MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Experimental or Investigational Services**
Policy Number	**11.01.03**
Category	**Contract Clarification**
Original Effective Date	**10/18/01**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

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

Refer to Pharmacy Management Drug Policy #32 Off-label Use of FDA Approved Drugs

Refer to Corporate Medical Policy #11.01.10 Clinical Trials

POLICY GUIDELINES

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. For the Health Plan to determine that a service is not experimental or investigational, **ALL** of the following conditions must be 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; and
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.

III. 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.

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.

A service is considered experimental/investigational when any of the following applies:

I. 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;
II. 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; or
III. 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).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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).

*Key Article

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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.