USE OF THE Q0 AND Q1 MODIFIERS

Background:

The Centers for Medicare & Medicaid Services (CMS) has discontinued the QA (FDA Investigational Device Exemption), QR (Item or Service Provided in a Medicare Specified Study), and QV (Item or Service Provided as Routine Care in a Medicare Qualifying Clinical Trial) HCPCS modifiers as of December 31, 2007. Effective for dates of service on and after January 1, 2008, CMS has created the following two new modifiers that will be used solely to differentiate between routine and investigational clinical services:

- **Q0** - Investigational clinical service provided in a clinical research study that is in an approved clinical research study.
- **Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study.

How to Use the Modifiers:

Use the Q0 and Q1 modifiers on outpatient provider claims for items/services provided in Medicare qualified clinical trials/studies. These include trials that fall under the 2007 Medicare Clinical Trial Policy, trials that are required by a specific National Coverage Determination (NCD), and IDE trials.

- Use **Q0** to designate the item under investigation in the trial/study
- Use **Q1** to identify routine services provided in the trial/study

When to Submit Claims for Clinical Trial Items/Services

Services/items provided as part of a Medicare qualified clinical trial (see Medicare Pub.100-3 Section 310.1)	Submit
Services/items provided as part of a investigator initiated trial (see Medicare Pub.100-3 Section 310.1)	Submit
IDE trials	Submit
Services/items provided in a clinical study required by an NCD	Submit
Sponsor is paying	Do not submit

Where to Submit Claims for Clinical Trial Services for Medicare Beneficiaries Enrolled in Medicare Advantage (MA) Plans

Type of Clinical Trial	Where to Submit Claim
IDE (Category A and Category B)	MA Plan
Clinical Trials that Qualify for Coverage Under a Specific NCD	Follow the instructions for coding and submitting claims in the Change Request associated with the NCD
Clinical Trials that Qualify for Coverage under the Clinical Trial Policy	Fee for Service Contractor

When to Use the "Q" Modifiers

Type of Claim	Q1 or Q0 Needed?
Inpatient	No (Use V70.7 and Condition Code 30 only)
Outpatient	Yes
On the line item for a item/service that was provided as part of a clinical trial, but is included on a claim with other non-study related care	Yes
On the line item for items/services that are not related to the clinical study, but are part of a claim that does include items/services that are part of a research study	No

No Cost Items/Services

Claim Processing System	Coding Instructions
Institutional Billing	**Do not bill no cost item/services**. However, for certain devices on Outpatient Prospective Payment System (OPPS) claims in which the no cost item must be reported to suppress system edits, providers must report a token charge in the "Covered" charge field on the no cost line, along with applicable HCPCS modifiers (e.g., -FB or –FC) on the associated procedural line. For claims where the administration (of the drug) is covered as part of the routine care in a clinical trial and the drug is covered by the sponsor, in order to bypass FISS edits providers must show the drug on the claim. The drug should be placed in NON_COVERED

	(making sure the beneficiary is not liable for the non-covered charges). (See Medicare Pub 100-4 Chapter 32 Section 67.)
Practitioner Billing	Do not submit on a claim (see Medicare Pub 100-4 Chapter 32 Section 67).

Outpatient Examples

1. The patient is in an arthritis research study where the sponsor pays for a CBC and Metabolic Panel every month.

2/1/08 visit

CBC	10.00	85025	***do not place on a claim***
Metabolic panel	15.00	80053	***do not place on a claim***
Dilantin Level	17.00	80186	***Q1***
Elbow X-ray	30.00	73070	***Q1***
Ankle X-ray	25.00	73600	***Q1***
Level 3 Est. Pt Visit	50.00	99213	***Q1***

The claim should be coded with V70.7 and condition code 30.

2. The patient comes in for a screening mammogram that is totally unrelated to the research study in which that patient is enrolled.

If the claim includes other charges that are part of the research study, use V70.7 and condition code 30, but do not include a modifier on the line for the mammogram. The appropriate "Q" modifier should be appended to the charges related to the research study.

If the claim is for the mammogram only, do not use V70.7, condition code 30, or a "Q" modifier.

3. Patient B is in a cancer research study. The drug is being paid for by the sponsor and all other charges are standard of care.

2/28/08 visit

IV Fluids	250	11.00	XXXXX ***Q1***
CBC		15.00	85025 ***Q1***
Level 4 Visit		100.00	99214 ***Q1***

As shown above, you should not report the drug since it is paid for by the sponsor. When reporting the IV fluids, you must report a HCPCS along with the Q1 to identify the line as a routine item/service. If it is necessary to report the drug (paid for by the sponsor) in order to suppress system edits that require the reporting of both the drug

and its administration, then the drug should be reported with a non-covered token charge along with any appropriate non-covered modifiers.

4. **4.** The patient is admitted for a bedded outpatient procedure that is part of a category B device trial. A portion of the services are "investigational" (i.e. device), while others are routine care as part of the procedure related to the device implant. There are also a couple of specific "research only" services (i.e. EKG, chest x-ray) that are to be paid by the sponsor.

You should code the device (item under investigation) with the Q0 modifier. Code services that are routine care associated with implanting the device with Q1. Do not include on the claim any services for which the sponsor is paying unless required by a systems edit. Please refer to Pub. 100.04 Chapter 32 Section 67, 68 and 69.

Inpatient Example

1. The patient is in the hospital for a clinically indicated reason and decides to enroll in a clinical trial (qualifying) which requires some additional ancillary services for research only (not used for clinical management of the patient) which are to be paid by the sponsor.

- Should charges for those services be removed from the claim and billed to the sponsor, while also submitting a claim to Medicare for only those charges that are routine care?

Charges for services paid for by the sponsor should not be placed on the claim.

GENERAL CLINICAL TRIAL/STUDY QUESTIONS

1. How is it determined if a Medicare beneficiary is participating in the clinical trial/study as a control (i.e., blinded).

There is no need for billing reasons to identify if the beneficiary is a part of the control group. All clinical trial claims (including those for the control arm), must include all appropriate clinical trial coding.

2. Is there a plan to eventually change the voluntary status to mandatory status for the placement of the unique 8 digit identifier assigned when a trial/study is registered at ClinicalTrials.gov on a claims form?

Changing the voluntary option to report the 8 digit registry to mandatory is not under consideration at the current time, unless it is required as a condition of coverage in a national coverage determination.