ADMINISTRATIVE POLICY STATEMENT **Ohio Medicaid**

Policy Name & Number **Date Effective** Experimental or Investigational Item or Service-OH MCD-AD-0006 06/01/2024 **Policy Type**

ADMINISTRATIVE

Administrative Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper field processed in intertessed and intertesse a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of5

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The ADMINISTRATIVE Policy Statement detailed above has received due consideration as defined in the ADMINISTRATIVE



actually subject to FDA oversight. This includes diagnostic testing for purposes of possible inclusion in a clinical trial

Devices that are FDA approved under the Humanitarian Use Device exemption are not considered to be experimental or investigational.

Drugs used in Phase 4 trials may be covered if they are part of the formulary.

- D. Policy
 - I. Any health care item or service CareSource determines in its sole discretion to be experimental or investigational is not covered.
 - II. Any health care item or service not deemed experimental or investigational based on the criteria in Section C. may still be deemed experimental or investigational if it is not supported by credible research that soundly demonstrates that such item or service will have a measurable and beneficial health outcome. In determining whether such health care item or service is experimental or investigational, CareSource, in its sole discretion, will consider the information and evidence from one or more of the sources in Section III below and assess whether:

Α. Τ

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