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The Coverage Analysis as a Guide, Not an Algorithm

Medicare Coverage Principles, Institutional Billing Decisions, and the Limits of Predictive Compliance in Clinical Research

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This White Paper is a companion to the Coverage Analysis Reminder video modules prepared by Hay Hill Advisors and Meade, Roach & Annulis, LLP. The themes in this White Paper are explored in depth in the book *Clinical Research & Health Insurance*.

The Coverage Analysis as a Guide, Not an Algorithm

A Coverage Analysis is a guide for charge review. This foundational principle, while seemingly straightforward, is frequently obscured by institutional practices that have transformed the Coverage Analysis from a practical compliance tool into an unwieldy document burdened with aspirations of predictive precision. The Coverage Analysis was never designed to anticipate every service that occurs during a study event. It was designed to orient charge reviewers to the billing designations that apply to the services scheduled by the study protocol, and to provide a framework for assessing whether charges for a research patient can be billed to the patient's health insurance or must be directed to the study.

Understanding this distinction is critical. Research institutions that treat the Coverage Analysis as an exhaustive catalog of every possible charge scenario set themselves on an impossible course. No document can predict a patient's clinical presentation, particularly for seriously ill patients who constitute the majority of the research patient population. The electronic health record system does not code services or an encounter in advance of the visit. The procedure codes and revenue codes used on the general Coverage Analysis format are starting points to help charge reviewers orient the charges in a work queue—they are not a definitive inventory of what will occur during a patient encounter.

> *A Coverage Analysis is a guide for charge review. It does not anticipate every service that occurs during a study event. Establishing an inclusive list of codes prior to a patient encounter is not possible.*

Establishing an inclusive list of codes prior to a patient encounter is simply not possible. The only element that can be predicted with any certainty is the protocol's required research services, identified by the names the protocol assigns to them. Even then, not all services scheduled by the protocol will appear in the charge review process because either the charge is not captured in the billing system or the treating physician determines, based on the patient's clinical state, that the service will not be performed. This inherent unpredictability is not a deficiency of the Coverage Analysis—it is a feature of clinical medicine itself. A physician encounters a research patient as a whole person, a complex clinical phenomenon, and the Coverage Analysis must be understood as a guide that a human charge reviewer applies to the charges that actually occur during a patient encounter.

Avoiding the Complexity Trap

If a research site wants to add additional codes to a service listed on a Coverage Analysis, there is no problem in doing so. It is very common for experience gained through charge review to reveal charge master changes or alternative methods of charge capture that merit reflection on the Coverage Analysis. Institutional learning from the charge review process is a valuable and expected part of managing a research billing compliance program.

However, research sites must be cautious about falling into what may be described as the "complexity trap"—the tendency to expand the Coverage Analysis to the point where it becomes so large and unwieldy that it is no longer usable as a practical tool for charge review. When a Coverage Analysis tries to manage phantom risks or anticipate all charge scenarios a research patient may encounter, the research institution pursues an impossible destination. As discussed in the book *Clinical Research & Health Insurance*, Coverage Analyses simply cannot anticipate all the possible charge capture scenarios prior to a patient encounter. There is no technology that can accomplish this because no technology can predict the future or anticipate a patient's clinical presentation.

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Three Reasons a Service Is Not Billable to Health Insurance

The basic Coverage Analysis format, applying Medicare coverage principles, identifies items and services as not billable to health insurance when the item or service falls into one of three categories. These three categories represent the fundamental analytical framework that every charge reviewer must internalize.

First, an item or service is not billable to health insurance when it is being paid by the sponsor. This is the most straightforward category: when a sponsor has contractually agreed to fund a service through the Clinical Trial Agreement budget, the service should not also be billed to the patient's health insurance.

Second, an item or service is not billable to health insurance when it is promised free in the study's Informed Consent Form. The informed consent is a legally binding document that creates obligations to research participants. When an institution promises through the ICF that a service will be provided at no cost to the participant, that promise must be honored regardless of whether health insurance might otherwise cover the service.

Third, an item or service is not billable to health insurance when it does not meet Medicare coverage principles. This third category is broader and more nuanced than the first two, encompassing not only CMS's National Coverage Determination 310.1 but also the variety of other coverage rules and principles operative within the Medicare program. Medicare coverage principles are not the same as whether a service is "standard of care." Medicare is a federal healthcare program with coverage crafted by statutes passed by Congress and regulations and policy decisions adopted by the Executive Branch through the Department of Health and Human Services and the Centers for Medicare & Medicaid Services. While clinical considerations are often important in determining Medicare coverage, the main standards for Medicare coverage are crafted by laws and regulations.

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It is important to view these as three distinct categories in order to ensure that the first two reasons—sponsor payment and informed consent promises—are not subsumed by the complexity of Medicare coverage analysis. The notion of Medicare coverage principles is broad because it involves not just NCD 310.1 but also the variety of other coverage rules and principles in play for the Medicare program. Charge reviewers should be trained to evaluate all three categories systematically, rather than defaulting exclusively to the third.

Medicare Coverage Is Not Standard of Care

Coverage Analyses applying Medicare coverage rules often appear at odds with clinical standards or what a physician considers "standard of care." This tension arises when there is a clash between what Medicare covers and the services the physician believes are medically necessary. The critical insight is that Medicare only covers a subset of medically necessary services. As the HHS Office of Inspector General has stated: "Physician practices should remember that 'necessary' does not always constitute 'covered.'"

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Two common examples illustrate this divergence between Medicare coverage and clinical standard of care. The first involves self-administered drugs in the outpatient setting. Drugs that are usually self-administered and provided in an outpatient setting—whether a hospital clinic or physician clinic—are not covered by Medicare unless they meet one of five statutory exceptions. This coverage exclusion is statutory in nature; it is not a clinical question. Hospitals face a business decision with these non-covered charges: they may bill the patient directly, invoice the study for the charges, or write off the charges following OIG guidance on writing off self-administered drug charges. The decision on how to handle the charge belongs to the hospital, not the study team, because it involves a cost to the hospital. Basic Coverage Analyses often list the self-administered drug as billable to the study by default as non-covered, but a hospital may reflect its own institutional position in the Coverage Analysis.

The second example involves diagnostics at the screening visit. Medicare generally does not cover diagnostic tests prior to drug therapy unless the patient presents with signs and symptoms of what the diagnostic is testing, or the patient's underlying condition carries a risk of advancing to a condition that the diagnostic test is designed to detect. The coverage landscape changes entirely once the patient receives the investigational drug, because the patient has been exposed to a toxic agent with potential side effects requiring monitoring. CMS has articulated this principle clearly, stating that it interprets the statutory provisions to prohibit coverage of "screening" services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury, except as explicitly authorized by statute. CMS further notes that a test service might be considered medically appropriate but nonetheless excluded from Medicare coverage by statute.

Cooperative Group Studies and Coverage Analysis

Sites that participate in cancer cooperative group studies should pay special attention to the Medicare coverage rules that are counterintuitive or diverge from standard of care determinations. National Coverage Analyses provided by a cooperative group are rarely coordinated with CMS and are intended as a starter tool for

developing a site-specific Coverage Analysis. These cooperative group analyses typically focus on standard of care and clinical rationale for study services, but they do not always account for the specific Medicare coverage rules that may render certain services non-billable. Moreover, cooperative groups do not always pay for all non-covered study services, creating potential gaps in funding that sites must identify and address during budget negotiations.

The Limits of Medicare Rules

Despite the considerable volume of Medicare regulations, there is not a specific "rule" for every item or service as to whether it is covered. In fact, some CMS officials have estimated that there are formal rules governing only approximately fifteen percent of all items and services that occur in a hospital or physician clinic setting. When Medicare does not address a specific item or service, coverage principles can be applied to the facts of the circumstances in which the item or service is ordered to assess coverage.

A Coverage Analysis assumes common factors among the research patients enrolled in the study, and it is not a guarantee of coverage because coverage can be contextual to the individual patient's presentation. A Coverage Analysis provides a good faith tool reflecting the likelihood of coverage based on the study design and the Medicare rules applicable to the scheduled services. This probabilistic character of the Coverage Analysis is another reason why it functions as a guide rather than as an algorithm.

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Coverage Does Not Equal Payment

Medicare coverage does not guarantee payment for a service. In fact, many "covered" services are not "paid" by Medicare. This is not a matter of claim denials but rather a structural feature of the variety of payment methodologies Medicare employs. Under Medicare's Outpatient Prospective Payment System, for example, many ancillary services that are covered are packaged into the payment for the primary service and do not generate separate reimbursement. As discussed at length in *Clinical Research & Health Insurance*, this divergence between coverage and payment has profound implications for how research institutions negotiate budgets with trial sponsors and structure their financial expectations around clinical trial participation.

The Medical Record and Research Charge Review

Best practice in reviewing research charges involves assessing the charges in the electronic health record work queue against documentation in the medical record. For institutions using the Epic system, the legal medical record is the information held in Epic related to patient encounters. A clinical trial management system offers a guide to orient research encounter days as supplemental information for charge reviewers, but it is not the authoritative source for billing determinations.

If there is a conflict between the medical record and the clinical trial management system, the medical record should prevail, assuming the medical record is accurate. If the medical record contains inaccurate information, clinicians should add corrections or addenda through the appropriate clinical documentation processes rather than relying on the trial management system to override what appears in the patient's chart.

> *If there is a conflict between the medical record and the clinical trial management system, the medical record should prevail. The CTMS is supplemental information; the legal medical record governs charge review.*

Managing Unscheduled Events

Unscheduled events can pose significant challenges for research charge reviews if the study team does not identify an encounter as study-related. All study-related encounters should be identified in the patient's chart and oriented to what part of the study or study event the encounter pertains to. Ideally, a clinical trial management system does not need to be referenced for research charge review if the study team adequately documents study-related encounters in the medical record.

For institutions using the Epic system, the "Research Studies" tab available for every patient enrolled in a research study provides a practical mechanism for linking encounters to active studies. Study teams should be educated on using this tab as well as marking encounters as clearly study-related in the chart. When unscheduled events are not properly identified, charge reviewers may fail to apply the appropriate billing designations, potentially resulting in charges being billed to insurance when they should be directed to the study, or vice versa.

Site-Specific Approaches and Institutional Decisions

Coverage Analyses following a general format focus on the "minimums" of Medicare coverage analysis—that is, determining

whether there is coverage for the scheduled services under applicable Medicare rules. Each research site may adopt approaches that are more risk-averse than the minimums of Medicare coverage analysis. For example, a site may decide not to bill insurance for a service that meets basic coverage principles for a variety of institutional reasons. In such cases, an appropriate comment on the Coverage Analysis could be: "It is institutional policy not to bill the research patient or insurance for this service."

There are several legitimate reasons a research site might choose not to bill health insurance for a covered service. These include: a history of denials for the service; difficulty of clinical staff in documenting medical necessity; past compliance problems with the service charges; confusion among research patients over co-pays for the service; the service fitting a discretionary invoiceable item in the sponsor budget; or an institutional position not to bill for the service for other reasons. If a research site decides not to bill health insurance for a service that meets basic Medicare coverage principles, then it should mark the service as not billable to insurance on the Coverage Analysis and document the institutional decision.

> *Each research site may adopt approaches that are more risk-averse than the minimums of Medicare coverage analysis. If a site decides not to bill a covered service, it should document that institutional decision on the Coverage Analysis.*

Final Documents and the Coverage Analysis as Living Document

The Coverage Analysis used for charge review should utilize final study documents: the protocol, the Clinical Trial Agreement budget, and the IRB-approved Informed Consent Form. For IDE device studies, the CMS IDE device trial approval website should also be checked. Some organizations use a Coverage Analysis during budget negotiations, which necessarily means the Coverage Analysis is based on draft documents. These sites should remember to update the Coverage Analysis to "final" status once the Clinical Trial Agreement is executed and the ICF is IRB-approved, applying the information contained in the final documents.

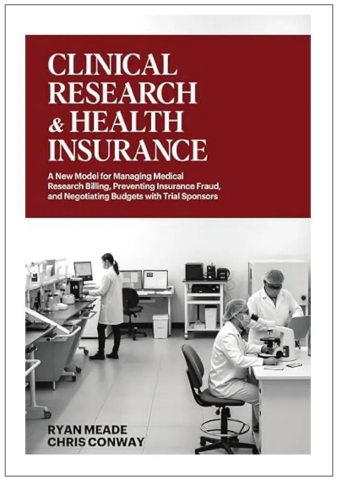
In a similar manner, protocol amendments that impact the Coverage Analysis should be incorporated when study documents are finalized. Keeping a Coverage Analysis updated is an important ongoing task for research sites, not a one-time event at study start-up.

Finally, research sites should recognize that the Coverage Analysis is not a rigid document that can never change. It is a guide for managing charge review, and the circumstances it addresses are inherently dynamic. Insurance rules and codes can change, the study design can be amended, charge capture approaches can evolve, the law can change, and institutional policy and the organization's risk profile can shift. The Coverage Analysis is an important tool to demonstrate a good faith effort to identify items and services that are covered under Medicare principles and those that are not covered. Treating it as a living document preserves both its practical utility and its legal significance.

White Paper Takeaways

Twenty practical principles for Coverage Analysis development and research charge review

1. The Coverage Analysis is a guide for charge review, not a predictive algorithm.
2. No document can anticipate every service a research patient will receive.
3. Procedure codes on a Coverage Analysis are starting points, not exhaustive inventories.
4. Avoid the complexity trap: an unusable Coverage Analysis helps no one.
5. Adding codes from charge review experience is valuable; but expanding endlessly is not.
6. Three reasons make a service non-billable: sponsor pays, ICF promises free, or Medicare doesn't cover.
7. Don't let Medicare claims process rules overshadow neglect risks related to sponsor payments and ICF free services obligations.
8. Medicare coverage is not the same as standard of care. "Necessary" does not always mean "covered."
9. Self-administered drugs in the outpatient setting are not covered unless a statutory exception applies.
10. Screening diagnostics before drug therapy are generally excluded from Medicare coverage.
11. Cooperative group Coverage Analyses are starter tools that always need adaption for site-specific billing management.
12. Medicare has formal rules for only about 15% of items and services. Apply coverage principles for the rest.
13. A Coverage Analysis assumes common patient factors; research patient charge review will be contextual to the individual's presentation.
14. Medicare has formal rules for only about 15% of items and services. Apply statutory coverage principles for the rest.
15. The legal medical record—not the CTMS—governs research charge review.
16. If the medical record and CTMS conflict, the medical record prevails.
17. All study-related encounters must be identified in the patient chart, not just in the CTMS.
18. Sites may choose not to bill covered services for institutional reasons—document that decision.
19. Always finalize the Coverage Analysis using executed CTA, IRB-approved ICF, and final protocol.
20. The Coverage Analysis is a living document. Update it as rules, codes, and study designs change.



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Hay Hill Advisors

Hay Hill Advisors grew out of nearly three decades of experience navigating federal research billing investigations for hospitals and medical schools. Along the way, our team built the Coverage Analysis — the methodology that became the industry standard for research-billing compliance.

That frontline experience also revealed a critical gap: clinical research administrators and revenue-cycle teams rarely speak the same language.

We bridge that gap by turning regulatory insight into actionable strategies that minimize risk of overpayments, support compliant billing, and recover the research revenue your institution has earned.

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