Coverage Analysis (CA)
Intro to CA at DGSOM at UCLA

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Industry Sponsored Clinical Trials

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What is Coverage Analysis?

Coverage Analysis documents the process of identifying procedural costs which may be billed to an insurer as “routine care” vs. research costs for procedures/services provided as a result of participation in a “qualified” clinical trial.

- **Routine Care (RC) – Billable to Insurer**
  - Provided to patients absent a clinical trial.
  - Required for administration of investigational item.
  - Necessary for subjects’ safety (clinical monitoring), or prevention of complication(s)
  - Medically necessary for diagnosis or treatment of complications arising from administration of investigational item.

- **Research Costs – Must be provided for by Sponsor or Other Funding Source**
  - All other procedures/services
  - Must be provided by sponsor or another source of funding/support (NIH, Foundation, Grant, Internal Research Funds, etc.).
Routine Care Costs Do NOT Include:

• The Investigational Item or Service, unless otherwise covered absent the clinical trial.

• Items/services provided solely for data collection and research analysis (not used in the direct clinical management of subjects).
Coverage Analysis – What is a Qualifying Trial?

**Must meet all of the following criteria to be considered a “qualifying trial”:**

- **Evaluates a Medicare benefit** – item/service falls within a Medicare Benefit category and is not statutorily excluded from coverage (e.g. cosmetic surgery, hearing aids); and
- **Has therapeutic intent** – i.e. not designed exclusively to test toxicity/pathology; and
- **Enrolls diagnosed beneficiaries** – enroll patients with diagnosed disease rather than only healthy volunteers (but may also enroll a healthy control group); and
- **Has desirable characteristics:**
  - Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA; or
  - Trials supported by centers or cooperative groups funded by same (above); or
  - Trials conducted under an IND reviewed by the FDA; or
  - IND exempt under 21 CFR 312.2(b)(1)
Why do we NEED to perform CA?!

Medicare

- September, 2000 – National Coverage Decision (NCD)
  - Provides coverage for Medicare beneficiaries participating in clinical trials for “usual” or “conventional care”
- 2005 – Rush Settles with Federal Government for $1 Million
- October, 2007 – Medicare Clinical Trials Policy (CTP)
  - NCD + clarifications
  - Provides expanded coverage for “qualified” clinical trials
  - Requires identification of all “billable” study procedures/services, regardless if “usual” or routine care.

UCOP

- 2010 UCOP Requires all UC medical centers to implement a system of Clinical Research Billing Compliance.
Recent False Claims Settlements:

- Yale University $7.6M
- Mayo Clinic $6.5M
- Medical College of Georgia $6.1M
- Northwestern University $5.5M
- UCSD $4.7M
- Cornell University $4.3M
- Johns Hopkins $2.6M
CA Rollout at UCLA

- Study Feasibility Performed
- Budget Development (all protocol required procedures identified)
- Identify any “Routine Care” (RC) procedures/services.
  - If no RC, Coverage Analysis is not required. All procedures/services must be provided by sponsor or another funding source.
  - If RC identified, is this a “qualifying” clinical trial?
    - If not “qualifying”, all procedures/services must be provided by sponsor or another funding source.
    - If a “qualifying” CT, determine which RC costs are eligible for reimbursement from insurer.
Coverage Analysis Decision Tree

Study Feasibility Performed

Budget Development (all procedures identified)

Identify any RC procedures/services

If no RC, CA not required. All costs paid for by Sponsor or other funding source

If RC identified, is this a “qualifying” CT? (CTCU checklist in development)

If it is a “qualifying” CT, determine which RC costs are billable to insurer
### Visit Schedule – Budget – CA

<table>
<thead>
<tr>
<th>Procedure/Service</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>EOT 360</th>
<th>Unscheduled Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen Collection and prep for Central lab shipment (to include Hematology Profile, Chemistry Profile, Coagulation Profile and fasting Lipid Profile)</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Comprehensive Physical Examination (includes vitals)</td>
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<tr>
<td>Limited (focused) Physical Examination (w/o vitals)</td>
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<td>12 lead ECG w/ interpretation</td>
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<td>Percutaneous Renal Biopsy (hospital, technical and professional fees Neph &amp; Path)</td>
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<td>Pneumococcal Vaccine</td>
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<td><strong>Local Labs:</strong></td>
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<td>Urinalysis - automated w/ microscopy</td>
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<tr>
<td>Pharmacy Dispensement Fee (oral study med)</td>
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## Visit Schedule – Budget – CA

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<tr>
<th>Procedure/Service</th>
<th>CPI/HCPCS</th>
<th>Unit Cost</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>EOT</th>
<th>Unscheduled Visit</th>
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<td>$11,585</td>
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</tbody>
</table>
CTCU

- Approves final CA and study budget.
- Maintains final CA and study budget with contract file.

Study Team (PI’s Responsibility)

- Must document the CA process.
- PI will certify CA and study budget.
- Supporting CA documentation must be maintained with study records.
  - Study Teams should be prepared for an internal compliance audit.
Additional Resources

- UCLA Clinical Trials Website:
  - [http://clinicaltrials.ucla.edu](http://clinicaltrials.ucla.edu)
    
    Username: Password:

- For Patient/Community
- For Faculty/Staff
- Contact us

Please note: Site access is limited to on-campus IT connections.
Participating in Clinical Trials

Latest News

- UCLA Stroke Researcher Honored by the American Heart Association
- Researchers uncover how new melanoma drug accelerates secondary skin...
- UCLA joins forces with White House to meet unique needs of veterans...
- Diet counts: Iron intake in teen years can impact brain in later life
- Young UCLA leukemia patient launches kid-friendly cookbook, hosts...

For Interested Research Participants
- Participating in Clinical Trials

Finding Clinical Trials at UCLA
- Cancer Trials at UCLA Jonsson Comprehensive Cancer Center
- Other Trials at UCLA

Create a free web page with ease to communicate with family and friends.
CTCU Distribution List

- CTCU Workshops
  - CT Budgets 101 – Intro to Industry CT Budget Development
  - CT Budgets 201 – Coverage Analysis
  - CT Budgets 301 – Advanced Budgeting (Investigator-Initiated)

- Email Updates, Upcoming Forums, etc.

- Contact: SEstrada@mednet.ucla.edu
Clinical Trials Contact Info

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Banastasi@mednet.ucla.edu
310-794-0545
Questions?