

## **51056.1 Experimental Services**

### **(a)**

Experimental services means those drugs, equipment, procedures or services that are in a testing phase undergoing laboratory and/or animal studies prior to testing in humans.

### **(b)**

Investigational services means those drugs, equipment, procedures or services for which laboratory and animal studies have been completed and for which human studies are in progress but: (1) Testing is not complete; and (2) The efficacy and safety of such services in human subjects are not yet established; and (3) The service is not in wide usage.

#### **(1)**

Testing is not complete; and

#### **(2)**

The efficacy and safety of such services in human subjects are not yet established; and

#### **(3)**

The service is not in wide usage.

### **(c)**

The determination that a service is experimental or investigational is based on:

(1) Reference to relevant federal regulations, such as those contained in Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration)

and Title 21, Code of Federal Regulations, Chapter I (Food and Drug Administration); (2) Consultation with provider organizations, academic and professional specialists pertinent to the specific service; (3) Reference to current medical literature.

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Reference to relevant federal regulations, such as those contained in Title 42, Code of Federal Regulations, Chapter IV (Health Care Financing Administration) and Title 21, Code of Federal Regulations, Chapter I (Food and Drug Administration);

**(2)**

Consultation with provider organizations, academic and professional specialists pertinent to the specific service;

**(3)**

Reference to current medical literature.