CareSource

Administrative Policy Statement
INDIANA MEDICARE ADVANTAGE

Policy Name	Policy Number	Effective Date
Experimental or Investigational Item or Service	AD-0881	01/01/2021-05/31/2021

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

Administrative Policy Statements 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 and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of 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 of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject

Experimental or Investigational Item or Service

B. Background

Experimental or Investigational items or services are not covered. This policy defines the medical review decision process around such treatment requests.

CareSource members have the right to refuse or participate in experimental or investigational items or services.

C. Definitions

- **Experimental or Investigational Items or Services** or **Experimental or Investigational** - Medical, surgical, diagnostic, psychiatric, substance use disorders treatment or other health care services, technologies, supplies, treatments, procedures, biologic drug therapies or devices that, at the time CareSource has made a determination regarding coverage in a particular case, as defined to be any of the following:
  - Not approved by the United States Food and Drug Administration (FDA) to be lawfully marketed for the proposed use; OR
  - Not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use; OR
  - Subject to review and approval by any institutional review board for the proposed use; OR
  - The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is 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.

D. Policy

I. Any drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, Injury, Illness, or other health condition which CareSource determines in its sole discretion to be experimental or investigational is not covered by CareSource.

II. CareSource will deem any drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply to be experimental or investigational if it is determined that **one or more** of the following criteria apply:

The drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply:

A. Cannot be legally marketed in the United States without the final approval of the United States Food and Drug Administration, or other licensing or regulatory agency, and such final approval has not been granted;

B. Has been determined by the United States Food and Drug Administration to be contraindicated for the specific use;

C. Is provided as part of a clinical research protocol or clinical trial or is provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply;
D. Is subject to review and approval of an Institutional Review Board (IRB) or other body serving a similar function; or
E. Is provided pursuant to informed consent documents that describe the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply as Experimental or Investigational, or otherwise indicate that the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply is under evaluation.

III. In addition, CareSource may determine, in its sole discretion, that any item or service is experimental or investigational based on all of the following:
A. The scientific evidence concerning the effect of the service on health outcomes;
B. The evidence demonstrates the service improves net health outcomes of the total population for whom the service might be proposed by producing beneficial effects that outweigh any harmful effects;
C. The evidence demonstrates the service has been shown to be as beneficial for the total population for whom the service might be proposed as any established alternatives; and
D. The evidence demonstrates the service has been shown to improve the net health outcomes of the total population for whom the service might be proposed under the usual conditions of medical practice outside clinical investigatory settings.

IV. When reviewing requests, CareSource will consider the following; but not limited to:
A. Published authoritative, peer-reviewed medical or scientific literature, or the absence thereof;
B. Evaluations of national medical associations, consensus panels, and other technology evaluation bodies;
C. Documents issued by and/or filed with the United States Food & Drug Administration or other federal, state or local agency with the authority to approve, regulate, or investigate the use of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply;
D. Documents of an institutional review board or other similar body performing substantially the same function;
E. Consent document(s) and/or the written protocol(s) used by your Providers studying substantially the same drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply;
F. Medical records; or
G. The opinions of consulting Providers and other experts in the field.

E. Conditions of Coverage

F. Related Policies/Rules

G. Review/Revision History

	DATES	ACTION
Date Issued	10/14/2020	
Date Revised		
Date Effective	01/01/2021	
Date Archived	06/01/2021	
Date Archived	05/31/2021	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. ECFR.io. (n.d.). E-CFR Title 21 Part 312 Investigational New Drug Application. Retrieved September 23, 2020, from www.ecfr.oi
2. ECFR.io. (2019, June 21). E-CFR Title 21 Part 812 Investigational Device Exemptions. Retrieved September 23, 2020, from www.ecfr.io
3. ECFR.io. (2019, June 21). E-CFR Title 21 Part 814 Premarket Approval of Medical Devices. Retrieved September 23, 2020, from www.ecfr.io
4. ECFR.io. (2019, June 21). E-CFR Title 21 Part 600 Biological Products. Retrieved September 23, 2020, from www.ecfr.io
5. ECFR.io. (2019, June 21). E-CFR Title 42 Part 405 → Subpart B → §405.212 Medicare Coverage IDE study criteria. Retrieved September 23, 2020 from www.ecfr.io
6. Department of Health and Human Services Centers for Medicare & Medicaid Services. (2015, January 1).Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies MLN Matters MM8921. Retrieved September 23, 2020, from www.cms.gov

The Administrative Policy Statement detailed above has received due consideration as defined in the Administrative Policy Statement Policy and is approved.