POLICY 29
Experimental or Investigational Medical Services and Supplies

Medical services and supplies (i.e. drugs, devices, technologies, medical treatments or procedures) are considered experimental or investigational if:

1. The services or supplies cannot be marketed lawfully without approval of the U.S. Food and Drug Administration (FDA); and
2. The services or supplies in authoritative studies are the subject of ongoing phase I, II or III clinical trials; and
3. Reliable evidence shows that the consensus among qualified objective experts regarding the inherent nature of the services or supplies is that further basic science research, laboratory-based clinical studies, clinical outcomes research, or clinical trials are necessary to determine their safety, efficacy and anticipated outcomes as compared with the standard means of treatment or diagnosis of the condition in question.

Reliable evidence is defined as evidence including, but not limited to, published studies in objective authoritative medical and scientific peer reviewed literature of adequate well-controlled clinical trials with their written protocol(s) and informed consent(s) which were used by the treating facility or substantiated by another facility investigating the same service or supply.

Experimental and investigational services may be considered medically necessary when:

1. Sponsored in a National Cancer Institute (NCI) program, a National Institute of Health (NIH) program, an FDA-approved experimental or investigational program, a Centers for Disease Control and Prevention (CDC) program, or other similar type of authoritative clinical trial; or
2. Not fully approved by the FDA, i.e. investigational new drugs (INDs)—drugs that appear to be safe, may be effective and therefore are the most appropriate treatment for immediate life-threatening or serious disease or illness which has no satisfactory alternative treatment. The assessment of immediate life-threatening or serious disease/illness is based on professionally recognized standards of care; or
3. Approved by the FDA Commissioner (i.e. as in Emergency INDs).

Treatments outside an approved FDA-labeled indication (e.g. medication package inserts), which are based on the applicable standard of care incorporating the concept of risk/benefit analysis in medical decision-making, are not considered experimental or investigational.

Medically necessary or not medically necessary or investigational services or supplies can be contractually excluded or limited by either private or governmental third party payors. This exclusion or limitation must, however, be clearly and unambiguously stated in their health care plans.

Research of experimental and investigational treatments must always be reviewed by objective review boards of qualified experts. Patients’ informed consent must always be obtained, as well as their right to know all the ramifications of the study, various treatment options, and their right to refuse participation or withdraw from a study. Each health care organization should have a system for both monitoring the conduct of biomedical research and investigating and reporting allegations of research misconduct.

Results of all trials and post-marketing surveillance should be communicated as soon as possible to the practicing medical community and third party payors. The peer reviewed process of publication in recognized medical journals is the preferred means of evaluation and communication of research results. When evidence is shown that the consensus of objective qualified experts and reproducible scientific data obtained by well-recognized methodologies is that services or supplies are neither safe nor efficacious, then their use must be discontinued immediately.

References:
Sampson WI. AIDS fraud, finances, and fringes. New York State Journal of Medicine, 93(2):92-95.


Bucks BA, RT. *Ethical Issues of Randomized Clinical Trials*. American Society of Radiologic Technologists: 202-203.


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