Clinical Validation in 2025: Back to the Basics—What Changed & How to Win

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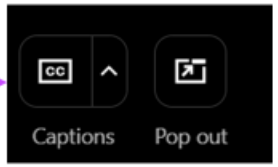

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There are no conflicts of interest to declare for any individual in a position to control the content of this presentation.

Presenter

Kendall Smith, MD

Chief Medical Officer & Chief Physician Advisor

Dr. Kendall Smith is a Senior Fellow in Hospital Medicine (SFHM) and currently acts as Chief Medical Officer and Chief Physician Advisor for PayerWatch, a leading appeal educator and appeal services firm for hospitals and health systems. He's been deeply involved in denial and appeals management throughout his hospitalist career, working collaboratively with UR/Case Management departments as well as Managed Care and Hospital C-Suite executives.

His familiarity with managed care denials led him to design and implement a number of CDI programs, including those at the Cleveland Clinic in Florida and the MedStar Washington Hospital Center. He has served as a physician leader on hospital revenue cycle management teams while also serving as a the Physician Advisor for Clinical Resource Management. Dr. Smith is also an AHIMA ICD-CM/PCS approved trainer/ambassador.

Presenter

Reggie Allen, MBA, RN, ACM
Chief, Clinical/Business Operations, PayerWatch

Reggie has more than 35 years of experience in a variety of healthcare positions, including staff nurse, nurse manager, Chief Nursing Officer, Chief Operating Officer, and Vice President, Clinical/Business Operations Transformation. He has been recognized nationally as an expert in care management and clinical operations. He is a results-driven leader who emphasizes operational transformation by integrating clinical and financial care aspects. He obtained a bachelor's degree in nursing from Vanderbilt University and an MBA from the University of Phoenix. He is a member of the American Case Management Association (ACMA) and the American College of Healthcare Executives.

Reggie possesses comprehensive knowledge and experience in all facets of care management, including case management, utilization management, disease management, quality management, and resource management. He has designed and implemented an enterprise-wide Clinical Appeals Unit and a clinical documentation program with success. Using six sigma and Lean principles, he is an expert in clinical and operational efficiencies that enhance clinical outcomes and financial performance through a variety of methodologies.

Learning Objectives

At the conclusion of the webinar, the learner will be able to:

- Distinguish **coding vs. clinical validation vs. dual** denials and pick the right evidence for each.
- Use **2024–2025 CMS MA rules** and the **Feb 2024 CMS FAQ** in your appeal language.
- Apply **sepsis/ARF/AKI** quick checks and “direct-rebuttal” structure that wins..

A few words about CONTRACTS

Somebody from the clinical side should be involved.

Why?

If a contract states they will only accept certain criteria for a particular diagnosis, you will likely not win an appeal from the payer using anything else but the criteria listed in the contract.

Guardrail #1: Medical Advantage must mirror Traditional Medicare

- For basic Part A/B benefits, MA **must apply Medicare statutes, regs, NCDs/LCDs**. Internal criteria are allowed **only** when Medicare is not fully established

- https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.101?utm_source=chatgpt.com

Guardrail #2: Internal criteria must be public & evidence-based

- When used, internal coverage criteria must be **publicly accessible** and based on **current evidence/guidelines** (e.g., specialty-society standards). Cite or link in every denial.

- https://www.govinfo.gov/content/pkg/CFR-2024-title42-vol3/pdf/CFR-2024-title42-vol3-sec422-101.pdf

Feb 6, 2024 CMS FAQ: Two Practical Levers

- **Public posting** means generally accessible to CMS, enrollees, and providers—**not behind a paywall** or “on request only.”
- **Algorithms/AI** may assist but **cannot replace** required criteria, and adverse decisions require **individualized clinical review**. Use this to challenge “tool says no.”

- https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf?utm_source=chatgpt.com

2025 Rulemaking Context (for Q&A)

- **CY 2026 MA Final Rule (Apr 2025)** did **not** undo §422.101(b)(6); transparency and evidence-basis for any internal criteria **remain**. Many additional UM/AI proposals were discussed but not comprehensively finalized.

- https://www.federalregister.gov/documents/2025/04/15/2025-06008/medicare-and-medicaid-programs-contract-year-2026-policy-and-technical-changes-to-the-medicare?utm_source=chatgpt.com

• Recognizing DRG / Clinical Validation Denials

- Letter Request for Additional Documentation
- Reason Code 252 on the EOB
- Claim Status 22 (Retracted Claim) with a new RA with a zero payment, lower payment amount, or change in DRG
- Unknown Reason

Is It a Coding or Clinical Validation Denial?

CMS tells us:

"The purpose of DRG validation is to ensure that diagnostic and procedural information and the discharge status of the beneficiary, as coded and reported by the hospital on its claim, matches both the attending physician's description and the information contained in the beneficiary's medical record. Reviewers shall validate principal diagnosis, secondary diagnoses, and procedures affecting or potentially affecting the DRG…

The contractor shall base DRG validation upon accepted principles of coding practice, consistent with guidelines established for ICD coding, the Uniform Hospital Discharge Data Set data element definitions, and coding clarifications issued by CMS…

Contractors shall ensure that the hospital reports the principal diagnosis and all relevant secondary diagnoses on the claim. The relevant diagnoses are those that affect DRG assignment…

The contractor shall exclude diagnoses relating to an earlier episode that have no bearing on the current hospital stay. Delete any incorrect diagnoses and revise the DRG assignment as necessary…

The contractor shall ensure that the hospital has reported all procedures affecting the DRG assignment on the claim…" *(emphasis added)*

Medicare Program Integrity Manual Chapter 6.5.3 -DRG Validation Review (Rev. 10365, 10-02-20)

Is It a Coding or Clinical Validation Denial?

DRG denials are denials based on coding guidance and are generally best appealed using coding guidelines, Coding Clinics, and coding conventions.

- *An appeal using clinical rationale for a coding denial will likely be unsuccessful.*
- *An appeal proving that the diagnosis or procedure in question was coded correctly per applicable coding sources should be successful.*

Is It a Coding or Clinical Validation Denial?

Example of a coding denial:

"**AKI is denied because there was no treatment.**"

- *This has to do with criteria for a reportable diagnosis, which is something a coder determines, based on coding guidance.*
- *Whether or not a diagnosis is reportable is not something a provider considers when making the diagnosis.*
- *Coding guidance is generally used as source documents for a coding decision.*

Is It a Coding or Clinical Validation Denial?

Clinical validation (CV) denials are denials based on clinical factors and generally best appealed using clinical criteria from evidence-based medical sources.

- *Coding guidance will likely not be effective in the argument for the clinical validity of a diagnosis.*
  - *though there is a place for just a little bit of coding info – more later….*

- *An appeal proving that the diagnosis in question was diagnosed correctly per applicable clinical sources should be successful*.

Is It a Coding or Clinical Validation Denial?

Example of a CV denial:

Encephalopathy is denied because the patient was described as being alert and neurologically intact.

- *This is clinical rationale that a **provider** considers when making the diagnosis.*
- *Coding rules and regulations do not govern clinical rationale.*
- *Clinical information from clinical journals, textbooks, etc. are generally used as source documents for a CV decision.*
  - *But not always! We will get to that later…*

Clinical Validation Denials

When you boil it all down, a CV denial is saying:

“Doctor, you misdiagnosed your patient and we are removing your diagnosis from the claim.”

The Dreaded Dual Denial

This type of denial is based on both clinical criteria AND coding guidance for one or more diagnoses.

- *A successful appeal should incorporate proof that the denied diagnosis was diagnosed correctly and then coded correctly.*
- *Source documents should be from both coding guidance and peer reviewed current clinical literature.*

The Dreaded Dual Denial

Example of a dual (coding and CV) denial without sources listed:

Sepsis will be removed from the claim as it was noted as a suspected condition in the ED and not corroborated, confirmed, or noted as still suspected at the time of discharge. In addition, the SOFA criteria was only 1.

Who Should Write CV Appeals?

Some hospitals use:

- coding professionals
- clinicians
- a combination of clinicians and coding professionals
- clinical documentation specialists
- vendors

Regardless of who writes the clinical validation appeals, be sure that reasons for denial are addressed thoroughly, and on a clinical basis.

Appeal Strategies

Appeal Strategies

First and foremost:

Never, EVER believe that the payer's rationale is correct.

- ***Scrutinize EVERY reason given to deny.***
- ***Push back at EVERY reason given that is not correct.***

Appeal Strategies – Direct Rebuttals

Example:

Payer: Best Insurance stated that Sepsis-3 criteria were not met.

Hospital Response: The patient had a SOFA score of 3, thus meeting Sepsis 3 requirements as evidenced by….

- Be sure to give page numbers where the information can easily be found in the medical record.
- Reference your medical source either here or in a separate section of your appeal.

Payer: Another erroneous statement

Hospital Response: specific response directly related to the erroneous statement

Appeal Strategies- Rebuttals

Your appeal should demonstrate:

1. **where** the diagnosis was documented.

In a perfect world:

- first time suspected
- when confirmed
- in the middle of the hospital stay
- in the discharge summary
- as a query answer, if applicable

Appeal Strategies- Rebuttals

Your appeal should demonstrate:

2. why the diagnosis was made:

- pertinent lab results
- pertinent physical exam findings
- pertinent VS
- pertinent radiology results
- surgical findings
- treatment
- response to treatment

Appeal Strategies- Rebuttals

3. Just a little bit of coding rationale

Note: you do not have to be a coder to learn and apply this.

a. If the principal diagnosis, insert the definition of the principal diagnosis.

b. If a secondary diagnosis, explain why the denied diagnosis met ONE of the following criteria to be a reportable diagnosis

- Clinical evaluation
- Or Therapeutic treatment
- Or Diagnostic procedures
- Or extended length of hospital stay
- Or increased nursing care and or monitoring

If a newborn, any of the above or:

- Has implications for future health needs

Appeal Strategies: Clinical Source Documents

Check source documents listed by the payer.

- Were they in effect at the time the patient was in the hospital?
- Do they apply to the reason for denial?
- Was the information misinterpreted or misrepresented?

Use pertinent excerpts from peer reviewed medical journals, textbooks, etc. in your appeal and reference them appropriately.

- Be sure they were in existence at the time the diagnosis was made.

When a payer uses clinical information from Coding Clinics, push back hard.

Your Standard Appeal “Rule-of-Decision” Ask (paste verbatim)

- Please identify the **NCD/LCD** applied or provide the **URL, version, and date** of any **publicly accessible** internal coverage criteria used per **42 C.F.R. §422.101(b)(6)**. If no posted criteria existed on the DOS—or if the decision relied on **non-public** or **undisclosed** criteria—the denial lacks a valid standard.

- https://www.govinfo.gov/content/pkg/CFR-2024-title42-vol3/pdf/CFR-2024-title42-vol3-sec422-101.pdf

Your Standard “Automation” Challenge (paste verbatim)

- CMS’s 2/6/2024 FAQ permits algorithms only as aids; adverse determinations require **individualized review** by qualified personnel and may **not substitute new criteria**. Please identify the **reviewing clinician** and the **posted criteria** they used beyond any tool output.

- https://www.aha.org/system/files/media/file/2024/02/faqs-related-to-coverage-criteria-and-utilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf

Appeal Strategies: Clinical Source Documents

Clinical criteria found in Coding Clinics are NOT acceptable to deny on a clinical basis or appeal on a clinical basis.

Source/Reference	**Applying Past Issues of AHA Coding Clinic for ICD-9-CM to ICD-10** ***Coding Clinic*, Fourth Quarter 2015: Page 20**
Practice Guideline Recommendation	*…Coding Clinic* may still be useful to understand clinical clues when applying the guideline regarding not coding separately signs or symptoms that are integral to a condition. **Users may continue to use that information, as clues—not clinical criteria.**

Appeal Strategies: Clinical Source Documents

Source/Reference	**Use of *Coding Clinic* as Clinical Criteria for Code Assignment** ***Coding Clinic*, Third Quarter 2008 Page: 16**
Practice Guideline Recommendation	**Question:** Can background clinical information published in Coding Clinic be used as clinical criteria for code assignment? **Answer:** **No, background material published in *Coding Clinic* cannot be used as clinical criteria for code assignment**. As stated in *Coding Clinic,* Second Quarter 1998, pages 4-5: "**Any clinical information published in *Coding Clinic*, is provided as background material to aid the coder's understanding of disease processes**. The information is intended to provide the coder with 'clues' to identify possible gaps in documentation where additional physician query may be necessary…

Appeal Strategies: Contracts and Policies

Payers often use their own criteria to deny.

- What does your contract with the payer say?
  - ➢ Did your facility agree to use only certain criteria for certain diagnoses (like Sepsis-3 for sepsis)?
    - ✓ If providers are using Sepsis-2, you will likely not get those denials overturned
  - ➢ Did the payer agree to accept Sepsis 2 criteria?
    - ✓ A copy of the contract could be sent with the appeal.

Does your facility have a policy about certain diagnoses, such as AKIN criteria is to be used to diagnosis AKI?

- If yes, send with your appeal.
  - ➢ It can't hurt.

Litigation Watch: MA algorithm cases moving forward

- **Estate of Lokken v. UnitedHealth/NaviHealth** (alleged AI-driven terminations of post-acute care in MA): **class action allowed to proceed**; courts are scrutinizing algorithmic determinations. Use to demand human clinical review + posted criteria.

- https://www.vitallaw.com/news/artificial-intelligence-d-minn-case-against-unitedhealth-over-ai-claim-denials-partially-survives/hld0193251beac919444a867a3ac407643fa3?utm_

Litigation Watch: “Batch denial” automation

- **Cigna PxDx**: separate class action over automated, rapid claim denials has **survived early challenges**; illustrates judicial discomfort with opaque automation. (Useful by analogy when plans won’t show criteria/clinician review.
  - "*Internal documents and former company executives reveal how Cigna doctors reject patients’ claims without opening their files. “We literally click and submit,” one former company doctor said."*

- https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims?utm_

Litigation Watch: Clinical Validation as a cause of action

- **AdventHealth Shawnee Mission v. Blue KC (Jul 2025): hospital alleges CV audits invalidating >350 diagnoses using undisclosed criteria, >$2M withheld. Good cite when a plan refuses criteria disclosure.**
  - *“BCBSKC’s determinations to clinically invalidate physicians’ diagnoses are purportedly based on criteria from various sources, but such criteria have never been disclosed to Advent in advance,” said the plaintiffs. “Upon information and belief, the criteria are often based on outdated literature, irrelevant medical guidance, or publications that do not reflect an industry standard definition for medical diagnoses"*
- https://www.fiercehealthcare.com/payers/blue-kc-wrongfully-denied-medical-diagnoses-hospital-alleges-ai-driven-claims-lawsuit?utm_

Acute Respiratory Failure (ARF): What wins

- Cite **objective hypoxemia and/or hypercapnia** with clinical context and response to therapy. Common thresholds in literature: **PaO_2 <60 mmHg** (hypoxemic) or **$PaCO_2$ ≥45 with pH <7.35** (hypercapnic), plus documented increased work of breathing/need for support. Tie to monitoring/treatment/MDM

- https://pmc.ncbi.nlm.nih.gov/articles/PMC10910131/?utm_

AKI: What wins

- Use **KDIGO**: ↑SCr ≥0.3 mg/dL in 48h, or ≥1.5× baseline (≤7 days), or **UO <0.5 mL/kg/h ≥6h**; include trend lines and precipitating factors. Don't let "no treatment documented" become a **coding** argument in a **clinical** dispute—anchor to diagnostics + monitoring.
- The KDIGO (Kidney Disease: Improving Global Outcomes) criteria are generally preferred over AKIN (Acute Kidney Injury Network) for diagnosing and staging Acute Kidney Injury (AKI). KDIGO is considered an evolution of AKIN and RIFLE, incorporating elements from both while offering a more comprehensive and refined approach, particularly in its use of serum creatinine and urine output criteria

- https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-AKI-Guideline-English.pdf?utm_

Sepsis: What wins (quick grid to paste)

- **Definition anchor (Sepsis-3):** life-threatening **organ dysfunction** from infection; operationalized as **SOFA +2** from baseline. Your grid should show: suspected/confirmed infection → organ dysfunction (SOFA components) → **response to therapy**. JAMA NetworkPMC
- **Appeal angle:** If payer insists on Sepsis-3 **exclusively**, require their **posted criteria** (URL/version) and rebut with patient-specific organ dysfunction and time-stamped interventions.

CASE STUDY

Denial 1:

Show the pertinent information and where it can be found (*don't stop with ED*)

ED Triage, date	**Mid 80s on RA. 93% on 2L**	56
ED Provider Note, date	91-year-old female with worsening dyspnea Worsening weakness Doesn't have enough energy to chew or lift her arms to eat Shortness of breath for quite some time but over the last couple of weeks it is **worsened substantially**. **Not typically on oxygen** **Pulse 100, SpO2 89%, RR 30** **Pulse ox: 88% on RA: abnormal oxygenation** Lungs: **Markedly diminished breath sounds on the right lung** She is **hypoxic on room air**. Chest X-ray with **large right-sided pleural effusion** and signs of fluid overload…**compressive atelectasis** versus pneumonia **Acute respiratory failure with hypoxia**	89, 51, 50, 53

Denial 1:

Justify your appeal.

Connect the dots for the reviewer.

Justification for Appeal

Per the medical record, the patient met the clinical criteria based on **new oxygen requirement due to shortness of breath with oxygen saturations in the 80's on room air due to compressive atelectasis and diffuse consolidation of her right lung.**

The patient's respiratory status was stabilized with titration of oxygen and a **thoracentesis that removed 750cc of fluid**.

Please note that she had **greatly diminished breath sounds in her right lung with diffuse right lung consolidation. In essence, her right lung had failed**.

High flow oxygen, a certain respiratory rate, and retractions **are not required for a licensed provider to establish the diagnosis.**

Of note, the reviewer was incorrect when it was stated that there were no documented respirations greater than 24.

Denial 1:

Just a bit of coding information….

ICD-10-CM Official Guidelines for Coding and Reporting

Section III. Reporting Additional Diagnoses
GENERAL RULES FOR OTHER (ADDITIONAL) DIAGNOSES
The UHDDS item #11-b defines Other Diagnoses as "all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received and/or the length of stay.

For reporting purposes, the definition for "other diagnoses" is interpreted as additional conditions that affect patient care in terms of requiring:

Clinical Evaluation; **MET as evidenced by provider documentation and treatment plan**

or Therapeutic Treatment; **MET as evidenced by oxygen titration and a thoracentesis**

or Diagnostic Procedures; **MET as evidenced by a thoracentesis and serial chest x-rays**

or Extended Length of Hospital Stay,

or Increased Nursing Care and/or Monitoring. **MET as evidenced by close monitoring of pulse oximetry**

Denial 1:

Why are you right on a clinical basis?

Source/Reference	**Pinson, R. (2013). Revisiting respiratory failure. Part one of a two-part series. *ACP Hospitalist*. As found on:** *http://www.acphospitalist.org/archives/2013/10/coding.htm*
Evidence Based . Guideline/Practice Guideline Recommendation	• "**Acute respiratory failure is defined by <u>any one of the following</u>**: ○ pO2 <60 mm Hg or **SpO2 (pulse oximetry) <91% breathing room air** ○ pCO2 >50 and pH <7.35 ○ P/F ratio (pO2 / FIO2) <300 ○ pO2 decrease or pCO2 increase by 10 mm Hg from baseline (if known)." [p.2] • "**On the normal oxygen/hemoglobin dissociation curve, a pO2 less than 60 mm Hg is equivalent to oxygen saturation less than 91%.** • **While the saturation measured by pulse oximetry (SpO2) is less precise than on the ABG (SaO2), it may be used as the only practical surrogate for serial monitoring of oxygenation**."[p.2] • **There ought to be some indication that a patient with acute respiratory failure has, for example, respiratory distress (even if mild), tachypnea (normal respiratory rate is generally 8 -16), dyspnea, shortness of breath**, wheezing, etc. [p. 2]

Summary

1. Read the denial rationale thoroughly and ascertain if it's a CV denial, coding denial, or a dual denial prior to starting to appeal
2. Never, EVER believe the payer is correct
3. Look for ways to rebut the auditor's reasons for denial
4. Make it easy for the reviewer – show them exactly where pertinent information in the medical record can be found
5. Use accepted medical and peer reviewed literature - in effect at the time of the patient's hospitalization - to support your arguments
6. Consider adding just a bit of coding information in your appeal
7. A clinician knowledgeable about CV denials should be involved with contract negotiations

Put It Together: “One-Pager per Dx” (how to standardize)

- **Header:** DOS, payer, denial type (CV vs coding vs dual).
- **Rule of decision:** NCD/LCD or **posted internal criteria** (URL/version/date).
- **Clinical facts:** vitals, labs, imaging, therapies, time-course.
- **Diagnosis proof set:** Sepsis (SOFA), ARF (ABG/SpO_2 + support), AKI (KDIGO), Malnutrition (≥2/6).
- **Disposition & risk:** why it mattered clinically.

Operations Checklist (tomorrow morning)

- Add a **standing paragraph** in all CV appeals requesting the plan's **posted criteria URL/version** and the **clinician reviewer's credentials**.
- Route any "tool-only" denials to **escalation** citing the FAQ (no algorithmic substitutions; individualized review required).
- Track payer responses to the posted-criteria ask; slow or missing responses are leverage for **escalation/ARO**

Questions and Answers

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Thank you for attending!

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