Clinical Research Billing Compliance

Key Terms

ADVANCE BENEFICIARY NOTICE (ABN)

A notice that a provider/physician or supplier should give to a Medicare beneficiary when furnishing an item or service for which Medicare is expected to deny payment.

ANCILLARY SERVICES

A term used to describe additional services that are performed related to care, such as lab work, x-ray, and anesthesia.

ANTI-KICKBACK STATUTE

A criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business.

BILLABLE EVENT

Patient care services or items such as clinic visits, procedures, radiology, labs, etc. that may generate a charge in the healthcare billing system. These events are typically associated with a CPT and/or HCPCS code.

BILLING CLAIM or INSURANCE CLAIM or CLAIM

A form filed with a Medicare or another insurance carrier that details the services provided and other pertinent data (date of service, diagnosis, codes, etc.) to receive payment.

BILLING COMPLIANCE PLAN

The billing compliance plan is a detailed assessment of the protocol events that will occur during of the study. This is an internal document which can be used to develop the study budget.

BILLING GRID for COVERAGE ANALYSIS

a Billing A grid used for qualifying clinical trials that identifies and differentiates routine costs that may be billed to the participant and/or any Third Party Payer from the Research Procedures and services.

BILLING DESIGNATION

Identification of how an individual patient care cost is covered within a study. The designation is intended to classify the party responsible for covering the cost of the item. Billing designations may include research related (RR), routine cost (RC), or non-billable (NB).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The federal agency that runs the Medicare, Medicaid, and Children's Health Insurance Programs, and the federally facilitated Marketplace. CMS and Medicare are synonymous and may be used interchangeably.

CLAIM HOLD

The process of holding a billing claim for a period of time for internal review. Typically, this is done to conduct a quality assurance check prior to submitting to the insurance company.

COVERED BENEFIT

A health service or item that is included in an individual's health plan, and that is paid for either partially or fully.

CURRENT PROCEDURAL TERMINOLOGY (CPT) CODE

The CPT code set (copyright protected by the AMA) describes medical, surgical, and diagnostic services and is designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. The code identifies the service rendered and the associated cost on a fee schedule.

DISALLOWANCE

A charge that has been determined as unallowable in accordance with the applicable cost principles, institutional policy or other terms and conditions contained in the agreement/award.

DOUBLE BILLING

Double billing occurs when the same service is paid for by two different sources.

ENCOUNTER FORM

An itemized billing statement listing the items/services that were rendered during a visit or date of service. An encounter form is used to note the diagnosis, treatment and related fees.

FALSE CLAIMS ACT

Federal law that imposes liability on persons and companies who defraud governmental programs. It is the federal Government's primary litigation tool in combating fraud against the Government. This legislation prohibits anyone from knowingly submitting or causing to be submitted a false or fraudulent claim.

FUNDING AGREEMENT

The legally binding agreement between all parties that includes the fiscal information (budget, payment terms, invoiceable, etc.) related to a study.

INDICATION

Description of use of an FDA approved drug in the treatment, prevention or diagnosis of a recognized disease or condition.

LOCAL COVERAGE DETERMINATION

A determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis. Local coverage determinations are based by regions by the Medicare Administrative Contractor.

MEDICALLY NECESSARY

Health care services or supplies needed to prevent, diagnose, or treat an illness, injury, condition, disease, or its symptoms and that meets accepted standards of medicine.

MEDICAID

A joint federal and state program that helps with medical costs for some people with limited income and resources. Medicaid programs vary from state to state.

MEDICARE

Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a transplant, sometimes called ESRD). Medicare is commonly referred to as CMS.

MEDICARE ADMINISTRATIVE CONTRACTOR (MAC)

The Centers for Medicare & Medicaid Services (CMS) uses a network of contractors called Medicare Administrative Contractors (MACs) to process Medicare claims, enroll health care providers in the Medicare program and educate providers on Medicare billing requirements. MACs also handle claims appeals and answer beneficiary and provider inquiries. CMS established MACs as multi-state, regional contractors responsible for administering both Medicare Part A and Medicare Part B claims.

MEDICARE COVERAGE ANALYSIS (MCA)

The Medicare Coverage Analysis is a process that is designed as a systematic review of the protocol, budget, informed consent, and funding agreement (if applicable). This process is intended to identify and document the funding source for each patient care billable event prior to initiation of the study. Items that are identified as billable to the patient/insurance must meet Medicare's criteria for routine costs.

MODIFIER

A two-digit alpha or numeric code (i.e. Q0, Q1) used with procedure codes to provide additional clarification or information of the circumstances related to the health care services provided.

NATIONAL COVERAGE DETERMINATION (NCD)

A National Coverage Determination (NCD) sets forth the extent to which Medicare will cover specific services, procedures, or technologies on a national basis. Medicare

contractors are required to follow NCDs. If an NCD does not specifically exclude/limit an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, it is up to the Medicare contractor to make the coverage decision.

NON-BILLABLE EVENT

An item that is provided at no cost and/or does not generate a charge in healthcare billing system. Examples include labs sent to central lab for processing, or an investigational product that is provided for free, etc.

QUALIFYING CLINICAL TRIAL

A study that meets Medicare's criteria under the National Coverage Determination (NCD 310.1) "Routine Costs in Clinical Trials".

ROUTINE COSTS

The following items and/or services will be covered as a "routine cost" of the study so long as it is not agreed to be paid or paid by the sponsor and it is not promised free to the subject in the informed consent:

1. Items and services that are otherwise generally available (e.g., conventional care) to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision, etc.);
2. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications
4. All other Medicare rules apply

RESEARCH RELATED

tems and/or services that are not an allowable expense to the patient, not considered routine or covered and paid by the Sponsor.