BlueCross BlueShield of Western New York

STAT Bulletin

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To: All PCPs and Specialists, Hospitals, MRI and Radiology Facilities

Contracts Affected: All Lines of Business

Clinical Trials

Effective October 1, 2008, **routine services** for (or associated with) qualifying clinical trials are eligible for coverage. The standard edits will apply including, but not limited to: prior approval, unbundling, investigational and contract in effect at the time of service. The item, device, drug or service that is the focus of the trial is **not** covered and will be rejected as investigational if billed to BlueCross BlueShield of Western New York.

All Medicare Advantage (Senior Blue/Medicare PPO /Medicare PFFS) claims related to clinical trials should be submitted to original Medicare. Only secondary balances should be submitted to BlueCross BlueShield, as these claims will not automatically cross over from Medicare.

Billing for Patients Participating in Clinical Trials

ICD-9 Diagnosis
List diagnosis code V70.7 (examination of participant in a clinical trial) on each service related to the clinical trial to indicate the member is participating in a clinical trial.

You must include all appropriate clinical trial codes and modifiers.

HCPCS

S9988 services provided as part of a phase I clinical trial

S9990 services provided as part of a phase II clinical trial

S9991 services provided as part of a phase III clinical trial

One of the above HCPCS codes **must** be included as a one-line entry on each claim with $0.00 indicated for the charge. These codes are informational and not separately reimbursed.

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Modifiers

One of the following modifiers needs to be indicated on **each** clinical trial service:

Q0 - Investigational clinical service provided in an approved clinical research study.

The Q0 modifier is used for the item, device, drug or service that is under investigation in the clinical trial or for services unique to the trial requirements, such as data collection.

Q1 - Routine clinical service provided in an approved clinical research study.

Routine services related to *qualifying* clinical trials submitted with a modifier have potential for coverage. However, if the modifier indicating the routine service is a part of a *qualifying* trial (Q1) is not documented, the service will be considered **investigational** as part of a non-qualifying trial, and therefore not eligible for payment.

Use of these modifiers attests to the services being performed in *qualifying* clinical trials.

Condition code 30 - Available for inpatient claims to indicate the admission includes qualifying trial services.

It is expected that we will not be billed for any services related to non-qualifying trials or for anything provided free of charge by trial sponsors.