



# Medicare Billing

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May 14, 2015

# Presentation Objectives

- ▶ Understand and incorporate Medicare's Clinical Trial policy into practice
- ▶ Understand how to interpret a Medicare Coverage Analysis
- ▶ Understand the “basics” of conducting a Medicare Coverage Analysis

# Medicare Coverage

## Clinical Trials Final National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1) --Clinical Trials Policy (CTP)

Effective for items and services furnished on or after July 9, 2007, **Medicare covers the routine costs of qualifying clinical trials**, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. **All other Medicare rules apply**

Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except...

# (NCD) for Routine Costs in Clinical Trials (310.1) --Clinical Trials Policy (CTP)

The investigational item or service, itself *unless otherwise covered outside of the clinical trial*;

Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and

Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

# Routine Costs in Clinical Trials

Routine costs include items and services:

- ▶ that are typically provided absent a clinical trial
- ▶ required solely for the provision of the investigational item or service (e.g., administration of an investigational drug)
- ▶ required for the clinically appropriate monitoring of the effects of the investigational item or service
- ▶ required for the prevention of complications
- ▶ needed for reasonable and necessary care arising from the provision of the investigational item or service (e.g., diagnosis of complications)

# Coverage (NCD) for Routine Costs in Clinical Trials (310.1)

## --Clinical Trials Policy (CTP) (Cont)

### A. THREE requirements:

- ▶ The subject or purpose of trial must be an evaluation of an item or service that fall within a Medicare Benefit Category and is not statutorily prohibited;
- ▶ The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
- ▶ Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteer. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group

### B. Deemed to be automatically qualified are:

- ▶ Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
- ▶ Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD and VA
- ▶ Trials conducted under an investigational new drug application (“IND”) reviewed by the FDA; and
- ▶ Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1)...until qualifying criteria are developed and certification process established

# (NCD) for Routine Costs in Clinical Trials (310.1) --Clinical Trials Policy (CTP) (Cont)

## C. The Desirable Characteristic Test

A clinical trial is a “qualifying clinical trial” if it has all 7 “desirable characteristics:”

- The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes
- The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use
- The trial does not unjustifiably duplicate existing studies
- The trial design is appropriate to answer the research question being asked in the trial
- The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
- The trial is in compliance with Federal regulations relating to the protection of human subjects; and
- All aspects of the trial are conducted according to the appropriate standards of scientific integrity

# How Do You Determine Routine Costs?

- ▶ Would you provide this service to a patient not in a clinical trial?
- ▶ Does your practice follow national practice guidelines, medical literature? If so, supporting documentation must be provided
- ▶ Is this a service covered by Medicare outside of a clinical trial?
- ▶ What is the intent or objective of the item or service?

# Supporting Documentation of Routine Care

- ▶ Specialty Practice guidelines i.e. NCCN Guidelines
- ▶ Statement from professional organization
- ▶ Peer-reviewed journal articles
- ▶ Institutional policies & procedures for medical necessity

# National Coverage Determinations (NCD) & Local Coverage Determinations (LCD)

Underlying theme...is the item or service reasonable and necessary; provided for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body party...(and falls under a Medicare benefit category)

- ▶ National Coverage Determinations (NCDs) are statutes: they define what is covered by Medicare
- ▶ Local Coverage Determination (LCD)-aka local medical review policy (LMRP) is a decision by a fiscal intermediary (FI) or carrier whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with §1862(a)(1)(A) of the Social Security Act (e.g., determination as to whether the service or item is reasonable and necessary)
  - ▶ LCDs are developed when there is no NCD or when there is a need to further define a NCD
  - ▶ LCDs cannot conflict with NCDs

# Medicare Administrative Contractors (MACs) As of April 1, 2015

MAC Jurisdiction	Previous MAC Jurisdiction	Processes Part A & Part B Claims for the following states:	MAC
DME A	DME A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont	NHIC, Inc.
DME B	DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	National Government Services, Inc.
DME C	DME C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands	CGS Administrators, LLC
DME D	DME D	Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
5	5	Iowa, Kansas, Missouri, Nebraska	Wisconsin Physicians Service Insurance Corporation
6	6	Illinois, Minnesota, Wisconsin <b>**HH + H for the following states:</b> Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US Virgin Islands, Wisconsin and Washington	National Government Services, Inc.
8	8	Indiana, Michigan	Wisconsin Physicians Service Insurance Corporation
15	15	Kentucky, Ohio <b>**HH + H for the following states:</b> Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, and Wyoming	CGS Administrators, LLC
E	1	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
F	2 & 3	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Noridian Healthcare Solutions, LLC
H	4 & 7	Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi	Novitas Solutions, Inc.

# The Billing/Coverage Analysis Provides:

- ▶ Detailed review of the study, informed consent, budget and contract
- ▶ Detailed review of who is paying for what item or service
- ▶ Detailed review and analysis of NCDs and LCDs
- ▶ Prevents financial surprises during a project
- ▶ A template for budget development (if applicable)
- ▶ A tool for audits
- ▶ A consistent methodology for research billing
- ▶ A template of subjects' financial liability for the ICF
- ▶ A guide for the IRB to review the cost section of informed consent (45 CFR 46.116 & 21 CFR 50.25)

**Medical Coverage Analysis for A091302:** Randomized Phase II Study of Sorafenib with or without Everolimus in Patients with Radioactive Iodine Refractory Hürthle Cell Thyroid Cancer

Summary of Study: Two arm study- Arm 1: Sorafenib alone, Arm II: Sorafenib + Everolimus, Crossover for Arm 1: Everolimus. Cycles are 28 days

Clinical Trials.gov Identifier: NCT02143726

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Is the study a qualifying clinical trial? Yes

1. Is the subject or purpose of the trial an evaluation of an item or service that falls within a Medicare benefit category  
 Yes  No
2. Does the trial have therapeutic intent?  
 Yes  No
3. Does the trial enroll patients with a diagnosed disease?  
 Yes  No
4. Do any of the following apply to this study?  
 Trials funded by NIH, CDC, AHRQ, HCFA, DOD and VA  
 Trials supported by centers or cooperative groups that are funded by the above federal agencies;  
 Trials conducted under an IND reviewed by the FDA  
 Drug trials exempt from having an IND under 21 CFR 312.2(b) (1)

	Prior to Registration	Day 1 & 15 of Cycles 1 & 2	Day 1 of each cycle start with Cycle 3 and after Crossover	Post Treatment Follow-up	Survival & Disease Status Follow-up	Comments
History & Physical	PS	N	N	N		
<b>LABORATORY</b>						
Triglycerides, cholesterol	PS	PS	PS	PS		Medicare has limitations on coverage- National Coverage Determination (NCD) 190.23. A side effect of Everolimus is hypercholesterolemia and hypertriglyceridemia: Package insert notes to monitor prior to therapy and periodically thereafter (7/14). Under the NCD 310.1, this may fall under the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications.
CBC w/diff, platelets		N	N	N		
Albumin, alk phos, total bilirubin, BUN, calcium, chloride, creatinine, glucose, potassium, total protein, SGOT [AST], SGPT[ALT], sodium, bilirubin	PS	N	N	N	N	
Serologic Hepatitis B Surface Ag & Hepatitis C RNA (physician discretion, not required)	PS					Medicare has limitations on coverage, (NCD) 190.33: 1. Detection of viral hepatitis when there are abnormal LFTs 2. Prior to and subsequent to liver transplantation
Serum B-HCG	PS		PS			For woman of child bearing potential, both agents have teratogenic/effects in pregnancy (FDA category D)
Thyroglobulin, Serum	PS					Suggested at cycle 3 and then every 4 cycles
Thyrotropin (Thyroid Stimulating Hormone or TSH), Serum	PS		N			Every 2 cycles, (NCD) 190.22
<b>XRAY/SCANS</b>						
EKG (as indicated)	PS					Medicare has limitations for coverage, (NCD) 20.15
CT/MRI Tumor Measurements	PS		N		PS	Every two cycles for the first 12 cycles, every three cycles thereafter, RECIST (version 1.1) guidelines.
<b>TREATMENT- cycles every 28 days</b>						
Sorafenib		N- at all-time points				Used as FDA approved, Micromedex
Everolimus		S- at all-time points				

## Legend:

**S=Sponsor is paying for or providing the item or service.** No Medicare billing or billing to third party payors for anything being paid for or being provided by the Sponsor. For this study, the Sponsor is Alliance.

**N=Conventional care, routine care.** Item or service would be conducted whether or not the subject is in the study. May bill Medicare and other third party payors. It is the physician's responsibility to document medical necessity in patient/subjects medical record.

**R=Research.** Research efforts only (time and effort for the conduct of the clinical trial). Medicare does not pay for collection of data, thus Sponsor (Alliance) either provides funding or site provides funding.

**CL=Central lab.** Typically used when labs are going to a central location and the Sponsor (Alliance) is providing payment for these services.

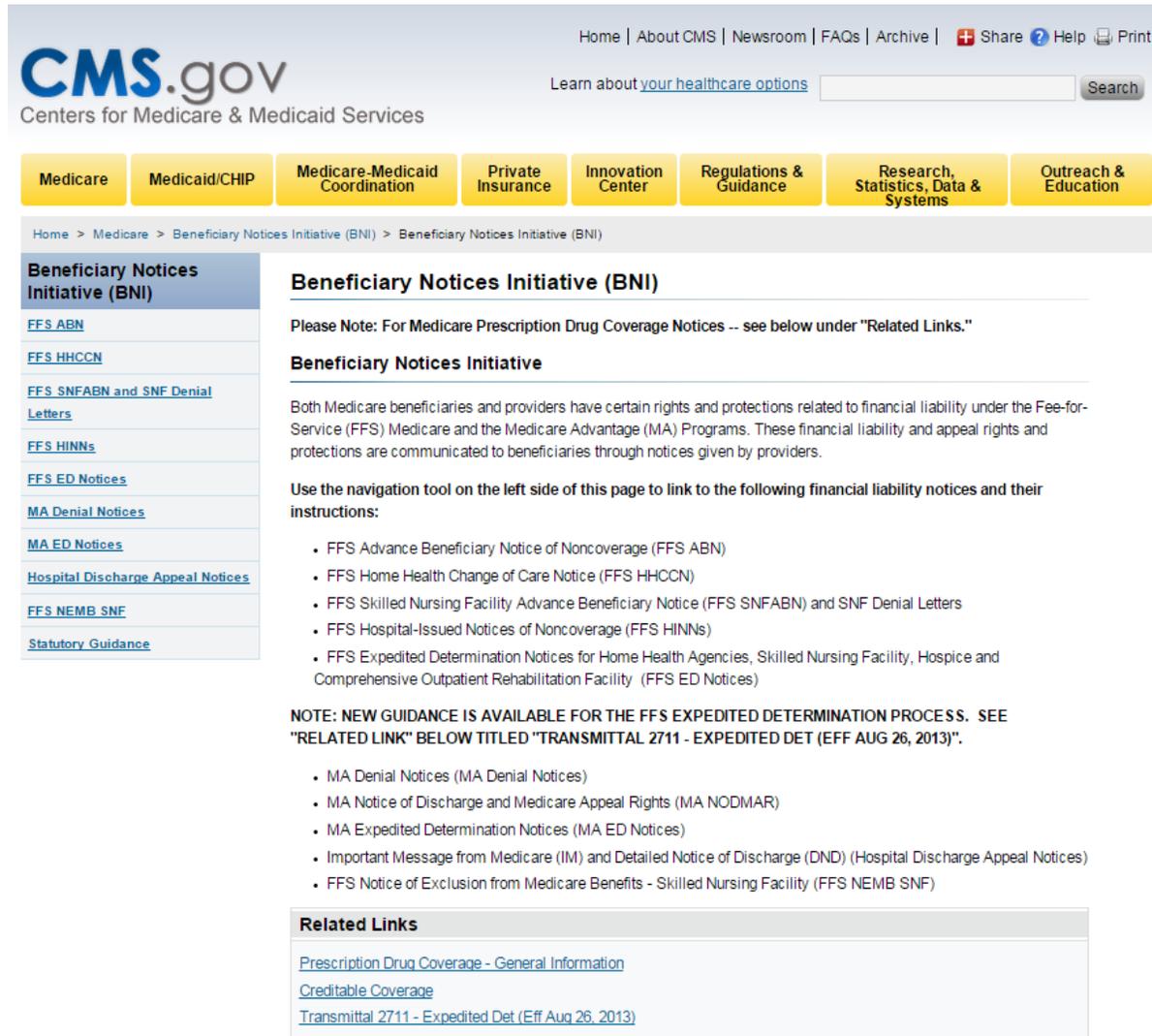
**PS=Patient specific.** An activity that may or may not be billable for all subjects at various time points as required by a study, such as at screening/baseline/pre-registration. The rationale is some subjects may have had these tests/procedures previously and they cannot be repeated to meet requirements of a study. Another example, is with items or services conducted at more frequent intervals. At the point of service, this will be an "S"- which means the Sponsor (Alliance) will pay for the item or service (no billing to Medicare or other third party payors), or it is an "N"- which means for this subject, this item or service is routine care at this point of time and can be billed to Medicare or to third party payors.

*\*\*This Medicare Coverage Analysis is a billing guide/tool and is based on Medicare's Clinical Trial Policy (NCD 310.1), Medicare National Coverage Determinations (NCDs), NCCN guidelines, Micromedex and RECIST (version 1.1) guidelines. It is recommended you follow your institution's policies and procedures and National and Local Coverage Determinations for clinical trial billing. The guide is based on study version date 7/9/14. Medicare Coverage Analysis date revised 10/14/14  
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# TIPS

- ▶ Review entire study
  - ▶ Focus on objectives, schedule of events and statistical section
- ▶ Review consent form
- ▶ Review budget and if there is a contract, review the contract
- ▶ Look at the disease and get a general sense of current treatments, trends and guidelines
- ▶ Work with the investigators as they are the content experts
- ▶ Contact your Medicare Contract Administrator for questions
- ▶ Review NCDs and LCDs

# Advanced Beneficiary Notice/ BNI



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### Beneficiary Notices Initiative (BNI)

[FFS ABN](#)  
[FFS HHCCN](#)  
[FFS SNFABN and SNF Denial Letters](#)  
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[Hospital Discharge Appeal Notices](#)  
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### Beneficiary Notices Initiative (BNI)

**Please Note: For Medicare Prescription Drug Coverage Notices -- see below under "Related Links."**

### Beneficiary Notices Initiative

Both Medicare beneficiaries and providers have certain rights and protections related to financial liability under the Fee-for-Service (FFS) Medicare and the Medicare Advantage (MA) Programs. These financial liability and appeal rights and protections are communicated to beneficiaries through notices given by providers.

**Use the navigation tool on the left side of this page to link to the following financial liability notices and their instructions:**

- FFS Advance Beneficiary Notice of Noncoverage (FFS ABN)
- FFS Home Health Change of Care Notice (FFS HHCCN)
- FFS Skilled Nursing Facility Advance Beneficiary Notice (FFS SNFABN) and SNF Denial Letters
- FFS Hospital-Issued Notices of Noncoverage (FFS HINNs)
- FFS Expedited Determination Notices for Home Health Agencies, Skilled Nursing Facility, Hospice and Comprehensive Outpatient Rehabilitation Facility (FFS ED Notices)

**NOTE: NEW GUIDANCE IS AVAILABLE FOR THE FFS EXPEDITED DETERMINATION PROCESS. SEE "RELATED LINK" BELOW TITLED "TRANSMITTAL 2711 - EXPEDITED DET (EFF AUG 26, 2013)".**

- MA Denial Notices (MA Denial Notices)
- MA Notice of Discharge and Medicare Appeal Rights (MA NODMAR)
- MA Expedited Determination Notices (MA ED Notices)
- Important Message from Medicare (IM) and Detailed Notice of Discharge (DND) (Hospital Discharge Appeal Notices)
- FFS Notice of Exclusion from Medicare Benefits - Skilled Nursing Facility (FFS NEMB SNF)

### Related Links

- [Prescription Drug Coverage - General Information](#)
- [Creditable Coverage](#)
- [Transmittal 2711 - Expedited Det \(Eff Aug 26, 2013\)](#)

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[Help with File Formats and Plug-Ins](#)

# Useful Links

- ▶ FDA device: <http://www.fda.gov/cdrh/devadvice/314.html>
- ▶ OIG: <http://oig.hhs.gov/>
- ▶ FDA: <http://www.fda.gov/>
- ▶ OHRP: <http://www.hhs.gov/ohrp/>
- ▶ States Requiring Coverage of Clinical Trials Cost <http://www.cancer.gov/clinicaltrials/learningabout/payingfor/laws>
- ▶ Centers for Medicare & Medicaid Services, <http://www.cms.gov/Medicare/Medicare.htm>
- ▶ Clinical Trials.gov. <http://www.clinicaltrials.gov/>
- ▶ International Committee of Medical Journal Editors ICMJE, <http://www.icmje.org/>
- ▶ Agency for Healthcare Research and Quality has a National Guideline Clearinghouse at [www.guidelines.gov](http://www.guidelines.gov)
- ▶ National Cancer Institute (NCI): <http://www.cancer.gov>
- ▶ National Comprehensive Cancer (NCCN): Network <http://www.nccn.org/index.asp>
- ▶ American College of Cardiology: <http://www.acc.org/>
- ▶ American College of Nuclear Medicine: <http://www.acnponline.org/>
- ▶ American College of Radiology (ACR): <http://www.acr.org/>
- ▶ American Academy of Professional Coders <http://www.aapc.com/>
- ▶ American Society of Clinical Oncology (ASCO) <http://www.asco.org/>
- ▶ American Heart Association (AHA): <http://www.americanheart.org/presenter.jhtml?identifier=1200000>
- ▶ MedlinePlus Health: <http://www.nlm.nih.gov/medlineplus/>
- ▶ Drug information: RxList The Internet Drug Index: <http://www.rxlist.com/script/main/hp.asp>
- ▶ Drug information: BlackBoxRx <http://blackboxrx.com/>
- ▶ Lab Tests: <http://www.labtestsonline.org/>

# Conclusion

- Questions from Audience
- Answers from Presenter

