

Policy Name: Experimental or Investigational Determination

Policy Number: CMO 509

Effective date of current policy: June 2, 2020

Description and Scope

This policy establishes guidelines for determining whether a service should be considered experimental or investigational (E/I). The policy applies to all lines of business.

Position Statement

"Experimental or Investigational treatment" means a drug, device, service, or treatment for which:

1. there is insufficient outcome data available from controlled clinical trials published in the peer-reviewed literature to substantiate its safety and effectiveness for the illness or injury involved; or
2. approval required from the FDA for marketing to the public has not been granted; or
3. a recognized national medical or dental society or regulatory agency has determined, in writing, that it is experimental or investigational, or for research purposes; or
4. it is a type of drug, device, or treatment that is the subject of an investigational new drug treatment pursuant to 21 C.F.R. § 312.21, or is the subject of an investigational device treatment pursuant to 21 C.F.R. § 812.36; or
5. the written protocol or protocols used by the treating facility or by another facility studying the same drug, device, procedure, or treatment, states that it is experimental or investigational; or
6. services are provided within a clinical trial; or
7. the provision of a pharmaceutical product for a use other than those uses for which such pharmaceutical product has been approved for marketing by the federal Food and Drug Administration, unless NYS or Federal law or regulations require that the specific use in question should be covered.

In order to determine whether a treatment is E/I, the above definition will be used. The above definition may be used itself, or a particular treatment may have an Affinity policy, MCG guideline, or Hayes recommendation. MCG guidelines for E/I treatments are given the Recommendation Grade (RG) of one of the following:

- **RG B:** Evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs. harm; additional research is recommended.
- **RG C1:** Evidence demonstrates a lack of net benefit; additional research is recommended.
- **RG C2:** Evidence demonstrates potential harm that outweighs benefit; additional research is recommended.

A Hayes rating of C, D1, or D2 may be considered E/I.

Background

If a requested service is covered, it may be reviewed for medical necessity. A covered service that is not medically necessary may be denied as "not medically necessary," "cosmetic and not medically necessary," or "Experimental or Investigational." This policy gives the framework for when a service should be considered

Experimental or Investigational. This framework may be used to construct other policies or to make decisions on requests where the policy has not yet been adopted.

Definitions

E/I: Experimental or Investigational

MCG: a company, part of Hearst Health, that constructs and licenses evidence-based care guidelines

Hayes: a company, part of TractManager, that licenses evidence-based assessments of health technologies

FDA: Food and Drug Administration

C.F.R.: Code of Federal Regulations

Coding

NOT APPLICABLE

References

- New York Codes, Rules and Regulations Title 10 Section 69-10.1
- Hayes Rating <https://evidence.hayesinc.com/static/HRating> Downloaded 06/02/2020
- MCG Content Guide to Ambulatory Care <https://careweb.careguidelines.com/ed24/index.html> Downloaded 06/02/2020

Medical Policy Committee History and Revisions

Date	Action
June 2, 2020	Policy adopted

Disclaimer

Affinity Health Plan has developed medical policies that serve as one of the sets of guidelines for coverage decisions. Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the medical policies. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and/or federal law. Medical policy does not constitute plan authorization, nor is it an explanation of benefits. The policies are not medical advice. Affinity Health Plan reserves the right to change medical policies.