



## Clinical Trials Billing Requirements Coming Soon

Effective May 1, we will implement the billing guidelines below for items and services furnished to members enrolled in approved clinical trials. For HAP Commercial plans, routine patient care costs are covered as required under the Affordable Care Act (ACA). For HAP Medicare Advantage (MA) plans, coverage of routine costs follows Medicare rules. In qualifying clinical trials, Original Medicare (FFS) processes trial-related services, and the MA plan coordinates secondary cost-sharing.

### Institutional (UB-04 / 837I) Claims

For hospital **inpatient and outpatient** clinical-trial claims, include the following required elements:

#### Institutional claim-level identifiers

- **Condition Code 30** – Qualified Clinical Trial (required on all institutional clinical-trial claims).
- **ICD-10-CM Z00.6** – reported as a **secondary diagnosis** on inpatient and outpatient clinical-trial claims.
- **National Clinical Trial (NCT) number** –
  - 837I: **Loop 2300 REF (P4)**
  - UB-04: **Remarks (FL 80)**  
(Required on all Medicare clinical-trial claims.)

#### Outpatient line-level identifiers (when applicable)

- **Modifier Q1** on routine clinical-trial service lines.
- **Modifier Q0 + IDE number** for **Category B IDE** investigational device/services.
  - IDE number is reported in REF (often qualifier **LX**).
  - When the **device itself** is billed, use **Revenue Code 0624** for the device line. (Do not bill a device supplied free by the sponsor.)

### Professional (CMS-1500 / 837P) Claims

For professional services furnished as part of a clinical trial:

- When billing **Q0 or Q1** on any service line, the claim must also include:
  - **ICD-10-CM Z00.6**, and
  - **The NCT number** (837P Loop 2300 REF (P4) or CMS-1500 Box 19).  
(Professional claims do **not** use condition codes.)
- **Do not report Q0 and Q1 on the same service line** (modifiers are mutually exclusive).
- For **Category B IDE** services billed with **Q0**, include the **IDE number** in claim notes/REF or Box 19.

### Investigational Device Exemption (IDE) Billing

For **Category B IDE** studies approved by CMS:

- The investigational device **may be covered** when billed according to Medicare rules:
  - Report **Q0**, the **IDE number**, and when the **device itself** is billed on an **outpatient institutional claim**, use **Revenue Code 0624**
- **Do not bill** the device when it is supplied **free of charge** by the study sponsor; only associated routine services may be billed.
- **Category A IDE** devices are **experimental and not covered**; only routine services may be billed.