BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY
	REFERENCE NO.: MPO-490-0138
EFFECTIVE DATE October 1, 2014	**SUBJECT:** Experimental/Investigative Services Medicine

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.

Actigraphy

A. BCNEPA will not provide coverage for actigraphy when used as the sole technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders as this is considered investigational.

Automated Point-of-Care Nerve Conduction Tests

B. BCNEPA will not provide coverage for automated nerve conduction tests as they are considered investigational.

Bioimpedance Devices for Detection of Lymphedema

C. BCNEPA will not provide coverage for devices using bioimpedance (bioelectrical impedance spectroscopy) for use in the diagnosis, surveillance, or treatment of patients with lymphedema; including use in subclinical secondary lymphedema, as they are considered investigational.

Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting

D. BCNEPA will not provide coverage in the ambulatory care and outpatient setting for, cardiac hemodynamic monitoring for the management of heart failure utilizing thoracic bioimpedance, inert gas rebreathing, arterial pressure/Valsalva, and implantable direct pressure monitoring of the pulmonary artery, as these are considered investigational.

Chromoendoscopy as an Adjunct to Colonoscopy

E. BCNEPA will not provide coverage for chromoendoscopy or virtual chromoendoscopy as they are considered investigational as an adjunct to diagnostic or surveillance colonoscopy.

Closure Devices for Patent Foramen Ovale

F. BCNEPA will not provide coverage for closure of patent foramen ovale using a transcatheter approach as this is considered investigational. (There are currently no transcatheter devices with FDA approval or clearance for this indication.)

Computerized 2-lead Resting Electrocardiogram Analysis for the Diagnosis of Coronary Artery Disease

G. BCNEPA will not provide coverage for computerized 2-lead resting electrocardiogram analysis (e.g., multifunction cardiogram) for diagnosing coronary artery disease as this is considered investigational.

Confocal Laser Endomicroscopy

H. BCNEPA will not provide coverage for the use of confocal laser endomicroscopy as this is considered investigational.

Cytoreductive Surgery and Perioperative Intraperitoneal Chemotherapy for the Treatment of Pseudomyxoma Peritonei, Peritoneal Carcinomatosis of Gastrointestinal Origin, and Peritoneal Mesothelioma

I. BCNEPA will not provide coverage for cytoreductive surgery and perioperative intraperitoneal chemotherapy for peritoneal carcinomatosis from colorectal cancer as this is considered investigational.

Diagnosis and Management of Idiopathic Environmental Intolerance (i.e., Clinical Ecology)

J. BCNEPA will not provide coverage for the following services in the diagnosis and management of idiopathic environmental intolerance as they are considered investigational:

1. Laboratory tests designed to affirm the diagnosis of idiopathic environmental intolerance;

2. Nutritional assessments, including intracellular analysis of micronutrients, in both asymptomatic persons and patients with symptoms suggestive of idiopathic environmental intolerance;

3. Treatments for idiopathic environmental intolerance, including but not limited to IVIg, neutralizing therapy of chemical and food extracts, avoidance therapy, elimination diets, and oral nystatin (to treat *Candida*).

Dynamic Posturography

K. BCNEPA will not provide coverage for dynamic posturography as this is considered investigational.

Electrocardiographic Body Surface Mapping

L. BCNEPA will not provide coverage for electrocardiographic body surface mapping for the diagnosis or management of cardiac disorders including acute coronary syndrome as this is considered investigational.

End Diastolic Pneumatic Compression Boot as a Treatment of Peripheral Vascular Disease or Lymphedema

M. BCNEPA will not provide coverage for end diastolic compression boots as a treatment of peripheral vascular disease or lymphedema and its associated complications including, but not limited to, ischemic lesions, claudication pain, necrotizing cellulitis, venous stasis ulcers, stasis dermatitis, chronic lymphedema, or thrombophlebitis, as this is considered investigational.

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

N. BCNEPA will not provide coverage for extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol or radial ESWT, as a treatment of musculoskeletal conditions, including but not limited to plantar fasciitis; tendinopathies including tendinitis of the shoulder, tendinitis of the elbow (epicondylitis, tennis elbow), stress fractures, delayed union and non-union of fractures, and avascular necrosis of the femoral head as it is considered investigational.

Ingestible pH and Pressure Capsule

O. BCNEPA will not provide coverage for measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule for the evaluation of suspected gastroparesis, constipation or other gastrointestinal motility disorders as this is considered investigational.

NOTE: BCNEPA MPO-490-0160 addresses the ingestible capsule imaging system.

Interventions for Progressive Scoliosis

P. BCNEPA will not provide coverage for vertebral body stapling for the treatment of scoliosis as this is considered investigational.

In Vitro Chemoresistance and Chemosensitivity Assays

Q. BCNEPA will not provide coverage for the following in vitro assays as they are considered investigational:

1. In vitro chemosensitivity assays, including, but not limited to, the histoculture drug response assay or a fluorescent cytoprint assay;

2. In vitro chemoresistance assays, including, but not limited to extreme drug resistance assays.

Low-Level Laser Therapy

R. BCNEPA will not provide coverage for low-level laser therapy for all indications including, but not limited to treatment of carpal tunnel syndrome as this is considered investigational.

Measurement of Exhaled Nitric Oxide and Exhaled Breath Condensate in the Diagnosis and Management of Asthma and Other Respiratory Disorders

S. BCNEPA will not provide coverage for the following techniques in the diagnosis and management of asthma and other respiratory disorders including but not limited to chronic obstructive pulmonary disease and chronic cough; as they are considered investigational:

1. Measurement of exhaled nitric oxide;

2. Measurement of exhaled breath condensate.

Mechanical Embolectomy for Treatment of Acute Stroke

T. BCNEPA will not provide coverage for mechanical embolectomy in the treatment of acute stroke as this is considered investigational.

Optical Coherence Tomography

U. BCNEPA will not provide coverage for optical coherence tomography as this is considered investigational in all situations, including but not limited to:

1. When used as an adjunct to percutaneous coronary interventions with stenting, and

2. Risk stratification of intracoronary atherosclerotic plaques and follow-up evaluation of stenting.

Neural Therapy

V. BCNEPA will not provide coverage for neural therapy (the injection of a local anesthetic into scars, trigger points, acupuncture points, tendon and ligament insertions, peripheral nerves, autonomic ganglia, the epidural space, and other tissues to treat chronic pain and illness) as it is considered investigational for all indications.

Non-Pharmacologic Treatment of Rosacea

W. BCNEPA will not provide coverage for non-pharmacologic treatment of rosacea, including but not limited to laser and light therapy, surgical debulking and electrosurgery as this is considered investigational.

Percutaneous Left-Atrial Appendage Closure Devices for Stroke Prevention in Atrial Fibrillation

X. BCNEPA will not provide coverage for the use of percutaneous left-atrial appendage closure devices for the prevention of stroke in atrial fibrillation as this is considered investigational.

Peroral Endoscopic Myotomy for Treatment of Esophageal Achalasia

Y. BCNEPA will not provide coverage for peroral endoscopic myotomy as a treatment for esophageal achalasia as this is considered investigational.

Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia

Z. BCNEPA will not provide coverage for the following treatments of damaged myocardium due to ischemia as they are considered investigational:

1. Progenitor cell therapy, including but not limited to skeletal myoblasts or hematopoietic stem cells;

2. Infusion of growth factors (i.e., granulocyte colony stimulating factor (GCSF)) as a technique to increase the numbers of circulating hematopoietic stem cells.

Prolotherapy

AA. BCNEPA will not provide coverage for prolotherapy as a treatment of musculoskeletal pain as this is considered investigational.

Quantitative Sensory Testing

BB. BCNEPA will not provide coverage for quantitative sensory testing including, but not limited to, current perception threshold testing, pressure-specified sensory device testing, vibration perception threshold testing, and thermal threshold testing, as this is considered investigational.

Transanal Radiofrequency Treatment of Fecal Incontinence

CC. BCNEPA will not provide coverage for transanal radiofrequency therapy as a treatment for fecal incontinence as this is considered investigational.

Transcatheter Closure of Patent Ductus Arteriosus

DD. BCNEPA will provide coverage for transcatheter closure of patent ductus arteriosus when medically necessary.

1. Transcatheter closure of a patent ductus arteriosus using an FDA-approved device may be considered medically necessary.

2. Transcatheter closure of a patent ductus arteriosus using other non–FDA-approved devices is considered investigational.

Transesophageal Endoscopic Therapies for Gastroesophageal Reflux Disease

EE. BCNEPA will not provide coverage for the following endoscopic therapies for gastroesophageal reflux disease as they are considered investigational:

1. Transesophageal endoscopic gastroplasty as a treatment of gastroesophageal reflux disease (e.g., the EndoCinch™, NDO Plicator™, or EsophyX™ procedures).

2. Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (i.e., the Stretta procedure) as a treatment of gastroesophageal reflux disease.

3. Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (e.g., biocompatible liquid polymer, polymethylmethacrylate beads, zirconium oxide spheres) as a treatment of gastroesophageal reflux disease.

T-Wave Alternans

FF. BCNEPA will not provide coverage for T-wave alternans as a technique of risk stratification for primary or secondary prevention* of fatal arrhythmias and sudden cardiac death in patients with a history of myocardial infarction, congestive heart failure, cardiomyopathy or other cardiac disorders such as long-QT syndrome (e.g., Brugada syndrome) as this is considered investigational.

1. *Primary prevention refers to patients that have *not* experienced a life-threatening arrhythmia.
2. *Secondary prevention refers to patients that have experienced a life-threatening arrhythmia.

Ultrafiltration in Decompensated Heart Failure

GG. BCNEPA will not provide coverage for the use of ultrafiltration in patients with heart failure as this is considered investigational.

Ultrasonographic Measurement of Carotid Intima-Medial Thickness as an Assessment of Subclinical Atherosclerosis

HH. BCNEPA will not provide coverage for ultrasonographic measurement of carotid artery intima-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis for use in the screening, diagnosis, or management of atherosclerotic disease as this is considered investigational.

V. 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

0019T	0179T	0296T	43257	95012
0101T	0180T	0297T	43499	95803
0102T	0206T	0298T	53899	95905
0106T	0223T	0299T	64450	95924
0107T	0224T	0300T	83987	95943
0108T	0225T	28890	88375	95999
0109T	0239T	37184	91112	L8612
0110T	0281T	37185	92548	S8948
0126T	0288T	43206	93025	
0178T	0293T	43252	93701	