SECTION 5: BILLING AND REIMBURSEMENT GUIDELINES

of the Member Provider Policy & Procedure Manual

5.29 CLINICAL TRIALS

This is a subsection of Section 5: Billing and Reimbursement Guidelines of the *Member Provider Policy & Procedure Manual*. If Blue Cross and Blue Shield of Louisiana (Louisiana Blue) makes any procedural changes, in our ongoing efforts to improve our service to you, we will update the information in this subsection and notify our network providers. For complete *Member Provider Policy & Procedure Manual* information, please refer to the other sections of this manual. Contact information for all manual sections is available in the Manual Reference Section.

For member eligibility, benefits or claims status information, we encourage you to use iLinkBlue (www.lablue.com/ilinkblue), our online self-service provider tool. Additional provider resources are available on our Provider page at www.lablue.com/providers.

This manual is provided for informational purposes only and is an extension of your Member Provider Agreement. You should always directly verify member benefits prior to performing services. Every effort has been made to print accurate, current information. Errors or omissions, if any, are inadvertent. The Member Contract/Certificate contains information on benefits, limitations and exclusions, and managed care benefit requirements. It also may limit the number of days, visits or dollar amounts to be reimbursed.

As stated in your agreement: This manual is intended to set forth in detail our policies. Louisiana Blue retains the right to add to, delete from and otherwise modify the *Member Provider Policy & Procedure Manual* as needed. This manual and other information and materials provided are proprietary and confidential and may constitute trade secrets.

CLINICAL TRIALS

A clinical trial is a research study designed to evaluate the safety and health outcomes of new tests and treatments. Providers must ensure clinical trial claims are billed according to the following guidelines.

Submit clinical trial claims with:

- The eight-digit National Clinical Trial (NCT) number.
- ICD-10 diagnosis code Z00.6 in the primary or secondary position.
- Modifier Q0 or Q1 when appropriate:
  - Use Modifier Q0 for an investigational clinical service provided in a clinical research study that is in an approved clinical research study.
  - Use Modifier Q1 for a routine clinical service provided in a clinical research study that is in an approved clinical research study.
- Condition code 30 for inpatient claims regardless of whether all services are related to the clinical trial or not.

If clinical trial and non-clinical trial services are submitted on the same claim, then separate line items must be used for each type of service.

The medical record must include the trial name, sponsor and sponsor-assigned protocol number. This information must be provided if requested for review.