

**SUBJECT: EXPERIMENTAL OR  
INVESTIGATIONAL SERVICES**

**POLICY NUMBER: 11.01.03**  
**CATEGORY: Contract Clarification**

**EFFECTIVE DATE: 09/16/99**  
**REVISED DATE: 02/01/01, 01/23/03, 02/26/04, 02/24/05,  
02/23/06, 02/22/07, 02/28/08**  
**ARCHIVED DATE: 02/26/09**  
**EDITED DATE: 02/25/10, 02/24/11, 02/27/12, 02/28/13,  
02/27/14**  
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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

## **POLICY STATEMENT:**

Experimental/ investigational procedures and/or services are excluded from coverage by Health Plan contracts.

Refer to Corporate Pharmacy policy regarding Off-label use of FDA Approved Drugs.

Refer to Corporate Medical Policy #11.01.10 regarding 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. In determining whether there is rigorous scientific evidence to determine if a service is or is not experimental or investigational we require that all of the following five criteria 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, medical 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 nonaffiliated, 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 of clinical investigatory settings.
- III. This exclusion shall not limit in any way benefits available for prescription drugs, otherwise covered under the member's subscriber contract, which 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.

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IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

**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.

Experimental/ investigational means that the service is defined as:

- I. Those where there is insufficient information to determine if the service is of proven benefit for a particular diagnosis or for treatment of a particular condition;
- II. Those not generally recognized by the medical community, as reflected in published, peer-reviewed, medical literature, as effective or appropriate for a particular diagnosis or for treatment of a particular condition; or
- III. Those not of proven safety for a person with a particular diagnosis or a particular condition (e.g., that which is currently being evaluated in research studies to ascertain the safety and effectiveness of the treatment on the well-being of a person with the particular diagnosis or in the particular condition).

**CODES:      Number      Description**

*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.

**CPT:**      No specific code(s)

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**HCPCS:**      No specific code(s)

**ICD9:**      Numerous

**ICD10:**      Numerous

**REFERENCES:**

BlueCross BlueShield Association. Investigational definition. Medical Policy Reference Manual. 2013 Issue 11.

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

**KEY WORDS:**

Experimental, Investigational.

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## **CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

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