MCA Integration into Alliance Clinical Trials

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Alliance Clinical Research Professionals Committee, 11/3/16

Presentation Objectives

- Describe Medicare's clinical trial policy
- Discuss the purpose of the Medicare coverage analysis and how to conduct a Medicare coverage analysis
- Discuss the integration of the Medicare Coverage analyses created by the Cancer Trials support unit into practice

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Medicare is managed by…

- Centers for Medicare & Medicaid Services (CMS) responsible for administering these programs formerly Health Care Financing Administration (HCFA)
- Payment for services by providers/hospital are under the prospective payment system (PPS)
- Payment for clinical labs and ambulance services under fee schedules
- Contract entities Medicare Administrative Contractors (MACs)- process claims & provide payments (16 total; 4 DEMs)

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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	Noridian Healthcare Solutions, LLC
DME B	DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	CGS Administrators, LLC
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 ****HH + H for the following states:** 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 ****HH + H for the following states:** 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.
J	10	Alabama, Georgia, Tennessee	Cahaba Government Benefit Administrators, LLC
K	13 & 14	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont ****HH + H for the following states:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	National Government Services, Inc.
L	12	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)	Novitas Solutions, Inc.
M	11	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) ****HH + H for the following states:** Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas	Palmetto GBA, LLC
N	9	Florida, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.

Medicare…Then & Now

1965: Congress passed legislation establishing the Medicare program as Title XVIII and Title XIX of the Social Security Act, established in response to specific medical care needs of the elderly

1973: Coverage expanded for certain disabled persons and certain persons with kidney disease

2000: Clinical Trial Policy. Prior to this National Coverage Determination Medicare beneficiaries could not participate in clinical trials- as Medicare would not cover the costs of routine care

2014: Coverage with Evidence Development (CED)

Then Two Parts: Hospital Insurance (HI *aka* Part A) and Supplementary Medical Insurance (SMI *aka* Part B)

Now Four Parts: Part A (Hospital coverage), Part B (Medical Insurance), Part C *aka* Medicare Advantage Plans (combines A, B and perhaps D into an HMO or PPO with a private insurer) and Part D (Prescription Drug coverage)

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Underlying theme
Medical Necessity

- Medicare's definition of medical necessity stems from the SSA of 1965 (1862[a][1][A])…states **no payment** under Medicare Part A or Part B for any expenses incurred for items or services which, except for certain named exceptions "are not **reasonable** and **necessary** for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body part"

- Not medically necessary: a particular service is not a benefit under the defined benefit, for this diagnosis, at this time (Article for Medical Necessity-A3369- WPS, 2/1/02)

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Not Medically Necessary

In other words…when Medicare does not pay, it does not mean the service should not be ordered or performed, nor does it mean it is not "standard of care"; it simply means Medicare does not pay

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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 nationally
- 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

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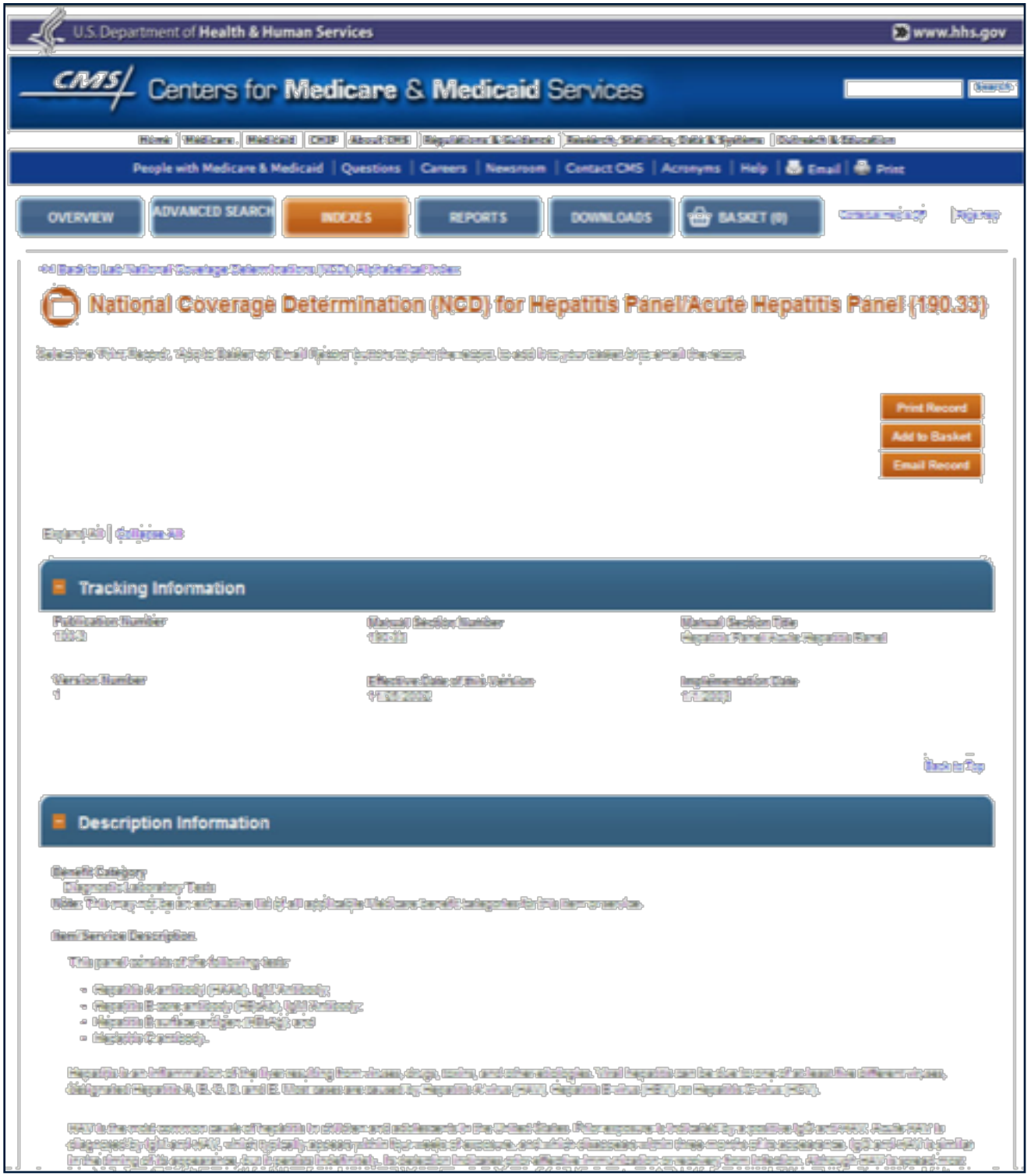
NCD for Hepatitis Panel (190.33)



Coverage with Evidence Development

- CMS released an updated guidance document on November 20, 2014 that describes Coverage with Evidence Development (CED)
- CMS, as part of the National Coverage Determination (NCD) may determine coverage of an item or service only in the context of a clinical study

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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…

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Qualifying Clinical Trial- Two Prong Analysis

Three Requirements:

1. 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;
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent
3. 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

Deemed to be automatically qualified:

- 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

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

The Desirable Characteristic Test:

A clinical trial is a "qualifying clinical trial" if it has all 7 "desirable characteristics"

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes
2. 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
3. The trial does not unjustifiably duplicate existing studies
4. The trial design is appropriate to answer the research question being asked in the trial
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity

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

Not considered routine cost:

- 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

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NGS Medical Policy Article

- …because Medicare may pay for certain costs in the study, but other payers will not …and the study sponsor provides those items or services for free…then Medicare likewise must not be billed for those items and services. Medicare must be on a level playing field with all payer types…
- Exception: Indigent patients for whom the hospital routinely offers free care…
- Article for clinical trials- Medical policy article (A5284), NGS, **https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52840&ver=2&DocID=A52840**, taken 10/19/16

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Medicare- Device Clinical Trials

- Analyzed using "1995 Device Regulations" Devices and Related Services 60 FR 48417
- Medicare Coverage: limited to those devices used in FDA and IRB approved studies and is case-by-case
- Devices which may be covered include pre-market approval (PMA), 510(k), IDE category B, Humanitarian Device Exemptions (HDE), post approval studies for carotid artery stenting
- Require prior approval from the Fiscal Intermediary (Medicare Part A) and the Carrier (Medicare Part B)
  - Medicare typically will pay for the device, provided the cost does not exceed a similar device

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The Billing/Coverage Analysis Provides:

- Detailed review of the study
- Detailed review of who is paying for what item or service
- Detailed review and analysis of NCDs and LCDs
- Documents supporting guidelines for coverage (RECIST, NCCN, etc.)
- Prevention of financial surprises during a project
- A template for budget development (if applicable)
- A tool for audits
- A consistent methodology for research billing
- A guide for the IRB to review the Cost Section of Informed Consent (21 CFR 50.25)
- A template of subjects' financial liability for the ICF

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Supporting Documentation of Routine Care

- Specialty Practice guidelines
- Statement from professional organization
- Peer-reviewed journal articles
- Institutional policies & procedures for medical necessity

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Creating a Billing Grid/ Matrix

	Screening	Randomization	Week 1	Week 2	Week 3
Informed Consent	X				
Inclusion/ Exclusion	X	X			
Exam	X		X	X	X
CBC	X		X	X	X
EKG	X		X		X
CT scan	X				X
Study Drug			X	X	

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Sample of coding

	Screening	Randomization	Wk 1	Wk 2	Wk 3
Informed consent	E				
PT/PTT	S		S		
Exam	PS	PS	PS	N	N
CBC/Chem Panel	PS	S	N	N	N
CT scan	S		S		S
Hep B Screen	S				
Rituxan			N	N	

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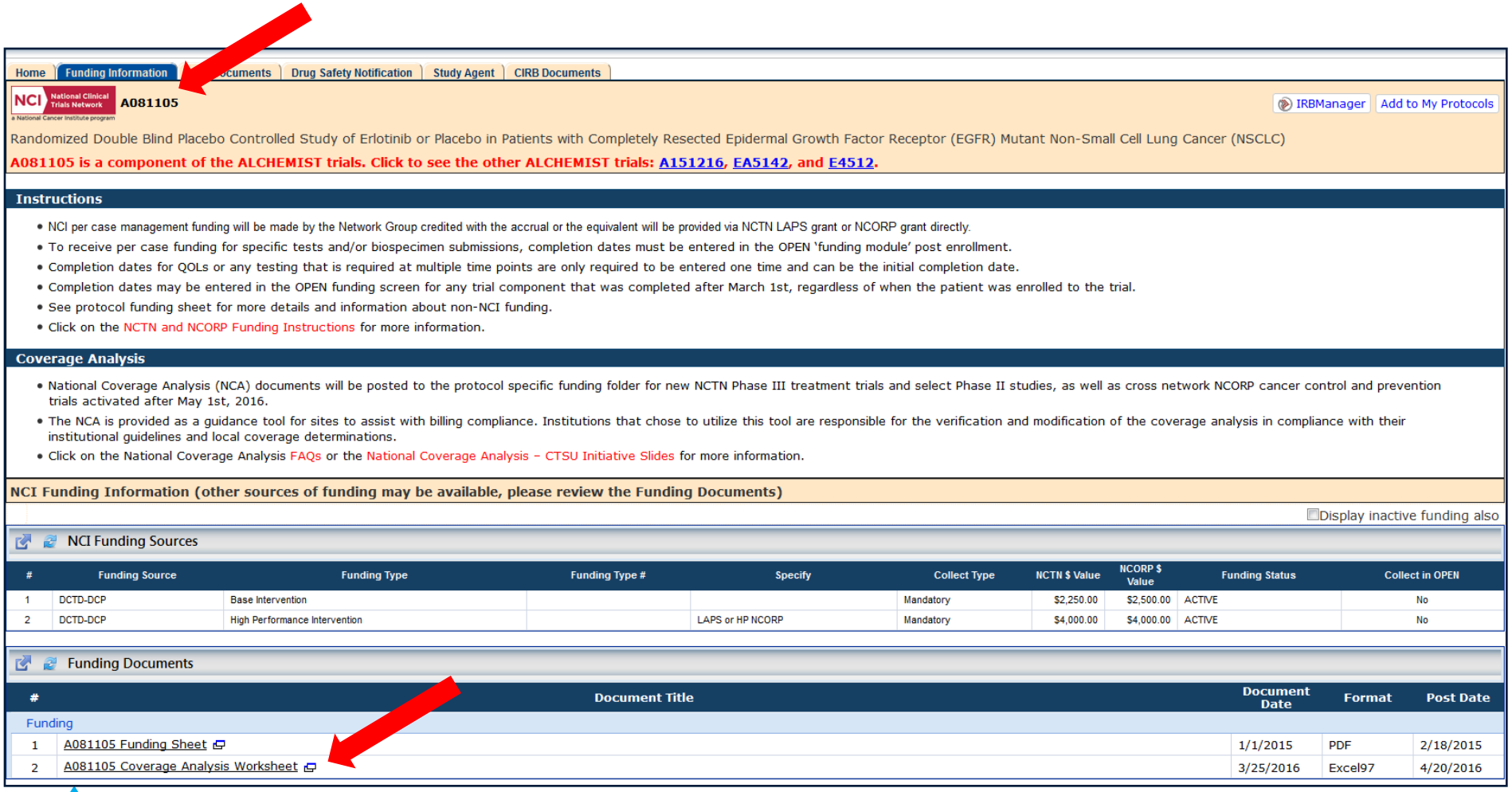
How to obtain the Medicare Coverage analysis



Home | Funding Information | ocuments | Drug Safety Notification | Study Agent | CIRB Documents

NCI National Clinical Trials Network — a National Cancer Institute program

A081105

IRBManager | Add to My Protocols

Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-Small Cell Lung Cancer (NSCLC)

A081105 is a component of the ALCHEMIST trials. Click to see the other ALCHEMIST trials: A151216, EA5142, and E4512.

Instructions

- NCI per case management funding will be made by the Network Group credited with the accrual or the equivalent will be provided via NCTN LAPS grant or NCORP grant directly.
- To receive per case funding for specific tests and/or biospecimen submissions, completion dates must be entered in the OPEN 'funding module' post enrollment.
- Completion dates for QOLs or any testing that is required at multiple time points are only required to be entered one time and can be the initial completion date.
- Completion dates may be entered in the OPEN funding screen for any trial component that was completed after March 1st, regardless of when the patient was enrolled to the trial.
- See protocol funding sheet for more details and information about non-NCI funding.
- Click on the NCTN and NCORP Funding Instructions for more information.

Coverage Analysis

- National Coverage Analysis (NCA) documents will be posted to the protocol specific funding folder for new NCTN Phase III treatment trials and select Phase II studies, as well as cross network NCORP cancer control and prevention trials activated after May 1st, 2016.
- The NCA is provided as a guidance tool for sites to assist with billing compliance. Institutions that chose to utilize this tool are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines and local coverage determinations.
- Click on the National Coverage Analysis FAQs or the National Coverage Analysis – CTSU Initiative Slides for more information.

NCI Funding Information (other sources of funding may be available, please review the Funding Documents)

Display inactive funding also

NCI Funding Sources

#	Funding Source	Funding Type	Funding Type #	Specify	Collect Type	NCTN $ Value	NCORP $ Value	Funding Status	Collect in OPEN
1	DCTD-DCP	Base Intervention			Mandatory	$2,250.00	$2,500.00	ACTIVE	No
2	DCTD-DCP	High Performance Intervention		LAPS or HP NCORP	Mandatory	$4,000.00	$4,000.00	ACTIVE	No

Funding Documents

#	Document Title	Document Date	Format	Post Date
Funding				
1	A081105 Funding Sheet	1/1/2015	PDF	2/18/2015
2	A081105 Coverage Analysis Worksheet	3/25/2016	Excel97	4/20/2016

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A RANDOMIZED DOUBLE-BLIND PHASE III STUDY OF IBRUTINIB DURING AND FOLLOWING AUTOLOGOUS STEM CELL TRANSPLANTATION VERSUS PLACEBO IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA OF THE ACTIVATED B-CELL SUBTYPE			
The National Coverage Decision 310.1, the NCCN Clinical Practice Guidelines and other resources were used to develop this National Coverage Analysis. This NCA is provided by the CTSU as a guidance tool for institutions to assist with billing compliance. Institutions that chose to utilize this tool are responsible for the verification and modification of the coverage analysis in compliance with their institutional guidelines and are ultimately responsible for modifications specific to their local coverage determinations. All items and services that are billable to Medicare must be supported by medical necessity.			
Investigational Item or Service Analysis			
Question	**Answer**		
What is the name and version of the protocol	ALLIANCE A051301		
What is the Clinicaltrials.gov #?	NCT 02443077		
What is the name of the investigational item?	ibrutinib (NSC #748645, IND #117241)		
What is the FDA status of the investigational item?	IND		
If FDA approved, is the investigational item being used off-label?	NA		
Is this study required by Medicare as a part of the "Coverage with Evidence Development" process? (http://cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html)	No		
Qualifying Clinical Trial Analysis			
Requirement	**Yes**	**No**	**Comment**
Does the investigational item or service fall into a Medicare benefit category? Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).	x		Drugs and Biologicals
Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with institutional policy?	x		To evaluate the ability of ibrutinib to improve 24-month progression free survival (PFS) compared to placebo.
Does the study enroll patients with diagnosed diseases?	x		Diagnosis of DLBCL, high grade B-cell lymphoma NOS, or BCLU
Is the study a deemed trial? (Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supported by	x		NCI
Is the study a qualifying clinical trial? **(All questions must be answered "Yes" to qualify)**	x		

Protocol #: ALLIANCE A051301				Today's Date: June 29th, 2016
Study Title: A RANDOMIZED DOUBLE-BLIND PHASE III STUDY OF IBRUTINIB DURING AND FOLLOWING AUTOLOGOUS STEM CELL TRANSPLANTATION VERSUS PLACEBO IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA OF THE ACTIVATED B-CELL SUBTYPE				
Principal Investigator: Charalambos Andreadis, M.D.				
Procedure	CPT Codes	Day 1 of each treatment cycle	At end of treatment, PD, withdrawal, or removal	Justification and Comments
EVALUATION & MANAGEMENT				
History and physical, Weight, PS	99201-99205, 99211-99215, G0463	RC	RC	NCD 310.1 allows for the coverage of routine cost of conventional care. Physical exams at workup and during therapy appear reasonable and necessary to monitor disease/ progression. Medical records must document medical necessity and support level of E&M performed.
Adverse Event assessment	NA	NB	NB	Part of history and physical exam. Not billed separately.
Patient medication diary	NA	NB	NB	Part of histoy and physical exam. Not billed separately.
Concomitant meds	NA	NB	NB	Part of history and physical exam. Not billed separately.
LABORATORY				
CBC, Differential, Platelets	85025, 85027	RC	RC	NCD 310.1 allows for the coverage of routine cost of monitoring toxicities. Chemotherapeutic agents used in this clinical trial can cause hematologic toxicities including, neutropenia and anemia (Protocol p. 45). Coverage also generally supported under NCD 190.15. Medical records must document medical necessity.
Na, K, Cl, BUN, Serum creatinine, Glucose, Calcium AST, ALT, Alk. Phos., Bil, Total protein, Albumin	80053, 84100, 84105	RC	RC	These are all included in the CMP. NCD 310.1 allows for the coverage of routine costs of monitoring toxicities. Chemotherapeutic agents used in this clinical trial can cause diarrhea, nausea, vomiting and renal and liver toxicities. (Protocol p.45). Medical records must document medical necessity.
SPECIMENS				
None				

Sample Coverage Analysis Template

I. Project Information
II. Items or Services
III. Contract and Informed Consent Review
IV: Additional Comments

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Clinical Trials Office Draft Billing Grid; 10/24/16

	Pre-registration assessment	Registration	Cycle 1		Cycles 2-13		Clinical Follow (18mo, 24 mo, then every 6 mo to 60 mo)	At PD, withdrawal, or removal
			Day -6 of	Weekly until day 29	Day 1 of Cycles 2, 3,7,10,11 & 13	Day 15 of Cycle 2, Day 1 of Cycles 4, 5, 6, 8, 9, 11, and 12		
Tests & Observations								
History and physical, Weight, PS		PS	N		N	N	N	N
Height		E						
Pulse, Blood pressure		E						
ECG		PS						
Adverse Event assessment		E	E	E	E	E	E	E
Patient medication diary			E		E	E		
Concomitant meds		E			E	E		E
Fatigue/ uniscale assessment		E						
Laboratory Studies								
CBC, Differential, Platelets		PS	N	N	N	N	N	N
Na, K, Cl, BUN, Serum creatinine, Glucose, Calcium		PS	N	N	N	N	N	N
AST, ALT, Alk. Phos., Bili, Total protein, Albumin		PS	N	N	N	N	N	N
Serum HCG		S						
PFTs		PS			N 3 months post Auto-HCT			
PT/INR/PTT (aPTT)		PS						

KEY:

1. N = Normal Care (bill to insurance)
2. S = Sponsor paying (bill to research)
3. PS = Patient specific (if not SOC at the time point bill to research; otherwise bill to insurance)
4. CL = Central lab
5. E = Research staff time/effort

Protocol: RANDOMIZED DOUBLE-BLIND PHASE III STUDY OF IBRUTINIB DURING AND FOLLOWING AUTOLOGOUS STEM CELL TRANSPLANTATION VERSUS PLACEBO IN PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA OF THE ACTIVATED B-CELL SUBTYPE A051301

Sponsor: Alliance

Conclusion

- Q & A

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