

Aetna Better Health[®] of Louisiana

Reimbursement Policy Statement Louisiana Medicaid

Original Issue Date Next Ani		al Review	Effective Date		
01-01-2018	06-26-2019		06-26-2018		
Policy Name			Policy Number		
La Policy Experimental and Investigational Services			ABHLA-RP-0043		
Policy Type					
Medical	Administrative	Pharmacy	Reimbursement		

Aetna Better Health of Louisiana implements comprehensive and robust policies to ensure alignment with Louisiana Department of Health (LDH) and to warrant that regulatory standards are met. The effective date of implementation for this reimbursement policy is contingent upon the Louisiana Department of Health's endorsement.

Aetna Better Health of Louisiana reimbursement policies are intended to provide a general reference for claims filing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims logic, benefits design and other factors not listed in this policy statement are considered in the development of reimbursement policies.

In addition to this Policy, reimbursement of rendered services are subject to member benefits, eligibility on the date of service, medical necessity, other plan policies and procedures, claim editing logic, provider contracts and all applicable authorization, notification and utilization management guidelines set forth by the Louisiana Department of Health (LDH) and the Centers for Medicare and Medicaid Services (CMS).

This policy does not ensure either an authorization or reimbursement of services. Please refer to the plan contract for the service(s) referenced therein. If there is a conflict between either this policy or the plan contract, then the plan contract will be the controlling document used to make an authorization or payment determination.

CONTENTS OF POLICY

Reimbursement Policy Statement Table of Contents		
B. Overview	3	
C. Definitions	3	
D. Reimbursement Guidelines	3	



Aetna Better Health® of Louisiana

E.	Codes/Conditions of Coverage	3
F.	Frequently Asked Questions	4
G.	Review/Revision History	4
Н.	Resources	4



Aetna Better Health[®] of Louisiana

A. Policy

Experimental and investigational procedures, items and medications are not covered. Investigational Device Exemption (IDE) studies are only covered when the Medicaid coverage requirements are met.

B. Overview

Experimental and investigational procedures are any medications, treatments or devices which are still part of an ongoing clinical trial.

C. Definitions

<u>Experimental or Investigational Procedures and Items</u>: Experimental procedures and items may include any procedure, study, test, drug, equipment or facility still undergoing study and which is generally not accepted as standard therapy in the medical community where alternative therapy exists. Any interpretations for specific cases must rely on and be consistent with Medicaid Rules, Statutes, Federal Regulations, Louisiana Department of Health Provider Manuals at the time the services are provided and that apply to the specific procedure and item requested.

D. Reimbursement Guidelines

Aetna covers experimental or investigational technologies (i.e., drugs, procedures and devices) when ALL of the following criteria are met.

- The member has a current diagnosis that will most likely cause death within one year or less despite therapy with currently accepted treatment; and
- Standard therapies have not been effective in significantly improving the condition of the member or would not be medically appropriate; and
- The proposed treatment is likely to be beneficial to the member based on at least two documents of medical and scientific evidence (as defined below); and
- The member must not be treated "off protocol" and actually be enrolled in the trail.

E. Codes/Condition of Coverage

The member is to be treated as part of a clinical trial satisfying ALL of the following criteria:

- The investigational drug, device, therapy or procedure is under current review by the FDA and has an Investigational New Drug (IND) number; and
- The clinical trial has passed independent scientific scrutiny and has also been approved by an Institutional Review Board (IRB) that will oversee the investigation; and
- The clinical trial is sponsored by the National Cancer Institute (NCI) or similar national cooperative body (e.g., Department of Defense, VA Affairs) and conforms to the rigorous independent oversight criteria as defined by the NCI for the performance of clinical trials; and



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The clinical trial is not a single institution or investigator study (NCI-designated ٠ Comprehensive Cancer Center trials are exempt from this requirement) Specific codes do not apply to this policy.

F. Frequently Asked Questions

Q: When Investigational (Experimental) Services are covered?

A: Investigational (Experimental) Services are not covered except as delineated in the Clinical Trial Services medical policy.

Q: What are the CPT codes that are denied under Experimental and Investigational services? *A*: G0176, S9451, T2036, T2037, 90880.

G. Review/Revision Date				
Action	Date	Comments		
Date Issued	01-01-2018			
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H. Resources

Louisiana Department of Health State Contract, regulations, Provider Manual, fee schedules and notices

http://www.lamedicaid.com/provweb1/Providermanuals/manuals/PS/PS.pdf

Individual state Medicaid regulations, manuals & fee schedules http://www.lamedicaid.com/provweb1/fee schedules/feeschedulesindex.htm

American Medical Association, Current Procedural Terminology (CPT®) Professional Edition and associated publications and services https://www.ama-assn.org/

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

https://www.cms.gov/