Provider preventable conditions and hospital acquired conditions

Clinical Policy ID: CCP.1215

Recent review date: 2/2020

Next review date: 6/2021

Policy contains: Hospital-acquired conditions; health care-acquired conditions; provider preventable conditions; other provider preventable conditions.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

This policy communicates AmeriHealth Caritas' reimbursement position for provider preventable conditions and hospital-acquired conditions. The reimbursement component of this policy is separate and distinct from other contracting policies regarding present-on-admission and hospital-acquired conditions.

AmeriHealth Caritas will comply with applicable law regarding nonpayment for provider preventable conditions, which include health care-acquired conditions and other provider preventable conditions. AmeriHealth Caritas will not reimburse facilities or professional providers for the increased incremental costs of inpatient care services that result when a member is harmed by any of the following (42 CFR.434, 42 CFR.438, 42 CFR.447, 42 CFR.447.26):

- Health care-acquired conditions (for any Medicaid inpatient hospital setting):
    - Foreign object retained after surgery.
    - Air embolism.

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- Blood incompatibility.
- Stage III and IV pressure ulcers.
- Falls and trauma including fractures, dislocations, intracranial injuries, crushing injuries, burns, electric shock.
- Catheter-associated urinary tract infection.
- Vascular catheter-associated infection.
- Manifestations of poor glycemic control including: diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemic coma, secondary diabetes with ketoacidosis, and secondary diabetes with hyperosmolarity.
- Surgical site infection following:
  - Coronary artery bypass graft – mediastinitis.
  - Bariatric surgery including laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery.
  - Orthopedic procedures including spine, neck, shoulder, elbow.
- A cardiac implantable electronic device.
- Deep vein thrombosis/pulmonary embolism following total knee replacement or hip replacement with pediatric and obstetric exceptions.
- Iatrogenic pneumothorax with venous catheterization.

- Other provider preventable conditions (for Medicaid inpatient and outpatient health care settings):
  - 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.
  - Other provider preventable conditions identified in the state's plan and according to the requirements of the final regulation.

For Medicare members only:

AmeriHealth Caritas will not reimburse facilities or professional providers for the increased incremental costs of inpatient care services that result when a member is harmed by one of the following hospital-acquired conditions (U.S. Centers for Medicare & Medicaid Services, 2008, 2015):
- Foreign object (e.g., sponge, needle) retention after surgery.
- Air embolism.
- Blood incompatibility.
- Stage III or Stage IV pressure ulcers.
- Certain falls and trauma that occur in the facility and result in:
  - Fracture.
  - Joint dislocation.
  - Head injury.
  - Crushing injury.
  - Burn.
  - Electric shock, excluding events involving planned treatments such as electric countershock or elective cardioversion.
- Catheter-associated urinary tract infection.
- Vascular catheter-associated infection.
- Manifestations of poor glycemic control, including the following:
  - Diabetic ketoacidosis.

- Nonketotic hyperosmolar coma.
- Hypoglycemic coma.
- Secondary diabetes with ketoacidosis.
- Secondary diabetes with hyperosmolarity.
- Surgical site infection following coronary artery bypass graft including mediastinitis.
- Surgical site infection following certain orthopedic procedures including the following:
  - Spine.
  - Neck.
  - Shoulder.
  - Elbow.
- Surgical site infection following cardiac implantable electronic device procedures.
- Surgical site infection following bariatric surgery for obesity including the following:
  - Laparoscopic gastroenterostomy.
  - Gastroenterostomy.
  - Laparoscopic gastric restrictive surgery.
- Iatrogenic pneumothorax with venous catheterization.
- Deep vein thrombosis/pulmonary embolism following certain orthopedic procedures including the following:
  - Total knee replacement.
  - Hip replacement.

AmeriHealth Caritas will not reimburse facilities or professional providers for the increased incremental costs of inpatient care services that result when a member is harmed by one of the following:
- 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.

Reporting requirements:

In addition to the reporting requirements of state, accrediting organizations, and participating provider contractual requirements, facilities and/or professional providers must report the following information to AmeriHealth Caritas within 10 days of the occurrence of the event:
- Member name and member ID number.
- A description of the event.
- Dates of services and occurrence of the event.
- Attending physician(s).
- Facility.

AmeriHealth Caritas may require the submission of clinical information before or after the processing of a claim for services rendered to members.

Limitations

No reduction in payment for a provider preventable condition or hospital-acquired condition will be imposed on a provider when one of these conditions for a particular patient existed prior to the initiation of treatment for that patient by that provider.

Reductions in provider payment are limited to the extent that the identified provider preventable condition or hospital-acquired condition would otherwise result in an increase in payment, and the state can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider preventable condition or hospital-acquired condition.

Members are held harmless in the case of a provider preventable condition or hospital-acquired condition; therefore, participating providers are not permitted to seek reimbursement from the member in any form (including copayments, deductibles, or coinsurance).

When a retrospective medical record review substantiates a provider preventable condition or hospital-acquired condition as defined in this policy, reimbursement will be denied or adjusted accordingly.

AmeriHealth Caritas may conduct reviews and audits of services to members, regardless of the participation status of the provider. All documentation is to be made available to AmeriHealth Caritas upon request.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

In a 1999 landmark report, the Institute of Medicine estimated that preventable medical errors resulted in as many as 98,000 deaths per year in U.S. hospitals and substantial additional health care costs (Institute of Medicine, 1999). Most medical errors are preventable, and some can cause harmful or even disastrous results. Few of these medical errors are related to negligence or professional misconduct. The Institute of Medicine called for a 50% reduction in the number of deaths due to medical errors in five years.

Accordingly, in 2002 the National Quality Forum developed an initial standardized list of 27 serious reportable events that would facilitate reporting of such occurrences. Serious reportable events consist of never events (i.e., alarming medical errors that should never happen) and preventable adverse events (i.e., events that could be reasonably prevented if evidence-based policies and procedures are followed). Since then, the serious reportable events list has been revised twice, most recently in 2011, and now consists of 29 serious reportable events grouped into seven categories: surgical, product or device, patient protection, care management, environmental, radiologic, and criminal (National Quality Forum, 2011a; Appendix A at the end of this policy). Each serious reportable event meets the following criteria (National Quality Forum, 2011a):
- They are of serious concern to patients, policy makers, and health care professionals and providers.
- They are clearly identifiable and measurable (and thus feasible to include in a reporting system).
- The risk of their occurrence can be reduced by application of evidence-based protocols, policies, and procedures within the health care organization.

The National Quality Forum-endorsed serious reportable events list formed the basis for a uniform national state-based reporting system and triggered a number of quality initiatives to facilitate learning, improve patient safety and reduce avoidable errors in the spirit of providing a nonthreatening environment for patients and providers (National Quality Forum, 2011a). Transparency in the disclosure of serious reportable events and root-cause analysis may facilitate a substantial reduction in medical malpractice lawsuits, lower litigation costs, and cultivate a more safety-conscious environment (Chen, 2015). However, significant gaps remain in the measurement of patient safety. Many, but not all, states have enacted systems for mandatory reporting of serious reportable events with variable reporting requirements (National Quality Forum, 2011b). Lack of feedback and fear of

personal consequences are common barriers to reporting, which make it difficult to help practitioners identify and learn from these mistakes (Noble, 2010).

A systematic review found strengthening policy and supporting health care professionals through training improved both disclosure practices and provider-patient relationships, and fostered an environment of quality improvement (O'Connor, 2010; American Congress of Obstetricians and Gynecologists, 2008). The presence of strong leadership supported by organizational commitment to patient safety is essential in driving these changes (Kalra, 2004).

U.S. Centers for Medicare & Medicaid Services policy development:

The U.S. Centers for Medicare & Medicaid Services expressed concerns that it had not reached the Institute of Medicine's goal of a 50% reduction in the number of deaths due to medical errors in five years (U.S. Centers for Medicare & Medicaid Services, 2006). As part of Medicare payment reforms set forth in the Deficit Reduction Act of 2005, the U.S. Centers for Medicare & Medicaid Services pursued ways to reduce or eliminate the occurrence of never events and preventable adverse events in the Medicare population and their associated costs of care. The U.S. Centers for Medicare & Medicaid Services developed quality standards to serve as the basis for public reporting and payment, and launched a number of demonstrations aimed at improving quality of care, including tying payment to quality.

In 2007, the U.S. Centers for Medicare & Medicaid Services issued a final rule to end additional payments to hospitals for certain preventable hospital-acquired conditions (i.e., not Present on Admission), which are considered:
- High volume and/or high cost.
- A complication or comorbidity or major complication or comorbidity for purposes of Medicare-severity diagnostic-related group assignment.
- Reasonably preventable based on application of published, evidence-based guidelines.

These rules also encouraged states to consider the entire Medicaid population, including dual-eligibles, and all of the National Quality Forum-endorsed serious reportable events in creating individual state policies, with the guiding principle of linking payment and performance (U.S. Centers for Medicare & Medicaid Services, 2008). The U.S. Centers for Medicare & Medicaid Services rule prohibits passing these charges on to patients. In 2009, the U.S. Centers for Medicare & Medicaid Services initiated three Medicare National Coverage Determinations to address coverage for surgery on the wrong body part, surgery on the wrong patient, and wrong surgery performed on a patient.

Using a rigorous, systematic and comprehensive process for identifying preventable hospital-acquired conditions, the U.S. Centers for Medicare & Medicaid Services published subsequent fiscal year final rules expanding the list of selected hospital-acquired conditions that have Medicare payment implications (U.S. Centers for Medicare & Medicaid Services, 2015; Appendix B). The U.S. Centers for Medicare & Medicaid Services final list of nonreimbursable hospital-acquired conditions is not identical to, but aligns with, the National Quality Forum-endorsed serious reportable events.

The U.S. Centers for Medicare & Medicaid Services understood the hospital-acquired conditions developed for the Medicare population may not directly apply to various subsets of Medicaid's population. Effective July 1, 2011, U.S. Centers for Medicare & Medicaid Services enacted a final rule implementing the requirements of Section 2702 of the Patient Protection and Affordable Care Act of 2010, specifically requiring states to implement

nonpayment policies for provider preventable conditions in the Medicaid population (42 CFR Parts 434, 438, 447, and 42 CFR.447.26).

The umbrella term "provider preventable conditions" is used for hospital and nonhospital acquired conditions identified by the state for nonpayment to ensure the high quality of Medicaid services. The adoption of a new term was necessary to incorporate existing state practices, comply with existing statutory definitions of hospital-acquired conditions, and provide some consistency across health care payers (Medicare and Medicaid). Provider preventable conditions are defined as two distinct categories: Health Care-Acquired Conditions and Other Provider Preventable Conditions (Appendix C).

Health Care-Acquired Conditions:
- Apply to Medicaid inpatient hospital settings.
- Are defined as the full list of Medicare's hospital-acquired conditions, with the exception of deep vein thrombosis/pulmonary embolism following total knee replacement or hip replacement in pediatric and obstetric patients, as the minimum requirements for states' provider preventable conditions nonpayment programs.

Other Provider Preventable Conditions:
- Apply broadly to Medicaid inpatient and outpatient health care settings where these events may occur.
- Are defined to include at a minimum, the three Medicare National Coverage Determinations (surgery on the wrong patient, wrong surgery on a patient, and wrong site surgery).
- Would allow states to expand to settings other than inpatient hospital with U.S. Centers for Medicare & Medicaid Services approval by nature of identifying events that occur in other settings.
- Would allow states to expand the conditions identified for nonpayment with U.S. Centers for Medicare & Medicaid Services approval, based on criteria set forth in the regulation.

Findings

Not applicable.

References

On November 11, 2019, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "provider preventable" and "hospital acquired." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

1/2016: initial review date and clinical policy effective date: 7/2016

12/2018: The policy number was changed from 18.04.04 to CCP.1215.
11/2019: Policy references updated.

Appendix

<u>Appendix A</u>. **National Quality Forum list of serious reportable events**

Unless otherwise indicated, each event is applicable in hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices, and long-term care/skilled nursing facilities.

1. Surgical or invasive procedure events:

   1A. Surgery or other invasive procedure performed on the wrong site (updated).

   1B. Surgery or other invasive procedure performed on the wrong patient (updated).

   1C. Wrong surgical or other invasive procedure performed on a patient (updated).

   1D. Unintended retention of a foreign object in a patient after surgery or other invasive procedure (updated).

   1E. Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists Class 1 patient (updated).

2. Product or device events:

2A. Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting (updated).

2B. Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used or functions other than as intended (updated).

2C. Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting (updated).

Applicable in: hospitals, outpatient/office-based surgery centers, long-term care/skilled nursing facilities.

3. Patient protection events:

3A. Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person (updated).

3B. Patient death or serious injury associated with patient elopement (disappearance) (updated).

3C. Patient suicide, attempted suicide, or self-harm that results in serious injury, while being cared for in a health care setting (updated).

4. Care management events:

4A. Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration) (updated).

4B. Patient death or serious injury associated with unsafe administration of blood products (updated).

4C. Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting (updated).

Applicable in: hospitals, outpatient/office-based surgery centers.

4D. Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy (new).

Applicable in: hospitals, outpatient/office-based surgery centers.

4E. Patient death or serious injury associated with a fall while being cared for in a health care setting (updated).

4F. Any Stage 3, Stage 4, and unstageable pressure ulcers acquired after admission/presentation to a health care setting (updated).

Applicable in: hospitals, outpatient/office-based surgery centers, long-term care/skilled nursing facilities.

4G. Artificial insemination with the wrong donor sperm or wrong egg (updated).

Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices.

4H. Patient death or serious injury resulting from the irretrievable loss of an irreplaceable biological specimen (new).

4I. Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results (new).

5. Environmental events:

   5A. Patient or staff death or serious injury associated with an electric shock in the course of a patient care process in a health care setting (updated).

   5B. Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances (updated).

   5C. Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting (updated).

   5D. Patient death or serious injury associated with the use of physical restraints or bedrails while being cared for in a health care setting (updated).

6. Radiologic events:

   6A. Death or serious injury of a patient or staff associated with the introduction of a metallic object into the magnetic resonance imaging area (new).

   Applicable in: hospitals, outpatient/office-based surgery centers, ambulatory practice settings/office-based practices.

7. Potential criminal events:

   7A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider (updated).

   7B. Abduction of a patient/resident of any age (updated).

   7C. Sexual abuse/assault on a patient or staff member within or on the grounds of a health care setting (updated).

   7D. Death or serious injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting (updated).

Appendix B. Medicare nonreimbursable hospital-acquired conditions (through fiscal year 2015)
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions. Accessed November 14, 2019.

- Foreign object retained after surgery.
- Air embolism.
- Blood incompatibility.
- Stage III and IV pressure ulcers.
- Falls and trauma:
    - Fractures.
    - Dislocations.

- Intracranial injuries.

    - Crushing injuries.

    - Burn.

    - Other injuries.

- Manifestations of poor glycemic control:

    - Diabetic ketoacidosis.

    - Nonketotic hyperosmolar coma.

    - Hypoglycemic coma.

    - Secondary diabetes with ketoacidosis.

    - Secondary diabetes with hyperosmolarity.

- Catheter-associated urinary tract infection.

- Vascular catheter-associated infection.

- Surgical site infection, mediastinitis, following coronary artery bypass graft.

- Surgical site infection following bariatric surgery for obesity:

    - Laparoscopic gastric bypass.

    - Gastroenterostomy.

    - Laparoscopic gastric restrictive surgery.

- Surgical site infection following certain orthopedic procedures:

    - Spine.

    - Neck.

    - Shoulder.

    - Elbow.

- Surgical site infection following cardiac implantable electronic device.

- Deep vein thrombosis/pulmonary embolism following certain orthopedic procedures:

    - Total knee replacement.

    - Hip replacement.

- Iatrogenic pneumothorax with venous catheterization.

Appendix C. U.S. Centers for Medicare & Medicaid Services nonreimbursable provider preventable conditions

Category 1 – Health Care-Acquired Conditions (for any inpatient hospitals settings in Medicaid)

- Foreign object retained after surgery.

- Air embolism.

- Blood incompatibility.

- Stage III and IV pressure ulcers.

- Falls and trauma; including fractures, dislocations, intracranial injuries, crushing injuries, burns, electric shock.

- Catheter-associated urinary tract infection.

- Vascular catheter-associated infection.

- Manifestations of poor glycemic control; including diabetic ketoacidosis, nonketotic hyperosmolar coma, hypoglycemic coma, secondary diabetes with ketoacidosis, secondary diabetes with hyperosmolarity.

- Surgical site infection following:

    - Coronary artery bypass graft – mediastinitis.

    - Bariatric surgery, including laparoscopic gastric bypass, gastroenterostomy, laparoscopic gastric restrictive surgery.

    - Orthopedic procedures, including spine, neck, shoulder, elbow.

- Deep vein thrombosis/pulmonary embolism following total knee replacement or hip replacement with pediatric and obstetric exceptions.

Category 2 – Other Provider Preventable Conditions (for any health care setting)

- 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.

- Other provider preventable conditions identified in the state's plan and according to the requirements of the final regulation.