BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY
	REFERENCE NO.: MPO-490-0132
EFFECTIVE DATE July 1, 2014	**SUBJECT:** Experimental/Investigative Services Obstetrical/Gynecological

Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice. Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure. In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

I. DESCRIPTION:

BCNEPA defines experimental or investigational as the use of any treatment, procedure, facility, equipment, drug, device or supply that is determined not to be supported by evidence-based medicine.

II. BENEFIT POLICY STATEMENT:

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

BCNEPA does not cover services which BCNEPA determines in its sole discretion, are experimental or investigative and the covered services related to them; the fact that the treatment, procedure, equipment, drug, device or supply is the only available treatment for a particular condition will not result in coverage if the service is considered to be experimental or investigative.

III. EXPERIMENTAL OR INVESTIGATIVE:

The use of any treatment, procedure, facility, equipment, drug, device or supply that is determined to be not supported by evidence-based medicine and therefore:

a) Not accepted by the general medical community as standard medical treatment of the condition being treated or does not have definitive outcome studies in peer-reviewed medical literature demonstrating safety and efficacy for treating or diagnosing the condition or illness for which its use is proposed and/or lacks studies comparing outcomes to existing approved modalities of therapy or diagnosis; or

b) Not approved by the U.S. Food and Drug Administration ("FDA") to be lawfully marketed for the proposed use and not identified in the American Hospital Formulary Service Drug Information or the United States Pharmacopeia Drug Information for the Health Care Professional as appropriate for the proposed use at the time services were rendered; or

c) Subject to review and approval by any institutional review board for the proposed use.

IV. MEDICAL POLICY STATEMENT:

This policy addresses those specific services that are determined by BCNEPA to be experimental/investigational based on the definition in BCNEPA's benefit contracts. The services that are listed are considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of these services cannot be established by review of the available published peer-reviewed literature.

Myolysis of Uterine Fibroids

A. BCNEPA will not provide coverage for laparoscopic and percutaneous techniques for myolysis (e.g., laser and bipolar needles, cryomyolysis, laparoscopic radiofrequency ablation [HALT procedure]) in the treatment of uterine fibroids as they are considered investigational.

Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea

B. BCNEPA will not provide coverage for laparoscopic uterine nerve ablation (LUNA) and laparoscopic presacral neurectomy (LPSN) as techniques to treat primary or secondary dysmenorrheal as they are considered investigational.

IV. DEFINITIONS:

Technology: Refers to any medical or surgical treatment, medical or surgical device, therapeutic or diagnostic procedure, drug, biological or therapeutic or diagnostic agent.

Technology Assessment: Practical process of determining the value of a new or emerging technology in and of itself or against competing existing technologies using efficacy and outcomes.

Clinical Drug Trials: The Food and Drug Administration (FDA) tests new drugs in humans in three stages:

Phase 1: An investigational drug is tested over several months on 20 to 100 volunteers for safety and chemical action.

Phase 2: As many as several hundred people who have the condition in question participate for up to two years, mainly to test the drug's effectiveness.

Phase 3: Usually the last stage before FDA approval, the drug is tested for safety, dosage levels and effectiveness in hundreds to thousands of volunteers. Typically the study is randomized and controlled to yield the most valid results.

About 25 percent to 30 percent of all applicant drugs pass all three phases, according to FDA Consumer magazine; about 20 percent are ultimately approved for marketing.

FDA Accelerated Approval or "Fast Track" Process-Based on FDA's determination that based on an assessment of preliminary studies, the product provides meaningful therapeutic benefits to patients over existing treatments (generally Phase IV trials) post-approval to validate or confirm the effect on clinical outcomes.

Clinical Trial/Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s), with the object of ascertaining its safety and/or efficacy.

Investigational New Drug: A drug allowed by the Food and Drug Administration (FDA) to be used in clinical trials but not approved by the FDA for commercial marketing.

Protocol: The outline or plan for use of an experimental procedure or experimental treatment.

Randomized Clinical Trials: A study in which patients with similar traits, such as extent of disease, are chosen or selected by chance to be placed in separate groups that are comparing different treatments. Because irrelevant factors or preferences do not influence the distribution of patients, the treatment groups can be considered comparable and results of the different treatments used indifferent groups can be compared.

Peer Reviewed Medical Literature: Means two (2) or more U.S. scientific publications which require that manuscripts be submitted to acknowledged experts inside or outside the editorial office for their considered opinions or recommendations regarding publication of the manuscript. Additionally, in order to qualify as Peer Reviewed Medical Literature, the manuscript must actually have been reviewed by acknowledged experts before publication. Devices are categorized into three classes:

- Class I devices are the least regulated devices. These are devices that FDA has determined need to be subject only to general controls, such as good manufacturing practice regulations.

- Class II devices are those which cannot be classified into Class I or Class II because insufficient information exists to determine that either special or general controls would provide reasonable assurance of safety and effectiveness.

- Class III devices require Pre-Market Approval (PMA).

CODING:

- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

PROCEDURE CODES

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