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Thorny Medicare coverage issues

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At the 20-year anniversary of the issuance of National Coverage Determination on Clinical Trials (clinical trials NCD),[1] and the 15-year anniversary of the first settlement of overpayments solely related to the clinical trials NCD,[2] it is timely to review the historical context for Medicare coverage of clinical trials and to bring understanding to the present. The Medicare coverage and billing rules still pose great complexities for reviewers in the area of clinical trials, even though the clinical trials NCD has only been updated just once—in 2007.[3] This article discusses three areas of concern from which misreadings of Medicare rules within clinical trials are most likely to arise, listed below, and provides solutions for them.

1. The Medicare rules are organized and distributed across many different sources,
2. There is not one single way to conduct a review, and
3. The documents required to think through a review are multidisciplinary.

Identifying and applying Medicare rules

Table 1 provides a historical perspective of how Medicare coverage and billing rules were developed to the present day. Medicare coverage and billing rules are formed of statutes, regulations, program and policy manuals, the clinical trials NCD, national coverage determinations (NCDs), and local coverage determinations (LCDs). These rules form a hierarchical framework that provides consistent outcomes based on the unique facts of each clinical trial. It is crucial to return to the primary source materials noted in Table 1 when thinking through a Medicare coverage issue, as well as when auditing, monitoring, and creating educational materials.

Nuances in Medicare coverage

The ambiguity of the clinical trials NCD creates greater complexity, yet the nuances also permit healthcare entities to make coverage decisions according to their mission, risk profile, and institutional process. The same clinical trials may have different coverage outcomes for certain items and services at different institutions. The different fact patterns of each clinical trial, as well as institutional risk profiles and processes, create complicated considerations.

Documents from different disciplines and work streams

The position of a Medicare coverage analyst for clinical trials has existed only over the last 15 years or so. At the start of this profession around 2006, it was still unclear what operational structure would emerge to conduct clinical trial coverage analyses. For example, a clinical research trial billing manual from 2006 states that a healthcare entity "may find it easier to have different departments or offices perform the different stages

depending upon the expertise of people within the organization."[4] Today, in most institutions, one analyst reviews materials from at least five disciplines—billing and coding, finance, law, medicine, and science—and creates a Medicare coverage analysis. As these documents interact with many departments across a healthcare entity, the misinterpretation and subsequent misapplication of the Medicare rules can lead to improper billing, documents that do not coordinate, errors in negotiating clinical trial agreements, and inaccurate informed consent forms. Most clinical research billing work streams revolve around the development and use of the Medicare coverage analyses, which is often applied to other payers.

Solutions

Solutions to the three areas of concern above include returning to the first principles of Medicare billing and coverage rules, specialization, communication, documentation, auditing, monitoring, and education.

Start from the first principles of Medicare rules

The Medicare coverage and billing rules within clinical trials can be categorized into these general principles:

- Items and services must be reasonable and necessary to be billable to Medicare,
- Noncovered items and services are not billable to Medicare,
- Items and services bundled or included with other services cannot be billed separately to Medicare, and
- Items and services provided free or paid by another entity cannot be billed to Medicare.[5]

Now that the first principles of Medicare coverage and billing rules are understood, here is how the clinical trial billing rules work within each principle category.

Reasonable and necessary

The question of whether a trial is a qualifying clinical trial is part of every Medicare coverage analysis and is related to whether items and services within the clinical trial are reasonable and necessary based on the clinical trials NCD, including:

- Whether items and services are reasonable and necessary to use to diagnose and treat complications arising from clinical trial participation,
- Whether coverage with evidence development applies,
- Whether the item or service evaluated falls within a benefit category,
- Whether the trial has therapeutic intent,
- Whether the trial is a therapeutic intervention that enrolls patients with diagnosed disease, and
- Whether the clinical trial is "deemed."[6]

Some of these may be difficult questions to answer in some clinical trial fact patterns. Tables 1 and 2 can be used to provide reminders related to the history and purpose of Medicare rules and to inform critical thinking regarding difficult questions about the rules that apply within a clinical trial.

As seen in Table 1, billing and coding rules are included in the "other Medicare rules" that also apply per the

clinical trials NCD and are related to the principle of "reasonable and necessary." The International Classification of Diseases, Tenth Revision (ICD-10) are code sets used to judge whether an item or service is reasonable and necessary by the Medicare administrative contractor (MAC) to determine coverage. The procedure must make sense with the diagnosis. In all healthcare settings in the US, such as physician clinic visits, the system uses ICD-10-CM code sets to report diagnoses on claims. For Medicare billing, CMS maintains the Healthcare Common Procedure Coding System (HCPCS) code sets for procedures, which must also align with the ICD-10 diagnostic code. For inpatient coding, providers include both the ICD-10-CM diagnosis and ICD-10-PCD procedure codes to submit claims to the MAC. Hospitals are paid using Medicare Severity Diagnosis Related Groups (MS-DRG).

Further, the concept of routine costs in the clinical trials NCD is related to billing within clinical trials, yet the idea is also associated with the term "reasonable and necessary"—"Medicare covers the routine costs of qualifying clinical trials, as such costs are defined..., as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials."[7] The clinical trials NCD defines routine costs as including items or services typically provided absent a clinical trial or conventional care, items or services required only to provide the investigational item or service, and 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." This last quote in particular demonstrates how the idea of routine cost related to coverage within clinical trials is folded into the broader Medicare principle of reasonable and necessary.

Noncovered items and services

As seen in Table 1, there may be statutory exclusions, a benefit category may not exist, or there may be a national determination for noncoverage:

- The clinical trials NCD starts by listing the benefit categories, which implies the exclusion of any categories not listed. The clinical trials NCD excludes items and services used for research purposes only, as well as the investigational item or service unless it is covered outside the clinical trial.
- NCDs and LCDs may contain coverage limitations that relate to whether an item or service is reasonable and necessary at a given time point based on the facts of a clinical trial.
    - For example, in the Complete Blood Count NCD 190.15, the NCD contains four limitations on coverage.[8] The most relevant to clinical trials is the first limitation. It provides that the complete blood count testing of asymptomatic patients, or patients without a condition that would result in a hematological abnormality, is a screening and is not covered.
- Billing and coding rules also may contain coverage limitations.
    - For example, HCPCS code 99211 cannot be billed when performed with a drug administration service, whether an IV or injection, and with both non-chemotherapy and chemotherapy drugs.[9]

Bundled or included items and services

The principle that some items and services are bundled, or are included with other items and services, and not separately billable can be researched in medical coding books. Even without a coding background, looking up services in medical coding books can assist the reviewer to objectively think through which services would be bundled together or to identify which services would be part of another charge. One example of bundled services frequently seen in clinical trials is that components of evaluation and management services, such as the weight

and history of the participant, are not separately billable if performed on the same day as a physical exam.[10] Further, services that are part of another charge are often services that are part of the surgical charge or hospitalization charge.

Medicare Secondary Payer Rule

The clinical trials NCD notes the principle that items and services provided free for any trial participant are not covered. This principle is also called the Medicare Secondary Payer Rule. For example, items and services provided for free in the informed consent are not permitted to be billed to Medicare. As seen in Table 2, it is very important to cite the informed consent form in the coverage analysis documentation when items and services are provided free. It is also important that the informed consent coordinate with the protocol and clinical trial agreement/budget in terms of which items and services are provided for free to participants.

Similarly, variable payment language refers to language that provides that if items and services are not covered by the participant's insurance, such as Medicare, they will be reimbursed by the sponsor. This language should not be present in any clinical trial documents. This rule is also the reason items and services that were once billed to the sponsor or provided free should never be billed to Medicare if the Medicare coverage analysis is conducted again.

	Type	Purpose	History	Application to coverage analyses	Citation or example
Title XVIII and Title XIX of the Social Security Act	Law, codified in statute, found in the United States Code	Establishes the Medicare program, including Parts A and B	The Medicare program was established by Congress in 1965.	This law is referenced in the National Coverage Determination on Clinical Trials (clinical trials NCD): "all other Medicare rules apply."	42 U.S.C. §§ 1395c–1395i-5

Medicare regulations	Regulation, promulgated in the *Federal Register* and codified in the Code of Federal Regulations	Provides the details needed to carry out the Medicare rules, including conditions for payment	Medicare regulations are issued by the Centers for Medicare & Medicaid Services (CMS). CMS is part of the executive branch of the US government. CMS carries out the underlying law/statute through regulations, enforcement, and penalties.	The Medicare regulations are referenced in the clinical trials NCD: "all other Medicare rules apply."	42 C.F.R. § 406
Medicare program and policy manuals	Interpretive guidance	Published by CMS to provide additional information on managing the day-to-day operations of the Medicare program through instructions, policies, and procedures. Manuals cannot create new laws or regulations, only interpret existing laws and regulations.	The components of the CMS program, such as contractors and state survey agencies, use these issuances to administer the CMS programs.	The clinical trials NCD appears in the *Medicare National Coverage Determinations Manual*. The manuals include important Medicare coverage and billing interpretations such as medical necessity for coverage of off-label use of drugs, self-administered drugs, and medical devices. These program and policy manuals are included in the "all other Medicare rules apply" reference in the clinical trials NCD.	http://go.cms.gov/3nJL88E

MLN Matters fact sheet	Interpretive guidance through education	The title is an abbreviation for "Medicare Learning Network." MLN articles and fact sheets are published by CMS as educational materials related to Medicare rule updates.	MLN fact sheets provide education on topics such as coding and Medicare rules.	Fact sheets and booklets provide easy-to-read explanations of Medicare program updates. For example, the clinical trials NCD was announced in an *MLN Matters* transmittal.	https://go.cms.gov/2KKx28m
Clinical trials NCD (NCD 310.1)	National rule	Establishes that Medicare covers routine costs in qualifying clinical trials	This is the only NCD to be created after a presidential memorandum requiring the now-CMS to create rules allowing the coverage of routine costs in qualifying clinical trials.	Defines routine costs within a clinical trial; identifies the idea of "medically necessary and reasonable," as well as coverage limitations and implied exclusions	http://go.cms.gov/3mr9674
National Coverage Determinations (NCDs)	National US rules	Defines Medicare coverage criteria for specified items and services. NCDs apply to beneficiaries nationwide	Section 1862(a)(1)(A) of the Social Security Act directs CMS to create NCDs to define coverage and to apply to all beneficiaries nationwide.	Further defines the idea of "medically necessary and reasonable," as well as coverage limitations	http://go.cms.gov/3pcDRyr

Local Coverage Determinations (LCDs)	Regional US rules set by Medicare administrative contractors (MACs)	Defines coverage for an item or service in a MAC's jurisdiction and applies only to states that are within a contractor's jurisdiction	Section 1862(a)(1)(A) of the Social Security Act directs MACs to develop LCDs.	Further defines the idea of "medically necessary and reasonable," as well as coverage limitations	http://go.cms.gov/2Kr7UUf
Physician billing and coding	National coding handbook	Code sets used to judge whether an item or service is reasonable and necessary by the MAC to determine coverage	The American Medical Association developed and maintains Level I HCPCS. Codes follow CMS guidance.	Further defines the idea of "medically necessary and reasonable" and is referenced in the clinical trials NCD: "all other Medicare rules apply."	https://go.cms.gov/2KKx28m
Hospital billing and coding	National and International: Countries customize code sets	For inpatient coding, providers include both the ICD-10-CM diagnosis and ICD-10-PCS procedure codes to submit claims to the MAC. Hospitals are paid using MS-DRG.	Most recently developed by CMS and the National Center for Health Statistics	Further defines the idea of "medically necessary and reasonable" and is referenced in the clinical trials NCD: "all other Medicare rules apply."	https://go.cms.gov/2KKx28m

Table 1: Sources of Medicare rules

Document	Discipline	Application
Informed consent form	Binding legal contract with the patient/participant	To identify and support potential side effects of investigational drugs or devices; to prove medical necessity for the diagnosis or treatment of complications, clinically appropriate monitoring, and conventional care; and to support any items or services provided for free in coverage analysis documentation for the Medicare Secondary Payer Rule

Protocol	Medicine, science	To identify the schedule of events for the clinical trial and the main source from which to identify and cite primary and secondary clinical trial objectives for therapeutic intent and, to a lesser extent, to identify and support medical necessity, clinically appropriate monitoring, and conventional care
Clinical trial agreement/Budget	Legal, financial; binding legal contract between the sponsor, the institution, and (sometimes) the principal investigator	These documents must coordinate with the informed consent form, financial terms, and the schedule of events in the protocol to properly identify and support which items and services are paid by the sponsor.
Investigator's brochure	Medicine, science	To provide supplemental information and clarification regarding the clinical trial, such as possibly the Investigational New Drug Application number, though not generally cited as a source in Medicare coverage analysis
Drug monograph	Pharmacology	To identify and support side effects to prove medical necessity for diagnosis or treatment of complications, clinically appropriate monitoring, and conventional care
Conventional care guidelines	Medicine	To identify and support side effects to prove medical necessity for diagnosis or treatment of complications, clinically appropriate monitoring, and conventional care. Examples include: National Comprehensive Cancer Network guidelines, Response Evaluation Criteria in Solid Tumors guidelines, medical specialty guidelines, and peer-reviewed literature

Table 2: Medicare coverage analysis documents

Specialization

One way to minimize the three areas of concern is to train and develop specialists. A few institutions are asking clinical research coordinators to be responsible for completing Medicare coverage analyses. This is not recommended for several reasons. Hospital billing applies a more complex formula that is calculated in a different way than physician billing. Further, clinical research coordinators are already very busy with their main work responsibilities. Lastly, it is possible to have unintended conflicts when considering whether an item or service is conventional care. If the work is delegated to clinical research coordinators, there should at least be a thorough quality assurance review.

Communication

Medicare coverage analyses can be interpreted in different ways even among teams at the same institution. Therefore, it is important to anticipate conflicts and teach that the crux of disagreements is often simply based on topics in Tables 1 and 2. To encourage calm resolutions through critical thinking, remind reviewers to turn to

the primary source documents in Tables 1 and 2; if an analysis is difficult or conflict arises, assess against the first principles of Medicare rules rather than turning to memory or past experiences with other studies.

Documentation

Given that a review of the details of each clinical trial must be undertaken to understand what is billable to Medicare and what is not, it is important to document decision processes carefully with an eye toward both internal and external auditors. This is to support the reasoning behind the decisions, as there are different interpretations as to the ambiguities in the clinical trials NCD. It is also important to document any unusual features about the clinical trial facts or any missing documents referenced within the clinical trials NCD.

Documentation should be brief and written in plain language. If the reason for an item or service is not obvious, the documentation should include a simple explanation of why the item or service is provided at that time point in that specific clinical trial, because this helps focus both internal and external auditing. If applicable, the comment should then include why the item or service is a routine cost. Routine costs may be linked to conventional care in that the item or service is "typically provided absent a clinical trial."[11] Routine costs may also be associated with "items or services required solely for the provision of the investigational item or service." Finally, routine costs are also items and services that are for the prevention, detection, and treatment of complications. The applicable Medicare rules should be cited. To save space, it is possible to cite the clinical trials NCD generally within a coverage analysis once and note that it applies to all items and services.

Auditing and monitoring

Auditing should be conducted not only of the Medicare coverage analysis work product, but also of all educational materials before they are used to ensure that the materials align with the Medicare rules. The educational materials should be used by an auditor to determine coverage for a variety of different clinical trials to test whether the materials are correct. Monitoring should also be conducted as to whether the time to complete education or coverage analyses has increased.

Education

Education should teach the first principles of Medicare rules and how they may be applied across all clinical trial fact patterns rather than teaching highly specific examples that apply to only one trial. Education should also discuss how to read the primary source documents together and how to apply the meaning of the documents to the facts of any clinical trial. The entire life cycle of a clinical trial should be explained. Materials should also address key information about each document in Table 2, how to use each document, and for what purpose. Education should also be provided to the quality assurance teams.

Here are ideas for education:

- The nuance that there are many ways to achieve a correct analysis should be part of the training and may be shown through case studies; and
- Education should teach the framework provided by the Medicare rules, as it applies to a wide range of facts in a unique way to each clinical trial.

Conclusion

Through returning to first principles, specialization, communication, documentation, auditing, monitoring, and education, it is possible to avoid misreading of the Medicare coverage and billing rules. As there is not one way to

conduct a Medicare coverage analysis, it is important that the thought process is memorialized in a record for external and internal auditors. This article may be used to support and create auditing and monitoring plans by healthcare entities at different points in the work stream, as well as a range of educational materials targeting the most frequent areas of concern.

Takeaways

- The Medicare coverage and billing rules provide a structure and consistency for coverage reviews.
- Recognize that there is not one way to determine coverage for an item or service.
- Acknowledge in training that the documents needed for analyses arrive from different disciplines and work streams.
- Audit and monitor education closely for misreading and misapplication.
- Return to the first principles of Medicare coverage and billing rules for each review.

1 Steve Phurrough, Patricia Graves, and Leslye K. Fitterman, "Decision Memorandum for the Clinical Trial Policy (CAG-00071R)," July 9, 2007, http://go.cms.gov/3mr9674.
2 John Pontarelli, "Rush Settlement with Government May Help Clarify Billing Requirements for Medicare Patients in Research Studies: Sets Model for Provider Compliance with National Coverage Decision on Clinical Trials," news release, Rush University Medical Center, December 8, 2005, https://bit.ly/37osa1A.
3 Ryan D. Meade and Andra M. Popa, "Managing Billing Compliance During Clinical Research amid Changing Medicare Coverage: Health Care Providers Should Turn to Core Medicare Principles for Compliance Program Guidance," *Journal of Health Care Compliance* (September–October 2007), https://bit.ly/3acPkKc.
4 Ryan D. Meade, "How to Analyze a Research Study for Medicare Compliance: A Training Manual for Clinical Trial Services Billing," March 2006.
5 Centers for Medicare & Medicaid Services, "Items and Services not Covered under Medicare," *MLN Booklet*, August 2018, https://go.cms.gov/3nqgWPB.
6 Centers for Medicare & Medicaid Services, "National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)," transmittal, July 2007, http://go.cms.gov/3cDQqx7.
7 Centers for Medicare & Medicaid Services, "National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)."
8 Centers for Medicare & Medicaid Services, "National Coverage Determination (NCD) for Blood Counts (190.15)," transmittal, November 2002, http://go.cms.gov/34hjZ5c.
9 CMS, "Chapter 12 - Physicians/Nonphysician Practitioners," *Medicare Claims Processing Manual*, Pub. 100-04, revised September 18, 2020, https://go.cms.gov/2WCZQ5k.
10 American Medical Association, *CPT 2020 Professional Edition* (American Medical Association, 2020), 6.
11 Centers for Medicare & Medicaid Services, "National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)."