THE OHIO STATE UNIVERSITY
HEALTH PLAN

Subject: Experimental and Investigational Services **Review Date:** 12/22

DESCRIPTION

According to The Ohio State University Faculty and Staff Health Plans Specific Plan Details Document (SPD), no coverage will be provided for services or supplies that are considered by OSU Health Plan to be experimental/investigative. This includes investigational medical, surgical, or mental health procedures and pharmacological regimens, as well as associated health services and/or supplies as defined by the medical plan. The SPD further defines experimental/investigative as any healthcare service, supplies, procedures, therapies, or devices not recognized as standard medical care for the condition, disease, illness, or injury being treated. The determination of whether any of the above is experimental or investigational is based on, but not limited to:

- Applicable governmental regulations, such as FDA approval,
- Available scientific evidence is inconclusive regarding safety and efficacy and there is no clear medical consensus regarding its safety and/or efficacy, i.e., a lack of an abundance of scientific literature and well-designed clinical trials,
- When the service is not proven to be as safe or effective as alternative accepted treatment or when the service does not improve health outcomes, or
- When the service is not proven outside the research setting.

Governmental approval of a service will be considered in determining whether a service is experimental or investigational. However, governmental approval alone does not necessarily mean that it is of proven benefit or appropriate or effective treatment for a particular diagnosis or for a particular condition.

POLICY

Experimental and Investigational

Consistent with the guidelines established by the SPD, The OSU Health Plan further defines experimental or investigational as any drug, device, treatment, or procedure if any of the following apply:

- The drug or device cannot be lawfully marketed in the United States without the approval of the Food and Drug Administration (FDA) and such approval has not been granted; or

- Reliable Evidence shows that the drug, device, treatment, or procedure is the subject of on-going Phase I or Phase II clinical trials; is the research, experimental, study or investigational arm of on-going Phase III clinical trials; or is otherwise under study to determine its toxicity, safety or efficacy as compared with a standard means of treatment or diagnosis; or

- The patient informed consent documents describe the drug, device, treatment, or procedure as experimental or investigational or in other terms that indicate the service is being evaluated for its safety, toxicity, or efficacy; or

- Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, treatment, or procedure is that further studies or clinical trials are necessary to determine its toxicity, safety or efficacy as compared with a standard means of treatment or diagnosis.

- The drug, device, treatment, or procedure is provided pursuant to oversight by an institutional review board or other body that approves or reviews research concerning safety, toxicity, or efficacy.

For the purposes of this policy, *Reliable Evidence* is defined by OSU Health Plan as Level I or II evidence based on the Rating System for the Hierarchy of Evidence:

- **Level I:** Evidence from a systematic review or meta-analysis of all relevant Randomized Controlled Trials (RCTs)

- **Level II:** Evidence obtained from well-designed multi-center, prospective RCTs

Additionally, The OSU Health Plan utilizes Milliman Care Guidelines (MCG) to support the determination of an experimental or investigational drug, device, treatment, or procedure.

Clinical Trials

The Patient Protection and Affordable Care Act (PPACA) requires non-grandfathered health plans to cover routine patient costs incurred by a qualifying individual who is participating in an approved clinical trial. Routine patient costs include all items and services consistent with the coverage provided in the plan that is typically covered for a covered individual who is not enrolled in a clinical trial.

I. Criteria for an approved clinical trial

1. An approved clinical trial is defined as:
    a. Phase I, Phase II, Phase III, or Phase IV clinical trial, and
    b. Conducted in relation to the prevention, detection or treatment for cancer or other life- threatening disease or condition, and
    c. That meets the requirements under Section 2 below.

    For purposes of this benefit, a life-threatening disease or condition is one from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

2. The clinical trial must be described in paragraph a, b, or c below.
    a. The study or investigation is approved or funded by one or more of the following:
        i. National Institutes of Health (NIH) [Includes National Cancer Institute (NCI)]
        ii. Centers for Disease Control and Prevention (CDC)

iii. Agency for Healthcare Research and Quality (AHRQ)
iv. Centers for Medicare and Medicaid Services (CMS)
v. A cooperative group or center of any of the entities described above or the Department of Defense (DOD) or the Veterans Administration (VA)
vi. A qualified non-governmental research entity identified in the guidelines issued by the NIH for center support grants
vii. The VA, DOD, or the Department of Energy if the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet both of the following criteria:
    1. Comparable to the system of peer review of studies and investigations used by the NIH
    2. Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
viii. Additionally, clinical trials that are not funded by any of the above institutions may still qualify if the following are met:
    1. The principal purpose of the trial is to evaluate whether the intervention potentially improves the participants' health outcomes;
    2. The trial is well-supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
    3. The trial does not unjustifiably duplicate existing studies;
    4. The trial design is appropriate to answer the research question being asked in the trial;
    5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
    6. The trial complies with Federal regulations relating to the protection of human subjects; and
    7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Or

b. The study or investigation is conducted under an investigational new drug application reviewed by the FDA, or
c. The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

3. Additional Requirements
    a. The clinical trial must have a written protocol that describes a scientifically sound study that has been approved by all relevant institutional review boards (IRBs) before participants are enrolled in the trial. OSU Health Plan may, at any time, request documentation about the trial.
    b. The subject or purpose of the trial must be the evaluation of an item or service that meets the definition of a covered service and is not otherwise excluded under the SPD.

II. <u>Qualified Individual</u>

1. A qualified individual must be:

a. Covered under the health plan, and
b. Eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition, and who either:
    i. The referring health care professional is a network provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in Section I above; or
    ii. The participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in Section I above.

Network Plans

If one or more network providers are participating in a clinical trial, OSU Health Plan requires that a covered individual participate in the trial through a network provider, if the provider will accept the individual as a participant in the trial. According to PPACA, OSU Health Plan is not required to provide benefits for routine services provided outside of the plan's provider network unless out-of-network benefits are otherwise provided under the plan (with Prime Care Choice or Out of Area).

PRIOR AUTHORIZATION

All utilization management rules and coverage policies that apply to routine care for members not in clinical trials will also apply to routine patient care for members in clinical trials. Members must meet all applicable plan requirements for prior authorization.

EXCLUSIONS

Any drug, device, treatment, or procedure deemed experimental or investigational according to the criteria specified in this policy.

Clinical Trial

According to the PPACA, routine patient costs do not include the following:

- The investigational item, device, or service
- Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the covered individual
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis
- Items and services provided by the trial sponsor without charge
- Travel, lodging and meals

REFERENCES

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