I. SCOPE

All clinical research protocols that include patient care costs as defined by NIH Policy and protocols in support of Coverage with Evidence Development (CED) National Coverage Determinations will undergo a coverage analysis (CA). The CA is completed in support of compliance with the Medicare National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1).

The purpose of this Standard Operating Procedure is to provide guidance on the CA development and approval process. LUMC Clinical Research (LUMC CR) is responsible for tracking the development and approval process in the CA Development Tracker.

II. PROCEDURES

A. Submission

1. LUMC CR receives notification via the Research Channel of a new protocol that intends to utilize LUMC resources.
2. LUMC CR assess if the protocol requires a CA.
   a. If the protocol does not require patient care services, LUMC CR indicates a CA is not needed in the Research Channel and notifies the Principal Investigator or his/her designee ("Study Team").
   b. If the protocol requires minimal patient care services, all of which will be billed to the research study, LUMC CR and Revenue Integrity may agree it does not require a CA. In this case, LUMC CR will instead create a Billing Guidance document that lists the services to be billed to the study (see Section H).
   c. If the protocol requires patient care services, and the patient care services will be billed to insurance or are of sufficient complexity, a CA is required.
3. To request a CA, LUMC CR emails the following documents to PFS-Clinical, a third party vendor:
   a. Protocol
   b. Draft Contract or Award
   c. Draft Budget or Funding Sheet
   d. Draft Informed Consent Document (if available)
   e. CMS Approval Letter (for IDE studies, if applicable)
   f. Medicare Administrative Contractor Approval Letters (for IDE studies, if applicable)
   g. National Coverage Analysis (if available)
4. LUMC CR notifies the Study Team a CA was requested.

B. Development

1. PFS-Clinical conducts an initial review to confirm a CA is needed. If a CA is not needed, PFS-Clinical informs LUMC CR.
2. PFS-Clinical creates the CA workbook.
   a. Study Info worksheet
      (1) Study Information
         (a) Study Title
         (b) Principal Investigator
         (c) LU #

(d) Sub Studies
(e) Study Protocol #
(f) Sponsor(s)
(g) IND #
(h) Clinicaltrials.gov (NCT) #
(i) Protocol Version Date
(j) Informed Consent Form (ICF) Version Date
(k) Name of the Investigational Item, Procedure, or Service
(l) Coverage Analysis Version Date
(m) Prepared By:

(2) Qualifying Trial Determination
   (a) Investigational drug trials: routine costs as defined in NCD 310.1 may be billed to patients or third party payers if the trial is determined to be a Qualifying Clinical Trial. To be qualifying, the study must meet the three required characteristics and be deemed.
   (b) Investigational device trials: routine costs as defined in NCD 310.1 may be billed to patients or third party payers if the investigational device trial is approved by CMS or the local Medicare Administrative Contractor.
   (c) CED trials or registries that investigate an item or service under a CED: routine costs as defined in NCD 310.1 may be billed to patients or third party payers if the trial or registry is approved by CMS.
   (d) Other studies: studies that do not investigate a drug, device, or item covered under a CED are not subject to NCD 310.1.

(3) Informed Consent Form (ICF): notes language in the ICF with billing implications, including items/services promised free and subject injury compensation
(4) Clinical Trial Agreement/Grant: notes language in the contract or grant with billing implications, including items/services promised free and subject injury compensation
(5) Notes for Institution (No Response Needed): notes potential discrepancies between protocol, contract, and ICF; items that PFS-Clinical had to interpret so should be clarified; if the Billing Grid was based off draft documents; and other comments that support successful interpretation of the CA
(6) Questions for Sponsor/CRO: lists PFS-Clinical's questions that require sponsor or CRO input

b. Billing Grid worksheet
   (1) The billing grid is based off the protocol, consent document, and budget or funding memorandum.
   (2) Each arm of the study will be on a separate tab.
   (3) The payer designations are based on:
      (a) PFS-Clinical's analysis if the item is justifiable as a routine cost or not.
      (b) If coverage of an item is limited by NCD or LCD, the payer will be set at Research, even if the item could be justified as medically necessary.
      (c) For non-qualifying trials, only items and services that are justifiable as routine for patients not participating in a clinical trial as billable to insurance. A patient neither loses benefits nor gains the additional coverage offered in NCD 310.1 when participating in a non-qualifying trial.
   (4) The research coding guidance follows the following parameters:

(a) Research coding is not needed after a patient completes the investigational intervention or treatment, and there are no further research-paid items or services.
(b) Item and services provided in the context of a non-qualifying trial are not coded as research-related.

3. PFS-Clinical emails the draft CA to LUMC CR.

C. Study Team review

1. LUMC CR sends the draft CA to the Study Team for review.
2. Study Team reviews the draft CA and emails requested revisions and additional information to LUMC CR, including:
   a. Missing information from the Study Info worksheet if now available
   b. The Deactivation Milestone (the study visit after which there are no research-paid patient care services or patient care services that require research coding)
   c. Changes to payer designations based on modifications to the budget or investigator justification
3. LUMC CR emails the Study Team's requested revisions to PFS-Clinical.
4. PFS-Clinical reviews the requested revisions.
   a. If revisions will impact the integrity of the CA or conflict with Medicare guidelines, PFS-Clinical will inform LUMC CR.
   b. If the revisions are acceptable, PFS-Clinical revises the CA and sends the updated version to LUMC CR.
5. LUMC CR emails the CA to the Study Team for final review.
6. The Study Team performs a final review and approval of the CA.

D. Revenue Integrity Review

1. LUMC CR forwards the CA to the Revenue Integrity billing specialist or designee for review and approval.
2. Revenue Integrity reviews the Billing Grid to:
   a. Ensure the billing acronym matches the comment for each item or service.
   b. Ensure the items and services marked as bundled are confirmed to be included as part of another item and/or service and ensure the acronyms for the bundled items and services match.
   c. Ensure routine costs incurred during an inpatient encounter are not noted as research-paid, and non-routine costs incurred during an inpatient encounter to be research-paid do not potentially affect the DRG for the encounter.
   d. Ensure clear and consistent directives in the comment sections.
3. If revisions are requested, Revenue Integrity emails the request to LUMC CR.
   a. LUMC CR emails requested revisions to PFS-Clinical.
   b. PFS-Clinical reviews the requested revisions.
      (1) If revisions will impact the integrity of the CA or conflict with Medicare guidelines, PFS-Clinical will inform LUMC CR.
      (2) If the revisions are acceptable, PFS-Clinical revises the CA and sends the updated version to LUMC CR.
   c. LUMC CR emails the CA to Revenue Integrity for final review.
4. Revenue Integrity informs LUMC CR when the CA is approved.

E. Escalation

1. If the Study Team, Revenue Integrity, LUMC CR, and/or PFS-Clinical do not agree on a coverage determination, LUMC CR forwards the current version of the CA and a summary of the discussion to the Director of Revenue Integrity and the Chief Integrity Officer. They provide a final determination to LUMC CR.
2. The LUMC CR reviews the Director of Revenue Integrity's and the Chief Integrity Officer's determination with the parties.
3. The LUMC CR informs PFS-Clinical of the final decision so the CA may be updated.

F. Final Synchronization and Upload

1. For studies with contracts, the final synchronization is performed when the contract language is finalized.
   a. LUMC Office of the General Counsel forwards the final version of the contract to LUMC CR.
   b. LUMC CR reviews the contract, budget, consent, and CA for alignment.
      (1) LUMC CR reviews the following sections of the consent form:
         (a) The Financial Information section to confirm no services noted as provided free of charge for participants are to be billed to the patient/insurance per the CA.
         (b) The Research Related Injury section to confirm the consent template language included aligns with the contract. Consent template language either states sponsor compensation for injury is not available or sponsor compensation for injury may be available.
      (2) LUMC CR reviews the following content of the contract:
         (a) The budget or payment section that details the institution's financial compensation for conducting the study to:
            i. Ensure no items or services to be paid by the study funds are designated as bill to patient/insurance in the CA.
            ii. Ensure participant co-pays or deductibles are not paid for by study funds.
            iii. Ensure that in the case of an insurance denial for a routine service, study funds are only available if the participant meets the hospital's Financial Assistance and Charity Care policy.
         (b) The section that states if sponsor compensation for injury is available, if such a section is included in the contract, to confirm it aligns with the language in the consent form.
   c. If the documents are not aligned, LUMC CR notifies the Study Team of the discrepancies. The Study Team informs LUMC CR which document(s) will be modified to resolve the discrepancy.
   d. LUMC CR facilitates modifications to the CA. The Study Team facilitates modifications to the contract, budget, or consent.
   e. LUMC CR reviews the updated and final versions of the contract, budget, consent, and CA for alignment.
   f. LUMC CR forwards the final approved version of the contract to the LUMC signatory for execution.
2. For studies that do not have contracts, the final synchronization is performed after Revenue Integrity approves the CA.

a. LUMC CR reviews the CA, the budget (if applicable), and the consent form for alignment.
   (1) LUMC CR reviews the following sections of the consent form:
      (a) The Financial Information section to confirm no services noted as provided free of charge for participants are to be billed to the patient/insurance per the CA.
      (b) The Research Related Injury section to confirm the consent template language included aligns with the budget. Consent template language either states sponsor compensation for injury is not available or sponsor compensation for injury may be available.
   (2) LUMC CR reviews the following content of the budget (if applicable):
      (a) The section that details the institution's financial compensation for conducting the study to ensure no items or services to be paid by the study funds are designated as bill to patient/insurance in the CA.
      (b) The section that states if sponsor compensation for injury is available, if such a section is included in the budget, to confirm it aligns with the language in the consent form.
b. If the documents are not aligned, LUMC CR notifies the Study Team of the discrepancies. The Study Team informs LUMC CR which document(s) will be modified to resolve the discrepancy.
c. LUMC CR facilitates modifications to the CA. The Study Team facilitates modifications to the budget or consent.
d. LUMC CR reviews the updated and final versions of the budget, consent, and CA for alignment.

3. LUMC CR confirms the Study Info worksheet is complete, including all applicable Study Information and a complete and accurate Qualifying Trial Determination.
4. LUMC CR confirms all noted discrepancies on the Study Info worksheet of the CA are resolved and deleted from the final CA, including notes in the ICF, CTA/Grant, and Notes for Institution sections.
5. LUMC CR updates the CA to reflect the final synchronization of documents.
   a. Updates the Informed Consent Form section by:
      (1) Adding "Synchronization based on consent version _____."
      (2) Copying and pasting the final financial section language from the ICF
      (3) Copying and pasting the final research related injury language from the ICF
   b. Updates the Clinical Trial Agreement/Grant section by:
      (1) Adding "Synchronization based on CTA version _____." This wording should be modified to accurately reflect incorporation of a CTA amendment, a Funding Sheet, or grant award.
      (2) Revising the language to reflect the wording of the finalized CTA.
6. LUMC CR uploads and approves the CA in the Research Channel.
7. LUMC CR forwards the final CA to the Study Team and to PFS-Clinical via email.
8. The PI receives an email that the CA has been approved by LUMC CR. The PI approves the CA in the Research Portal.

G. Amendments

1. The Study Team notifies LUMC CR if an amendment to the CA may be necessary due to a protocol amendment, a contract amendment, or other change to services in the study by emailing pertinent documentation to LUMC CR.

2. LUMC CR assesses if revisions to the CA are needed. LUMC CR makes minor revisions to the CA internally.
3. If the amendment requires significant changes, LUMC CR submits the amendment request to PFS-Clinical and includes supporting documents as applicable:
   a. Updated protocol with summary of changes
   b. Tracked version of the revised Consent Form
   c. Contract amendment template
4. PFS-Clinical determines if the CA should be revised (e.g. addition, alteration, or removal of items or services). If revision is not necessary, PFS-Clinical notifies LUMC CR.
5. If PFS-Clinical determines the CA should be revised, PFS-Clinical revises the CA and emails the updated version to LUMC CR.
6. If patients have been consented to the study, LUMC CR confirms the billing designations do not vary between versions of the CA before routing the CA for approvals.
7. Review and approval of the amendment proceeds as described in sections C, D, E, and F.
8. The date the amendment is approved by the IRB serves as the effective date for the revised CA. All charges incurred after that date are to be segregated according to the revised CA.
9. The Study Team provides a list of study visits that occurred from the time the amendment was approved by the IRB to the time the CA amendment was uploaded to the Research Channel.

H. Studies that do not require a CA

1. If a study does not require a CA but there are patient care services to be billed to the research study, LUMC CR drafts the Billing Guidance document.
2. The Billing Guidance document contains:
   a. LU
   b. Study Title
   c. List of items/services to be billed to the research study
   d. The visits and timelines for the items/services
3. LUMC CR forwards the document to Revenue Integrity for review.
4. Revenue Integrity revises as needed and returns to LUMC CR.
5. After Final Synchronization, LUMC CR uploads the Billing Guidance document to the Research Channel.
6. LUMC CR emails the Billing Guidance document to the Study Team.

III. REFERENCES

A. NIH Patient Care Costs policy
B. Centers for Medicare and Medicaid Services Website
C. National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)
D. National Government Services Clinical Trials – Medical Policy Article A52840
E. MLN Matters Number SE0822 Revised
F. MLN Matters Number SE1344
G. MLN Matters Number MM8401 Revised
H. LUMC Financial Assistance and Charity Care policy

IV. ASSOCIATED DOCUMENTS

A. Coverage Analysis Template
B. Coverage Analysis Development Tracker

V. APPROVALS

Chief Integrity Officer (or designee) — Date: 11/12/18

Director Revenue Integrity (or designee) — Date: 10/16/18

Revision History

Effective Date	Summary of Changes
1/April/2016	
20/Sep/2016	
1/Nov/2018	Clarified the definition and handling of non-qualifying trials; inserted Billing Guidance and amendment processes