the patient and the family that because of an error, the wrong knee was operated on. The physician apologizes for the error and agrees not to bill the patient for the procedure. Later that day, a hospital official also discusses the error and apologizes to the family and agrees that the hospital will not bill the patient or his insurance carrier for the procedure. In this case, the operative procedure on the right knee was not medically necessary as it was not required to diagnose or treat an illness, injury, disease or its symptoms and/or was not within generally accepted standards of practice.

Concurrent Review:

We review admissions with identifiable Never Events. Never Events identified through the Continued Stay Review process will be denied for payment due to lack of medical necessity, as these services are not consistent with generally accepted standards of medical practice.

Pre Payment Review:
Claim submissions are monitored via ICD-09 CM diagnosis codes to identify claims that have been submitted with a Never Event diagnosis.

Provider Transparency:

CIGNA believes our members should have access to information concerning hospital quality and safety. Information concerning mortality rates, hospital complications, patient safety, and participation in National Quality Forum's Leapfrog Initiatives are included in CIGNA's hospital quality tool available on CIGNA's website for our members. For more information, see CIGNA's website at:
http://cigna.benefitnation.net/cignams/searchhosp.asp.

Hospitals are encouraged to adopt the Leapfrog Group's policies on patient safety to help reduce hospital errors and improve the quality and affordability of health care. To review the Leapfrog Hospital Quality and Safety Survey, or to determine if a hospital has implemented one or more patient safety standards outlined by the Leapfrog Group, click on the following link:
http://www.leapfroggroup.org/cp.

SUMMARY

CIGNA's policy on Never Events is designed to encourage hospitals to improve patient safety and reduce avoidable error rates. Operations on the wrong site, wrong operation, or wrong person are Never Events and are not medically necessary.

Consumers should have access to information concerning hospitals comparative rates of complications, quality and patient safety measures, as well as whether the facility participates in Leapfrog Initiatives.

Hospitalizations and all services related to a Never Event are not medically necessary and are not covered.

All services, both inpatient and outpatient, facility and health care professional relating to a Never Event are not covered.

Coding Requirements

As part of CIGNA's Quality Management Program, CIGNA may request additional medical records for admissions and/or outpatient procedures involving Never Events.

In administering this policy, CIGNA will seek to use published CMS Medicare guidelines, whenever such are consistent with our benefit plans and hospital contracts.

Never Events

"Never Event"	ICD-9 CM Code	ICD-9 CM Code Description
Wrong surgery; wrong patient	E876.5	Performance of wrong operation (procedure) on correct patient
	E876.6	Performance of operation (procedure) on patient not scheduled for surgery
	E876.7	Performance of correct operation (procedure) on wrong side/body part

The following modifiers are to be used by practitioners, ambulatory surgical centers (ASC's) and hospital outpatient facilities to report surgical procedures referred to in this policy as "Never Events".

Modifier	Modifier Description
PA	Surgery wrong body part
PB	Surgery wrong patient
PC	Wrong surgery on patient

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Policy History/Updates

Date	Change/Update
05/30/2011	Policy template updated
11/30/2010	Updated to include CMS "Never Events" modifiers PA, PB, PC, and additional ICD-9 codes. Clarified that all services related to the Never Event are not medically necessary and not covered. Separated Never Events from Avoidable Hospital Conditions to create two policies.
05/06/2009	Updated format. No policy changes
10/01/2008	Policy effective date for CIGNA HealthCare and former Great-West Healthcare network.
08/29/2008	Updated to include 4 additional conditions
04/15/2008	Notification date of policy for CIGNA HealthCare and former Great-West Healthcare network.

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