I. SCOPE

This procedure covers the review and release of claims for items/services that are unrelated to study participation.

II. PROCEDURES

A. Document Review

1. HARs will be reviewed by the review staff if held in WQ 1325 to determine if the services on the HAR are related to study participation. The following sources may be reviewed:
   a. Protocol and/or Schedule of Events (SOE)
   b. EPIC Medical Record (EHR)
   c. Informed Consent Document (ICD)
   d. EPIC Account Maintenance Hospital Tx Inquiry. Proviso: To the extent that this step in the procedure becomes too time-consuming, this step will be re-evaluated.
   e. EPIC Account Maintenance Diagnostic and Procedural Codes – This data is used. Rationale is noted below.

B. Rationale

1. The rationale for reviewing each of the sources noted above follows:
   a. The SOE provides a listing of the planned clinical research study events.
   b. EPIC medical record documentation is reviewed to determine the patient's current status in the study, and if the documentation references or contains language the items/services are related to the study.
   c. The ICD is reviewed for language that services will be provided at no cost to the patient and provides an overview of the study.
   d. The Hospital Tx Inquiry lists all billed items and services and may provide charge specific detailed information. (The diagnostic and procedural codes are used to determine why some items/services are performed. When laboratory/xray tests are ordered, the medical indication is translated into codes that are being utilized to compare to the study topic to see if the reason for performing the test is related to the study topic.)

C. Process

1. The review staff will determine if items/services are not related to a study based on a review of the above-captioned documentation. If the items/services are referenced in the EHR as related or there is any indication that a particular item/service may be paid by the sponsor, a more detailed review will be performed. (Note: Sometimes, the item/service is included on the SOE but may be appropriately ordered for a non-study related condition that is being treated and should not hold up the claim, e.g., CBC.)
2. If the item/service is included on the SOE, the review staff will review information in the Epic Oncology Navigator to determine whether the item/service is relevant to a particular study visit as identified in the Navigator or review the EHR documentation on the specific encounter date to determine whether the Ordering physician is the study physician or whether the order was entered by the RNC. Note: If the patient is enrolled in an oncology trial that has an associated BEACON treatment plan, then the reviewer can refer to the treatment plan flowsheet in the Epic Onc Navigator to correlate items and services to the SOE. If the patient is enrolled in a non-oncology trial and there is an associated Therapy Plan, then the reviewer can refer to the Therapy Plan to correlate items and services to the SOE.
3. If it is determined that the items/services on the HAR are related to the study after a review of the EHR documentation or the Epic Oncology Navigator, the HAR will not be released and the RNC will be further consulted.
4. If it is determined the items/services on the HAR are not related to the study after a review of the Epic Oncology Navigator, the HAR will be released for billing.
5. HAR account notes will be entered by the LUMC review staff explaining the rationale for releasing the claim.

6. The LUMC review staff or designee will track HARs including:
   a. HARs held in WQ 1325
   b. Date claim is released

III. REFERENCES

A. Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims Prepared by: Pat Brocato-Simons and Rosemarie Hakim, PhD (CMS Senior Research Technical Advisor), 10/31/14.

IV. ASSOCIATED DOCUMENTS

A. None

V. APPROVALS

Tina DeMarco, Interim 5/19/16

Vice President for Business Services (or designee) Date