curative

TITLE:	EXPERIMENTAL, INVESTIGATIONAL AND EMERGING TECHNOLOGY POLICY
POLICY #:	MM-PNP-014
VERSION #:	02
DEPARTMENT:	MEDICAL MANAGEMENT
ORIGINAL EFFECTIVE DATE:	10/22/2023
CURRENT REVISION DATE:	3/22/2024

1. PURPOSE

Curative is able to demonstrate to members and practitioners that Utilization Management (UM) decisions are made in a fair, consistent manner that serves the best interests of the members. Curative will follow this Policy and Procedure and will ensure that any delegated entities will also adhere.

2. SCOPE

Medical and Pharmacy UM Departments

3. DEFINITIONS

3.1. Experimental/Investigational services are defined as a treatment, procedure, facility, equipment, drug, service, or supply ('intervention') that has been determined not to be medically effective for the condition being treated.

3.2. Investigational means that the procedure, treatment, supply, device, equipment, facility, or drug (all services) does not meet the Company Technology Evaluation Criteria because it does not meet one or more of the following criteria:

3.2.1. have final approval from the appropriate government regulatory body; or

3.2.2. have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility, or drug (all services) on health outcomes; or

3.2.3. be proven materially to improve the net health outcome; or

3.2.4. be as beneficial as any established alternative; or

3.2.5. show improvement outside the investigational setting

In addition to the above criteria, the Medical Policy Committee (MPC) will consider recommendations of national physician specialty societies, nationally recognized professional healthcare organizations and public health agencies, and in its sole discretion, may consider other relevant factors, including information from the practicing community.

4. RESPONSIBILITIES

Medical and UM Department

5. POLICY

This policy addresses services considered to be experimental/investigational and, therefore, non-covered services. This policy will be used to make 'Medically Necessary' utilization decisions related to requests deemed to be experimental and/or investigational. Curative uses written utilization review decision criteria that are objective, measurable, and based on sound clinical evidence. UM decisions are made in accordance with currently accepted medical or health care practices, considering special circumstances requiring deviation from the norm.

Criteria

Services meeting **ANY** of the following criteria are considered experimental/investigational:

- The intervention does not have Food and Drug Administration (FDA) approval to be marketed for the specific relevant indication(s); **or**
- Available scientific evidence does not permit conclusions concerning the effect of the intervention on health outcomes; **or**
- The intervention is not proven to be as safe or effective in achieving an outcome equal to or exceeding the outcome of alternative therapies; **or**
- The intervention does not improve health outcomes; **or**
- The intervention is not proven to be applicable outside the research setting.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical UM Employees are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal and equitable remedies may apply.

9. DOCUMENTATION

Provide details regarding any specific documentation required for this policy or to meet any legal or regulatory requirements related to this policy.

10. REFERENCE DOCUMENTS AND MATERIALS

10.1. Regulatory Authority

10.1.1. N/A.

10.2. Internal - N/A

10.3. External - N/A

11. COLLABORATING DEPARTMENTS

11.1. Example Department

12. DOCUMENT CONTROL

APPROVED BY:		
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(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

N/A