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Complete Healthcare Compliance Manual 2024
Patient Care: Medical Necessity and Patient Status

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What Are Medical Necessity and Patient Status?

The Social Security Act (SSA) outlines that all services provided under Medicare must be reasonable and necessary as a basis for payment.[2] Section 1862(a)(1)(A) of the SSA further defines that payment may not be made for any expenses incurred for items or services which are not reasonable and necessary for the evaluation and management of a disease, condition, illness, or injury.[3] It is important to note this clarification, as the focus is on payment and not the quality of care received. For compliance professionals, this key point is center stage when discussing medical necessity with providers, ensuring proper documentation that supports medical necessity is within the medical record, and ensuring understanding that medical necessity is not a reflection of the care provided.

Medical necessity for healthcare services is evidenced through documentation. Documentation within the medical record serves several key functions—it is the communication vehicle between members of the team providing care to a patient across multiple settings to ensure continuity of patient care, serves as the legal document to support services provided, and demonstrates the justification to support payment for the medical care and services provided to the patient. Care must be considered reasonable when compared against current medical standards of care.

The Centers for Medicare & Medicaid Services (CMS) Conditions of Participation for Medicare and Medicaid and the SSA require that hospitals and health systems have an effective utilization review (UR) plan/UR function in place, with specific processes to review medical necessity, resource use, length of stay (LOS), denials, and outcomes, which directly affect reimbursement.[4] In addition, payers and health plans have contractual requirements that affect reimbursement. Given the role of the UR function and the regulatory complexities within healthcare, UR can be the bridge between quality, medical necessity, resources, coverage, and reimbursement and facilitate compliance with regulatory, risk, and quality requirements.

Coordination among UR, care management, revenue cycle, and the physician is imperative. Medicare reimbursement for inpatient and outpatient hospital services differ, with CMS providing payment for inpatient stays under the hospital inpatient prospective payment system (IPPS) in the Medicare Part A program or under payment structures for critical access hospitals, inpatient rehab, long term acute care, cancer, religious, or inpatient psych.[5] Whereas hospital outpatient visits are paid under the hospital outpatient prospective payment system (OPPS) under the Medicare Part B program.[6] When a patient presents to a hospital in need of medical care, the physician must determine whether the patient needs inpatient care or can be treated in an outpatient setting. This decision has implications for hospital payment and beneficiary cost sharing, and the physician documentation must support the level of care provided and that services are medically necessary regardless of the setting where the patient receives those services.

Two main clinical criteria are used as guidance for determining level of care: McKesson's InterQual Criteria and MCG. Both are evidence-based clinical guidelines used to assess whether a patient's level of care was appropriate.

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As these are guidelines, each physician must use their expertise to determine appropriate level of care, which may not align with clinical criteria. This is where it becomes critical for physicians to document their thought processes when making determinations of level of care and include in their documentation their evaluation of the patient, prior patient history, current symptoms or course of illness, and the details behind their clinical decisions. Patient evaluation does not always need to meet InterQual or MCG to admit the person as an inpatient.

CMS has two requirements to document and validate medical necessity of inpatient admission:

1. Reasonable expectation based on clinical standards of medical practice that the patient is likely to require two midnights or more of inpatient care, and
2. Specific explanation of the clinical conditions, circumstances, complications, comorbidities, and risks to the patient upon which that expectation is based.

Payment under Medicare Part A is generally not appropriate for hospital stays expected to span less than two-midnights, unless the admission falls into an exception as outlined by CMS, as either a procedure on the "inpatient only" list or qualifies for a case-by-case exception. To meet the qualification for the case-by-case exception, the medical record documentation must clearly support the physician's determination that the patient required hospital services in the inpatient setting regardless of the expectation of staying at least two-midnights. CMS' expectation is that an inpatient admission less than 24 hours would seldom qualify for the case-by-case exception to the two-midnight benchmark.

Effective October 1, 2018, CMS updated regulations that govern hospital admissions under Medicare Part A.[7] The changes removed the requirement that an inpatient admission order "must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A."[8] More importantly, CMS did not change the standard in that same regulation that an individual becomes an inpatient when formally admitted under an order for inpatient admission by a physician. According to CMS, this regulatory standard remains significant because it reflects a determination by the treating physician that inpatient services are medically necessary.

A physician order to admit a patient for inpatient services is binding and inpatient status begins at formal admission pursuant to the order. If after admission it is determined that the inpatient admission decision was incorrect or cannot be supported, the hospital can use the Condition Code 44 process to change the status to outpatient if the patient is still a patient in the hospital. To use the Condition Code 44 process, the attending physician and a UR Committee physician must both concur.[9] If the patient has already been discharged or the attending physician does not concur with the change to outpatient, the hospital may self-deny and rebill to Medicare part B.[10] In order to rebill, the attending physician must be afforded the opportunity to express his or her views but two physician members of the UR committee may approve self-denial without concurrence of the physician.[11] In both scenarios, the patient must be notified.

Prolonged Observation Services Guidance

Several CMS policies provide guidance relating to prolonged observation services: the definition provided for "observation services," Medicare Outpatient Observation Notice (MOON), comprehensive Ambulatory Payment Classification (APC) C-APC-8011, two-midnight rule, and Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act).

Observation Services and Medicare Outpatient Observation Notice (MOON)

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To be covered by Medicare, observation services must be reasonable and necessary. Observation is a short-term treatment that allows for assessment to determine whether a patient needs additional treatment as a hospital inpatient. An order by a qualified provider is required to place the patient in observation and start the clock to calculate the hours the patient is in observation for billing purposes. General supervision by the physician is required by CMS for observation services, and the presence of the physician is not required.[12] Notification to the patient if observation extends beyond 24 hours must occur through the MOON. Decisions to admit the patient to inpatient level of care or discharge the patient rarely extend beyond 48 hours.

Ambulatory Payment Classification (APC) C-APC-8011

Observation services are reported using HCPCS code G0378 for hourly observation services and is assigned a status indicator of N, identifying that payment is always packaged. As part of the CMS Comprehensive Ambulatory Payment Classification (C-APC) payment policy methodology, C-APC 8011 was established to capture claims that contain a specific combination of services provided to a patient during the same encounter; one of which must be eight or more units of service for G0378. In addition, the other criteria that qualify claims for payment under C-APC 8011 are: 1) HCPCS codes with a status indicator of T are not listed on the claim; 2) the claim contains one of the following codes: G0379 on the same date of service; 99281 – 99285 (emergency department visit); G0380--G0384 (type B emergency department visit); 99291 (critical care); or G0463 (hospital outpatient clinic visit) provided on the same date of service or 1 day before the date of service for G0378; and 3) HCPCS codes with status indicator J1 are not listed on the claim.

Two-Midnight Rule

Length of stay plays a key role in inpatient care decision-making, as outlined in the two-midnight rule adopted by CMS in 2014.[13] CMS recognizes that a patient with a hospital stay that does not cross two midnights may be appropriately considered an inpatient, if the medical record documentation supports the inpatient stay and it meets certain circumstances (such as death, transfer, leaving against medical advice, undergoing an inpatient-only procedure, or receiving ventilation). There are three concepts to consider:

1. Stays that are expected to last less than 24 hours should rarely be provided as an inpatient, except for patients undergoing a procedure on the Medicare inpatient-only list or medically necessary with extenuating circumstances where the physician determines inpatient admission is warranted. The patient should be admitted regardless of the expected length of stay.

2. Stays greater than 48 hours should rarely be considered an outpatient unless there are concerns regarding medical necessity.

3. Any stay between 24 and 48 hours should be under close observation of the physician.

Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act)

In 2016, Bill H.R. 876, the NOTICE Act, amended Title XVIII of the SSA to require hospitals to notify patients verbally and in writing if they have been in observation more than 24 hours and also outlined several other requirements to provide patients with information on their status, financial obligations, and documentation and signature specifications for compliance under the act.[14]

Utilization Review (UR) Function

Each hospital must also comply with the hospital conditions of participation (CoPs) in order to participate in the

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Medicare and Medicaid programs. 42 C.F.R. § 482.30 (Condition of Participation: Utilization Review) outlines the requirements of the hospital to establish a UR function: "The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs." This includes establishment of a UR committee for medical necessity reviews, denials, and internal processes for UR and physician advisor (PA) reviews.[15]

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