

Experimental/Investigational Treatments

Technology, treatments, procedures, drugs, biological products or medical devices that in Empire's judgment are:

- Experimental or investigative
- Obsolete or ineffective

Any hospitalization in connection with experimental or investigational treatments. "Experimental" or "investigative" means that for the particular diagnosis or treatment of the covered person's condition, the treatment is:

- Not of proven benefit
- Not generally recognized by the medical community (as reflected in published medical literature)

Government approval of a specific technology or treatment does not necessarily prove that it is appropriate or effective for a particular diagnosis or treatment of a covered person's condition. Empire may require that any or all of the following criteria be met to determine whether a technology, treatment, procedure, biological product, medical device or drug is experimental, investigative, obsolete or ineffective:

- (FDA) for the patient's particular diagnosis or condition, except for certain drugs prescribed for the treatment of cancer. Once the FDA approves use of a medical device, drug or biological product for a particular diagnosis or condition, use for another diagnosis or condition may require that additional criteria be met.
- Published peer review medical literature must conclude that the technology has a definite positive effect on health outcomes.
- Published evidence must show that over time the treatment improves health outcomes (i.e., the beneficial effects outweigh any harmful effects).
- Published proof must show that the treatment at the least improves health outcomes or that it can be used in appropriate medical situations where the established treatment cannot be used. Published proof must show that the treatment improves health outcomes in standard medical practice, not just in an experimental laboratory setting.

However, your plan will cover an experimental or investigational treatment approved by an External Appeal agent certified by the state. Refer to the Complaints, Appeals and Grievances Section.

In addition, your plan provides coverage to certain qualified individuals for approved clinical trials, and certain costs in connection with such clinical trials, as required by the Affordable Care Act. Please contact the Plan Administrator for more information regarding coverage of clinical trials.