



To Whom It May Concern:

This patient is participating in a research study which has therapeutic intent.

Prior to a research study's initiation at Loyola University Medical Center, Loyola completes a qualifying trial determination. We assess if the research study has therapeutic intent. If the research study does not have therapeutic intent, research related patient care services are not billed to third party payers.

Loyola also completes a coverage analysis, or an assessment of the patient care services mentioned in the research study's protocol. The study agreement, informed consent document, and coverage guidelines including CMS National Coverage Determination 310.1 Routine Costs in Clinical Trials and National Government Services Local Coverage Article A52840 Clinical Trials – Medical Policy Article are used to determine compliant billing of patient care items and services.

This research study includes patient care services that are routine costs. This means they are the standard of care both at Loyola and as supported by Medicare coverage determinations or national guidelines for the patient's medical condition. Since these services would likely be performed for the patient even if the patient were not participating in the research study, these services will be billed to the patient's third party payer. As with any patient care service, these services will only be billed to the patient's third party payer if they are medically necessary.

This research study also includes patient care services that are deemed research in nature. This means they are performed for research purposes only, are experimental or investigational in nature, or are paid for by the research study. These services will not be billed to the patient's third party payer.