National Coverage Analysis (NCA)

- What is a Clinical Trials Coverage Analysis?
  - A coverage analysis is a review of all tests, procedures, and interventions associated with a clinical trial (CT) to determine which ones are 'billable' and which are 'not billable' to a third party payer against the national guidelines and coverage rules
- Who performs the NCA's?
  - The Clinical Trials Support Unit (CTSU) creates the NCAs for NCTN and NCORP trials
- Why are NCA's performed?
  - NCAs are intended to be a ***guide*** for the sites as they consider their participation in SWOG trials
  - Sites should still make sure to do their own local coverage analysis (LCA) using their local coverage determinations
- Where can you find NCA's?
  - Once completed, official NCAs are posted on the CTSU dashboard

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How Do We Determine What's Billable?
CMS NCD for Routine Costs in Clinical Trials (310.1)

- "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:
  - 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**."

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true

What to Look for in an NCA?

- Cost categories
- CPT codes
- Study calendar
- Justification and comments
- Legend

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Sample NCA Document

Procedure	Sample CPT Codes	Pre-random	Within 7D after random	Within 30D after random	Beginning Within 14D after random	Within 14D after PCI completion	At Day 90 after random	At Day 180 after random	At Day 270 after random	At Day 360 after random	At Day 450 after random	At Day 540 after random	At Day 630 after random	At Day 720 after random	Off MRI Surveillance prior to 24 months	Follow Up after 24 months	Justification and Comments
EVALUATION & MANAGEMENT																	
History and Physical Exam	99201-99205, 99211-99215, G0463	M					M	M	M	M		M		M	M	M	Physical Exams at workup and during follow up would be considered conventional care to monitor disease/ progression. NCCN guidelines for Small Cell Lung Cancer (SCLC) v 1.2019 supports H&P follow up Q3 mo during yrs 1-2, Q6 mo during yr 3, then annually (SCL-6). Medical records must document medical necessity and support level of E&M performed. To be billable, evaluation must be done by a healthcare provider (MD, DO, NP) as part of an physical exam.
Weight & Performance Status		M															
Toxicity Notation					M	M	M										
Administer cognitive function testing	n/a		S				S	S		S		S		S	S		Study paid per funding sheet
Radiation therapy materials submission via TRIAD for review by IROC Rhode Island	n/a					NB											Would be considered staff time
Quality of Life Questionnaires (see Section 15.4)	n/a				NB		NB	NB	NB	NB				NB	NB		Would be considered staff time
Imaging Submission (see Section 15.2)							NB	NB		NB							Would be considered staff time
Monitoring for survival and disease status	n/a														NB	NB	Would be considered staff time
LABORATORY																	
Serum creatinine for calculated creatinine clearance	82565						M	M	M	M		M		M			It would be considered conventional care to assess kidney function prior to the use of contrast dye for imaging in patients with a history of cancer/chemotherapy treatment. Medical records must document medical necessity. (Per protocol section 9, testing is to be done within 14 days prior to each MRI).
venipuncture	36415, 36951, 36952			M*			M	M	M	M	M*	M	M*	M			Would be considered conventional care. ***Note per protocol section 15.3, the research blood specimen is to be collected only if a SOC blood draw is scheduled. If the patient does not have a standard of care blood drawn at a research blood specimen time point, *do not collect the research sample*.**
SPECIMENS																	
blood specimen submission	36415, 36951, 36952			S*			S	S	S	S	S*	S	S*	S	S		Sponsor paid per ICF and funding sheet. ***Note per protocol section 15.3, the research blood specimen is to be collected only if a SOC blood draw is scheduled. If the patient does not have a standard of care blood drawn at a research blood specimen time point, *do not collect the research sample.***

Legend

RC = Routine cost for a QCT and billable to Medicare/government payer/commercial payers
S = Sponsor paid/provided per study funding sheet
NB = Non-billable item
M = Billable as conventional care in a non QCT or in a clinical trial that does need to qualify for coverage

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Questions on NCAs?

- Visit the CTSU website to view active study NCAs and funding memos
- Email funding@swog.org with questions

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