MEDICAL POLICY

Medical Policy Title	**Experimental or Investigational Services**
Policy Number	**11.01.03**
Current Effective Date	February 20, 2025
Next Review Date	February 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. A service is considered experimental/investigational when **ANY** of the following criteria are met:

- A. There is insufficient information to determine whether the service or the manner in which it is provided (in terms of type, frequency, extent, site, and/or duration) is of proven benefit for a particular diagnosis or for treatment of a particular condition;
- B. As reflected in published, peer-reviewed, medical literature, the service or the manner in which it is provided (in terms of type, frequency, extent, site, and/or duration) is not generally recognized by the medical community as effective or appropriate for a particular diagnosis or for treatment of a particular condition;
- C. The safety of the service for a person with a particular diagnosis or a particular condition has not been proven (e.g., research studies are currently evaluating the service and/or the manner in which it should be provided (in terms of type, frequency, extent, site, and/or duration), to ascertain the safety and effectiveness of the treatment on the well-being of a person with the particular diagnosis or condition).

II. A service is considered **not** experimental or investigational, when **ALL** of the following criteria are met:

- A. A service that is a medical device, drug, or biological product must have received final approval from the appropriate government regulatory bodies, such as the United States Food and Drug Administration (FDA). Any other approval granted as an interim step in the FDA regulatory process (e.g., an Investigational Device Exemption or an Investigational New Drug Exemption) is not sufficient;
- B. Published, peer-reviewed literature must provide conclusive evidence that the service has a definite positive effect on health outcomes. The evidence must include reports of well-designed investigations that have been reproduced by non-affiliated, authoritative sources with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding scientific efficacy and rationale;
- C. Published, peer-reviewed, medical literature must provide demonstrated evidence that, over time, the service leads to improvement in health outcomes (e.g., the beneficial effects of the service outweigh any harmful effects).

D. Published, peer-reviewed medical literature must provide proof that the service is at least as effective in improving health outcomes as established services or technologies, or is usable in appropriate clinical contexts in which an established service or technology is not employable;

E. Published, peer-reviewed medical literature must provide proof that improvement in health outcomes is possible in standard conditions of medical practice, outside the clinical investigatory settings.

RELATED POLICIES

Corporate Medical Policy

11.01.10 Clinical Trials

Pharmacy Management Drug Policy

32 Off-label Use of FDA Approved Drugs

POLICY GUIDELINE(S)

I. Governmental approval of a service will be considered in determining whether a service is experimental or investigational. The fact that a service has received governmental approval does not necessarily mean that it is of proven benefit or appropriate or effective treatment for a particular diagnosis or for a particular condition.

II. The experimental/investigational services exclusion shall not limit in any way the benefits available for prescription drugs that are otherwise covered under the member's subscriber contract and that have been approved by the FDA for the treatment of certain types of cancers, when those drugs are prescribed for the treatment of a type of cancer for which they have not been approved by the FDA, so long as the drugs so prescribed meet the requirements of Section 4303(q) of the New York Insurance Law.

III. Experimental/investigational procedures and/or services are excluded from coverage under Health Plan contracts unless mandated by state or federal law.

DESCRIPTION

Experimental or investigational services are those treatments, procedures (including organ transplantation), drugs, biological products, or medical devices which, in the judgment of the Health Plan, are experimental/investigational in nature.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

New York State Insurance Law, Section 4303 (q).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
No specific codes	

HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

Code	Description
Numerous	

REFERENCES

New York State Insurance Law, Section 4303 (q) [Internet]. [updated 2025 Jan 3; accessed 2025 Jan 29]. Available from: https://newyork.public.law/laws/n.y._insurance_law_section_4303

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, experimental or investigational services are not addressed in separate National or Regional Medicare coverage determinations or policies. Refer to policies specific to a procedure/technology for indications of when services are considered experimental/investigational.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

10/18/01, 01/23/03, 02/26/04, 02/24/05, 02/23/06, 02/22/07, 02/28/08, 02/26/09, 02/25/10, 02/24/11, 02/27/12, 02/28/13, 02/27/14, 02/26/15, 02/25/16, 04/27/17, 02/22/18, 02/28/19, 02/27/20, 02/25/21, 02/17/22, 02/16/23, 02/22/24, 02/20/25

Date	Summary of Changes
02/20/25	• Policy guidelines moved to statements; policy intent unchanged
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date