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



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



Sample NCA Document

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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



Questions on NCAs?

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

