MEDICAL POLICY

Excellus
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Medical Policy Title	**Experimental or Investigational Services**
Policy Number	**11.01.03**
Current Effective Date	**August 07, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Services, devices, delivery systems, drugs or biological products are considered **experimental/investigational** when there is insufficient peer-reviewed scientific evidence to support **ALL** of the following, for the requested indication:

   A. It is recognized by the Health Plan, in accordance with its standard policies and procedures, as standard medical care;

   B. It has final approval by applicable governmental agencies (e.g., U.S. Food and Drug Administration);

   C. Its safety and effectiveness have been proven;

   D. It improves the net health outcome;

   E. The health outcome improvements can be achieved outside the clinical investigational setting; **and**

   F. It is at least as beneficial as any established service or technology alternatives.

RELATED POLICIES

Corporate Medical Policy

11.01.10 Clinical Trials

11.01.15 Medically Necessary Services

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

Food

The United States Food and Drug Administration (FDA) regulates food, and food ingredients including dietary supplements, bottled water, food additives, and infant formulas to ensure they are safe and effective for human use. Refer to the FDA Food website. Available from: https://www.fda.gov/food [accessed 2026 Feb 20]

Food producers recall their products from the marketplace when the products are mislabeled or when the food may present a health hazard to consumers because the food is contaminated or has caused a foodborne illness outbreak. The FDA maintains a list of recalls, outbreaks, safety alerts and emergencies. Available from: Recalls of Foods & Dietary Supplements | FDA [accessed 2026 Feb 20]

Medical Devices

The United States Food and Drug Administration (FDA) regulates medical devices. All medical devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Feb 20]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Feb 20]

Labs

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA).

Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing. More information is available at: Clinical Laboratory Improvement Amendments (CLIA) | FDA [accessed 2026 Feb 20]

Drugs

The United States Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2026 Feb 20]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2026 Feb 20]

Vaccines, Blood and Biologics

The United States Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2025 Dec 29]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2026 Feb 20]

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
Not Applicable	

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

New York State Insurance Law, Section 4303 (q) [Internet]. [updated 2025 Dec 19; accessed 2026 Feb 20]. Available from: https://newyork.public.law/laws/n.y._insurance_law_section_4303

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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

09/16/99, 02/01/01, 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, 03/19/26

Date	Summary of Changes
03/19/26	• Annual review. Policy statements were revised for clarity. The policy intent is unchanged.
02/20/25	• Policy guidelines moved to statements; policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
09/16/99	• Original effective date