

## Coding Guidelines

### LCD Title

Proton Beam Therapy

### Contractor's Determination Number

RAD-040

### CMS National Coverage Policy

National Coverage Determination (NCD) for Routine Costs in Clinical Trials (310.1)

CMS Manual System, Pub 100-20 One-Time Notification, Transmittal 310, Date: JANUARY 18, 2008, Change Request 5790

CMS Manual System, Pub 100-04 Medicare Claims Processing, Transmittal 1418 ,Date: JANUARY 18, 2008, Change Request 5805

### Coding

1. The proton delivery codes are technical component only codes and can only be billed by the facility delivering the treatment.
2. Selection of the correct code is based on the complexity and compensation of the treatment.
  - Simple** - Proton treatment delivery to a single treatment area utilizing a single non-tangential/oblique port, custom block with compensation (CPT 77522) and without compensation (CPT 77520).
  - Intermediate** - Proton treatment delivery to one or more treatment areas utilizing two or more ports or one or more tangential/oblique ports with custom blocks and compensators. (CPT 77523)
  - Complex** - Proton treatment delivery to one or more treatment areas utilizing two or more ports per treatment area with matching or patching fields and/or multiple isocenters, with custom blocks and compensators. (CPT 77524)
3. The physician work is billed under treatment planning and treatment management codes.

#### 4. **69.6 - Billing Requirements for Clinical Trials**

*(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)*

##### Routine Costs Submitted by Practitioners/Suppliers:

Services furnished to Medicare beneficiaries, who are control group volunteers participating in qualifying clinical trials, are to be coded/billed in the following manner:

*Claims with dates of service on or after January 1, 2008:*

- HCPCS modifier 'Q1'
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

*Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8 digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to change request 5790 for more information regarding the 8 digit number. Below are the claim locators that providers should use to bill the 8 digit number:*

- CMS-1500 paper form-place in Field 19 (preceded by 'CT')

- 837 P—Loop 2300, REF02, REF01-P4 (do not use “CT” on the electronic claim).

Routine Costs Submitted by Institutional Providers:

Services furnished to Medicare beneficiaries, who are control group volunteers participating in qualifying diagnostic clinical trials, are to be coded/billed on the in the following manner:

*Claims with dates of service on or after January 1, 2008:*

- Condition code 30 (qualifying clinical trial) is reported at the claim level
- HCPCS modifier ‘Q1’ (only for *institutional* outpatient claims)
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis

*Effective for clinical trial claims received after April 1, 2008, (regardless of date of service) providers can begin to report an 8 digit clinical trial number. The reporting of this number is voluntary at this time. Refer to change request 5790 for more information regarding the 8 digit number. To bill the 8 digit clinical trial number, institutional providers shall code value code ‘D4’---where the value code amount equals the 9 digit clinical trial number. Below are the claim locators in which to bill the 8 digit number:*

- CMS-1450—Form Locator 39-41
- 837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)

**NOTE:** The QV/QI modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary’s participation in a Medicare covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV/QI modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV/QI modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/QI modifier will serve as the provider’s attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

**Practitioner billing for Group 2 services in this policy**

When the procedure is being performed under the auspices of a clinical trial append the Q0 or Q1 modifier to the treatment delivery code along with a diagnosis V70.7 as the primary and a diagnosis from Group 2 as the secondary diagnosis.

**Institutional Provider billing for Group 2 services in this policy.**

Diagnosis code V70.7 is the secondary diagnosis and a diagnosis from Group 2 as the primary diagnosis.

Definitions:

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

Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.

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

Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).

5. If the patient cannot clearly meet the criteria for coverage but desires Proton beam radiotherapy based on a marketed theoretical advantage, the claim should be billed with the GZ modifier appended to the treatment delivery code. The patient is then liable for payment of the procedure.

GZ – Item or service statutorily expected to be denied as not reasonable and necessary.