The Clinical Research Calendar Review and Analysis Office (CRAO) will always need to know certain pieces of information in order to conduct the billing calendar review. Our goal is to help study teams identify these items during the creation of the billing calendar by providing a template of these questions with explanation. This should reduce the amount of questions that CRAO asks of the study teams during the review process and will lessen the back and forth communication.

The items listed below are typically things that cannot be found in the core study documents that CRAO reviews. We rely on the study team for their help and expertise in these areas.

1. **Best Estimate for Number of Follow-Up Office Visits**

   **Reason:** Medicare requires a Q0 or Q1 modifier to be placed on items/services provided in Medicare qualified clinical trials/studies.

   The CRAO does the qualifying analysis; however, in MBECT always choose “yes” when asked if your trial is deemed and qualified unless you know otherwise. Your analyst will still complete the Medicare Coverage Analysis (MCA) and inform you if you have chosen incorrectly.

   a. The protocol is not always explicit in stating the number of follow-up visits needed in a clinical trial. This may be because the visit schedule is dependent upon the disease progression. The PI and study team are in the best position to know the disease process, and the likely number of follow-up visits. It is understood that this is an estimate, and could vary between subjects based on disease progression. Please use the greater number when estimating.

   **Example:** If the PI feels that most subjects will return for 2 visits, but there is a reasonable chance some could come in for 3 visits, you would want to use “3” on the billing calendar.

   b. The frequency of follow-up testing (ex. MRI, blood tests, etc.) is also needed on the calendar. Again, this may be based on disease progression, so please use the greater number when estimating.

   c. If items are only listed once on the billing calendar, they will only receive the appropriate billing modifier one time. If the item/service will occur more than once then that number needs to be noted on the billing calendar (see
above example), so that the appropriate billing modifier can be added each time the item/service occurs.

2. Frequencies on the Billing Calendar

   a. Frequency at other time points is also needed, not just at follow-up visits or testing. This can be the number of cycles for a therapy, or how many times a test is happening in one day.

**Example 1:** A study drug is given for 3 cycles, each cycle is 28 days. The drug is given on Day 1 and Day 15 of each cycle. If the 3 cycles are different, meaning there are different items and services happening in each cycle, then all 3 cycles should appear on the calendar. If the 3 cycles are identical, they can be combined, with a column heading saying “Cycles 1-3”. All of the items and services will then be multiplied out and noted on the calendar. The drug, for example, would appear as Sx3 on Day 1 and Sx3 on Day 15.

**Example 2:** A blood test needs to be drawn prior to drug administration, immediately following administration, and 15 minutes post administration. The drug is given once a day. The billing calendar should reflect 3 blood tests that day (Sx3). If the drug is administered twice a day, with 3 blood tests at each administration, then the billing calendar should reflect 6 blood tests that day (Sx6).

[“* using “S” for Study paid, as an example only. If the item is Routine Care, then you would use “RC”]

3. Research Space Used

   a. If a procedure or physical exam is taking place in research space, please note this on the billing calendar in the Comments column. This information will affect how the item/service is coded (CPT/CDM).

**Example 1:** Procedures or physical exams taking place in MCRU space and performed by research staff.

**Example 2:** Procedures or physical exams taking place in dedicated research space. Dedicated research space is space that is not being used for clinical purposes, and not using clinic resources or staff. It may also be space used after clinic hours.
4. Labs: Where are they Drawn, Who Draws Them, and Where are they Analyzed?

a. The location of the blood draw (venipuncture), as well as the type of personnel drawing the sample (clinic personnel vs. research staff) can make a difference in how that laboratory is coded (CPT/CDM) for billing purposes. This information is often not found in the study documents; therefore, the CRAO relies on the study team to provide this information.

Example 1: If a blood test is being drawn by research personnel, and analyzed in a private PI lab, or sent off-site for analysis, choose “Lab-Send Outs” then the CPT/CDM columns will receive an “NB” and in the Comments column you need to provide how many labs are being sent out. Please make sure that “NB” coded items have an explanation. If an item/service receives an “NB” in the CPT/CDM coding columns of the calendar, it means those charges are not being routed through the UMHS billing system.

Example 1a: A blood draw is occurring in a non-billable manner, as noted above, the coding columns have an “NB” added, so the Comments column may read, “Drawn by study personnel, 7 labs sent to outside lab for analysis”, or “7 labs analyzed in PI lab”.

Example 2: If a blood test is being drawn in MCRU or by MCRU personnel (mobile unit) and the test is being analyzed off-site, choose “Lab-Send-Outs” and mark as “NB” because billing codes are not needed. If the test is being analyzed in UofM Pathology, list the name of the lab so that CDM codes will be on the calendar. This allows the billable portion of these charges to be routed through the UMHS billing system. The Comments column should provide explanation.

Example 3: If a blood test is being drawn in a blood draw station and sent through UofM Pathology for analysis, CDM codes will be applied. No explanation needed.

Example 4: Subject is having X, Y and Z Routine Care labs drawn at the blood draw station. The study coordinator has provided 2 extra tubes for the phlebotomist to draw off the vacutainer, during the same “poke”. The 2 extra research tubes are being sent off-site for analysis or being analyzed in the PI’s private lab. The billing calendar should reflect a “HC-CR-Specimen Collect ” line, and designate to study (“S”). Even though it was the same “poke”, there is still a fee associated with the processing or handling of the additional tubes.
Example 4a: Same scenario as above, but this time the research tubes are being sent to UoFM Pathology for analysis. An additional venipuncture line is not needed on the calendar in this case. List the name of the laboratory test being drawn/analyzed as you normally would. The research related labs will receive CDM codes, and charges will be routed according to the billing calendar designation (in this case to the study account).

Example 5: SEND OUT LABS: If all the labs are being drawn by MCRU or a member of the study team and sent out for analysis, it is not necessary to list out the individual names of the laboratories to be analyzed (CBCPD, Comp Panel, PK, LFT, etc.). You can make one entry on the calendar, for example, “Lab-Send-Outs”, rather than listing them individually. Choose “Mark all as non-billable” and a “NB” will appear in the CPT/CDM columns on the billing calendar. If the labs are being drawn at a blood draw station at UMHS, you will still need to add a venipuncture line to the calendar, HC-CR Specimen Collect. Also, list the number of labs that will be sent out. It is not necessary to note frequency of the labs in the comment section.

5. Imaging Studies

a. When listing imaging studies, X-ray, CT, MRI, PET, etc., please be sure and specify what part of the body is being scanned and the number of views when applicable. This is especially important if the protocol is not specific.

b. If the part of the body is to-be-determined based on the disease progression, please note that in the Comments column.

c. If the entire body is being scanned for metastases, please note that in the Comments column. Ex: Unknown areas to be scanned. Entire body to be scanned. (Specific area) to be scanned.

d. It is necessary to list the type of contrast and the amount given, as this is a billable item/service. If you do not know the type or amount of contrast, then you may select the appropriate bundle. Common bundles have been created to assist users in choosing the full list of items and services associated with a particular exam or procedure. If you have questions regarding codes, please contact Bect-Coders@umich.edu.

Example: CT Chest with and without Contrast. This bundle includes the following items: CT Chest with and without contrast, technical fee, CT Chest with and without contrast, professional fee and the contrast agent most commonly used for this procedure based on average volume of contrast.
If you prefer not to select a bundled item select the most common contrast used for the service and MBECT will pull over all CDMs associated within that grouping.

6. Physical Location of Surgical or Invasive Procedures

   a. MBECT will pull over all CDM’s, for all possible locations of a specific test or procedure, onto the detailed billing calendar. It is not necessary to know exactly where a procedure will take place.

7. Medications

   a. If the drug is being provided by the sponsor free of charge choose “Study Drug”, and note that in the Comments column. Choose non-billable so that “NB” appears in the CPT/CDM columns.

   b. Please be sure and note the route of administration (ROA) of the drug: Intravenous (IV), Intramuscular (IM), or Subcutaneous (SubQ), etc. on a separate line. If it is an oral drug, a separate administration line is not needed. If the item description does not reflect the drug form (i.e. topical, p.o., oral, etc.), then please note in the comments the study drug is oral (p.o) or topical, etc.

   c. If the drug is provided by prescription to the subject (to be filled at their local pharmacy), please note that in the Comments column, and “NB” will remain in the CPT/CDM columns.

8. Investigational Device Exemptions (IDE) and Investigational New Drugs (IND)

   a. If your study is using an IDE or a NSR (non-significant risk) device, and any portion of the study is being billed to Routine Care, you will want to write to our local Medicare Part A & Part B Contractors for approval of payment of those routine items. Please contact CRAO for further assistance.

   b. If your study is using an IND, the CRAO requires documentation of the FDA approval. If it is an industry sponsored study, and the IND # appears on the protocol, we will accept that as documentation. Otherwise, the preference is to have a copy of the FDA approval letter.

   c. The device will require a unique CDM be established by the CDM & Rate Setting team that has the IDE approval # within the CDM Description. This allows the device to be billed to health plans. (For Category B devices) you will choose “Study Device (Investigational)” in MBECT.
9. The Billing Key

a. Use the billing key that is provided on the template billing calendar to identify the appropriate designation for the service provided. A designation must appear for every item or service, in the corresponding time point.

b. If there is an item or service that could be considered Routine Care for some patients, but Research for others, populate the calendar with the designation (RC or S). Select the designation which identifies the highest percentage of subjects receiving the service as Routine Care or Study. Please make a comment on the billing calendar as follows: Approximately 80% of subjects will receive I/S as routine care.

Example 1: A large portion of the population you expect to enroll in the study (say 90%) would receive a CT scan at the second office visit, based on the disease and would be considered routine care whether or not they were in the study. But about 10% of the people with this disease would not receive a CT scan at the second office visit because it is not clinically indicated for whatever reason. For the purposes of the study though, a CT scan needs to be conducted and accounted for on the billing calendar. Therefore, for that subject, the cost of the CT scan should be paid for with study funds, and not billed to insurance or the subject. Since the CT scan will be considered Routine Care the majority of the time, the calendar designation should be RC. When the CT scan is not considered Routine Care, and the study account needs to be charged, it is the study team’s responsibility to contact the CRAO Coding & Audit Analysts at CRBlIssues-help@umich.edu as soon as possible so, they can facilitate the correct charge routing to the study account, or a charge reversal to the study account as necessary. Remember, it is the study team’s responsibility to make sure the charges are reconciled appropriately.

Example 2: Similar to the above example, but say about 50% of the subjects will receive a CT scan as Routine Care, and 50% will receive the CT scan as part of the study. The best practice is to designate this procedure as “S” for study paid, and contact the CRAO Coding & Audit Analysts at CRBlIssues-help@umich.edu as soon as possible so, they can facilitate the correct routing of the charges or facilitate any charge reversals to Routine Care, as needed. *In these cases, please be sure to make a note in the Comments section, indicating that the designation (RC or S) may be different for some subjects.

10. Correct Number of Study Arms
a. If a study has multiple arms, please make sure to address that in the calendar. Separate worksheets are not a requirement for multiple arms of a study. If you choose to have different arms in MBECT, you can link the trials by selecting which trial you want to link to your protocol. You can search for a particular protocol by typing in the list or by scrolling through the list. The list may be sorted by the list headers.

11. Inpatient Stays

a. If any portion of the clinical trial will require an inpatient stay/admission, please inform the CRAO by noting it on the billing calendar in the comments section.

b. If there is a planned admission, please follow the below instructions on the billing calendar:
   • For inpatient stays, every item/service to be paid for with research or sponsor funds must be listed on the billing calendar with adequate detail so that billing codes can be assigned. Items/services to be provided within the context of the research that are considered routine costs and will be billed to the subject and/or insurance should be listed in general terms. However, it is not necessary to list every billable item/service considered routine care during the inpatient stay.

Example: Just list the name of the procedure for a surgery, i.e. appendectomy. You do not need to identify all of the medications and supplies to be used during the surgery. When you are planning an inpatient admission you should contact the Manager in UMH Business Services.

Please contact the CRAO with any questions, CR2-AO@umich.edu or 998-6880.

Abbreviations and Definitions

• CRAO-Calendar Review and Analysis Office

• CDM-Charge description master
  o Inventory list of all items and services for which the hospital may bill patients or insurance companies.
UNIVERSITY OF MICHIGAN CLINICAL RESEARCH

CALENDAR REVIEW ANALYSIS OFFICE

Standard Questions for Billing Calendar Review

- CPT-Current procedure terminology
  - Five digit codes that informs the payer of the service being provided to the patient.
- CT-Computerized Tomography
- I/S-Items and services
- BC-Billing calendar
- FDA- Food and Drug Administration
- Revenue Cycle Research Billing Coordinators (RCRBC)
- IND-Investigational New Drug
- IDE-Investigational Device Exemption
- NSR- Non significant risk
- MCRU- Michigan Clinical Research Unit
- MCA-Medicare Coverage Analysis
- NB-non billable
- RC-Routine care
- SOC-Standard of Care
- SNB-study item non billable
- S-Study
- ST-Study Team