MEDICAL POLICY	Definition: Experimental/Investigational	
Effective Date: 1/1/2021	Section: MED	Policy No: 198
 1/1/2021	Medical Policy Approved Date: 6/11; 5/13; 12/15; 3/16; 6/16; 8/17; 8/18; 8/19; 5/2020; 11/2020; 12/2020	
Medical Officer Date		

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Medical and behavioral health care services may include medical, surgical, diagnostic, substance use or other health care technologies, supplies, equipment, treatments, procedures, services, biological products, or devices.

I. Medical and behavioral health care services are considered experimental or investigational, if **any one or more** of the following criteria is met:

A. The health care service does not have final approval from the appropriate governmental regulatory body to be lawfully marketed for the proposed use. The governmental regulatory body must have the authority to regulate new technology and medical/behavioral services and may include, but are not limited to, any of the following:

1. U.S. Food and Drug Administration (FDA);
2. American Hospital Formulary Service;
3. United States Pharmacopeia Dispensing Information;

4. American Medical Association Drug Evaluations; **or**

Note: Any approval that is granted as an interim step in the regulatory process (e.g. investigational device exemption [IDE]) is not a substitute for final market approval.

B. The medical or behavioral health care service is subject to review and approval by an institutional review board (IRB) for the proposed use; **or**

C. The medical or behavioral health care service is the subject of an ongoing clinical trial that meets the definition of a Phase I , II or III clinical trial set forth in the Food and Drug Administration (FDA) regulations regardless of whether the trial is actually subject to FDA oversight; **or**

D. The medical or behavioral health care service is not provided by an accredited institution or provider within the United States or is provided by one that has not demonstrated proficiency in the providing of the services or supplies; **or**

E. Current, prevailing, peer-reviewed medical literature does not demonstrate the medical or behavioral health care service to be safe and effective for treating or diagnosing the condition or illness for which its use is proposed. This includes, but is not limited to, the following (1.– 4.):
   1. The service is not as beneficial or more beneficial as any established alternative;
   2. The service does not effectively measure or alter the physiological changes related to a disease, injury, illness or condition;
   3. The evidence does not demonstrate that the service has a beneficial effect on health outcomes;
   4. The benefits of the service do not outweigh the harms; **or**

F. The medical or behavioral health care service has not been evaluated by a national professional medical society, a national healthcare organization, or a public health agency; or has been evaluated and determined not to be an appropriate standard of medical practice; **or**

G. The medical or behavioral health care service requested is not consistent with or does not address the patient's presenting complaint, injury or illness and is not considered standard of care in the medical community for that condition; **or**

H. The medical or behavioral test is requested as a panel of services that may be individually proven but when performed as a group or panel, the evidence-based literature does not support the requested service. If any single service/component of the panel test is investigational, then the entire panel is considered investigational. Services/components may include, but are not limited to, any of the following:
   1. Proteins
   2. Biomarkers
   3. Enzymes
   4. Analytes

5. Genes
6. Transcripts
7. Mutations

POLICY GUIDELINES

In order to make a determination of the investigational nature of any medical service the following sources of evidence should be considered:

1. Peer-reviewed publications of well-designed and well-conducted studies. Ideally, the overall body of evidence should be of high quality and reported outcomes should be consistent;
2. Technology assessments based on a systematic review of the evidence (e.g., Agency for Healthcare Research and Quality, Washington State Health Authority, Hayes, ECRI);
3. Evidence-based clinical practice guidelines developed by national organizations and other recognized authorities.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Clinical Trials and Devices (All Lines of Business Except Medicare)
- Clinical Trials and IDE Studies (Medicare Only)