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Topic: Clinical Validation

Question: What is clinical validation and why is it important? Why is there so much confusion on what should and should not be coded?

Answer:

Accurately capturing the patient's medical condition is the purpose of clinical documentation. Documentation not only guides patient care but it also forms the basis for hospital and physician statistics and, most importantly, ensures proper code assignment. Clinical validation is the process of reviewing a medical record for documented diagnoses and procedures to determine if the clinical criteria that are most widely accepted by the medical community, are present to support each diagnosis and procedure.

The main problem facing facilities today is that if the clinical documentation does not support the diagnoses in the record, the facility will lose revenue. If the facility submits claims in which the clinical documentation results in codes being submitted that are not valid, the facility could face severe penalties for over-payment of these claims.

Causes of Confusion

In 2016, Section I.A.19 Code Assignment and Clinical Criteria, was added to the ICD-10-CM Official Guidelines for Coding and Reporting (OCG), which stated, "The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis."

To help further clarify this guidance, AHA responded in Coding Clinic 4th Qtr. 2016, pgs. 147-149: Clinical Criteria and Code Assignment, which stated, "Coders should not be disregarding physician documentation and deciding on their own, based on

clinical criteria, abnormal test results, etc., whether or not a condition should be coded."

Does this mean that clinical validation of documented diagnoses or procedures is no longer required for code assignment on a claim?

Clinical validation is necessary due to statutory and regulatory requirements. CMS regulations and policy manuals govern claim submission and reimbursement.

- **CMS RAC Statement of Work:** Clinical validation is a process in which a clinical review of the case is required to ensure that every diagnosis submitted on the claim can be supported by documentation in the medical record. Clinical validation goes beyond the scope of DRG (coding) validation, and the skills of a certified coder. This type of review can only be performed by a clinician or may be performed by a clinician with approved coding credentials.
- **CMS Medicare Program Integrity Manual:** The purpose of DRG validation is to ensure that diagnostic and procedural information that is coded and reported by the hospital on the claim, matches the attending physician's description and the information documented in the medical record.
- **The False Claims Act of 1863:** CMS does not allow providers to submit claims with codes for conditions that cannot be clinically validated or supported based on an established diagnostic standard, IF it results in an overpayment. This act imposes civil liability on any person or organization who knowingly submits false or fraudulent claims to the Federal government.

The consequences of submitting clinically invalid diagnoses and procedures are numerous and include:

- Improper DRG reimbursement
- Excessive denials
- Unnecessary appeals
- Increased risk of regulatory audits and penalties
- Over coding can lead to MCC/CC classification downgrades

How to Avoid Clinical Validation Denials

- In 2019, AHIMA issued the Clinical Validation: The Next Level practice brief, which stated that clinical validation is "the process of validating each diagnosis or procedure documented within the health record, ensuring it is supported by clinical evidence."
- Furthermore, AHIMA's Code of Ethics Principal 4.8, prohibits participating in, condoning, or being associated with dishonesty, fraud, abuse, or deception including "allowing patterns of optimizing or minimizing documentation and/or coding to impact payment…" and "coding when documentation does not justify the diagnoses or procedures that have been billed….."
- In an issue of Coding Clinic 4th Qtr. 2017, pg. 110: Omitting ICD-10-CM Codes, AHA followed up with advice that stated "It is not appropriate to develop internal policies to omit codes automatically when the documentation does not meet a particular clinical definition or diagnostic criteria. Facilities may review documentation to clinically validate diagnoses and develop policies for querying the provider for clarification to confirm a diagnosis that may not meet particular criteria."

How to Ensure Diagnoses and Procedures Submitted are Accurate

1. **Rely on authoritative sources:** Use authoritative, evidenced-based consensus criteria and guidelines for clinical validation. The most commonly queried conditions have excellent authoritative resources, including:
   - KDIGO for acute kidney injury
   - Sepsis-2 and Sepsis-3 consensus definitions for sepsis
   - ASPEN or GLIM for malnutrition

2. **Make helpful clinical validation queries:** To address those situations in which physicians document diagnoses which do not appear to be clinically valid, the 2019 practice brief recommends a "clinical validation" query to the clinician requesting that the practitioner "confirm the presence of the condition and provide additional rationale." It is helpful if the person making the query can point to official consensus criteria to ensure that the basis of the query is clear.

3. **Notice patterns:** If there is a pattern of recurrent, clinically invalid diagnoses, or if certain physicians do not respond to clinical validation queries or add additional clinical information, a peer-to-peer intervention with a physician advisor can be helpful if your facility has one.

Each organization is responsible for developing its own policies and procedures that pertain to clinical validation. Make sure that you know what your facilities policies and procedures are concerning clinical validation, querying physicians and code submission before finalizing claims.

Happy Coding!

References

- AHA Coding Clinic 4th Qtr. 2016, pgs. 147-149
- AHA Coding Clinic 1st Qtr. 2017, pg. 110
- ICD-10-CM Official Guidelines for Coding and Reporting
- AHIMA Practice Brief, Clinical Validation: The Next Level of CDI (January 2019)
- AHIMA Code of Ethics
- 2022 ACDIS Pocket Guide
- [Medicare Fee for Service Recovery Audit Program | CMS](#)
- [100-08 | CMS](#)
- [CDI+ - Key References (cdiplus.com)](#)