

Chapter 3. Experimental Procedures

§305. Routine Care for Recipients in Clinical Trials

A. This rule applies to any person or entity prescribing or reviewing a request for Louisiana Medicaid covered services and to all providers of these services who are enrolled in, or registered with, the Louisiana Medicaid program.

B. Definitions

Clinical Trials—biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions, including new treatments and known interventions that warrant further study and comparison.

C. Coverage. Louisiana Medicaid reimburses for services as a result of a beneficiary participating in a clinical trial in accordance with the service-specific coverage policy when the services:

1. would otherwise be provided to a beneficiary who is not participating in a clinical trial;
2. are not unique to the experimental or investigational treatment; and
3. are not covered by the clinical trial sponsor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health, Bureau of Health Services Financing, LR 46:796 (June 2020).