Anthem Blue Cross and Blue Shield

Anthem follows CMS Guidelines for Clinical Trial-Related Claims

While most clinical trial related claims are paid by original Medicare, Medicare Advantage plans are responsible to pay for certain items and services associated with clinical trials designated by the Centers for Medicare & Medicaid Services. Per CMS guidelines, Anthem Blue Cross and Blue Shield Medicare Advantage and Medicare Medicaid Plans pay Clinical Trial related claims classified as Coverage with Evidence Development (CED) / Investigational Device Exemption (IDE) Studies for Cat B / Data Collections:

1. **Coverage with Evidence Development** - In National Coverage Determinations (NCDs) requiring Coverage with Evidence Development (CED), original Medicare covers items and services in CMS-approved CED studies. Medicare Advantage Organizations are responsible for payment of items and services in CMS-approved CED studies. At this time there are 22 CEDs that CMS requires MA plans to process.

2. **Investigational Device Exemption** - Medicare Advantage Organizations are responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE Investigational Device Exemption (IDE) Studies, however the MAO is only responsible for payment of the CMS approved Category B devices. Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category A IDE device billing to original Medicare since the Category A IDE device itself is considered experimental and, therefore is not eligible for payment. At this time there are 127 Approved Category B IDEs that CMS requires MA plans to process.

3. **Data Collection System** - Patients Enrolled in a CMS Qualifying Data Collection System registry. Providers shall use modifier Q0 to identify patients whose data is submitted to a data collection system.
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