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 investigational 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.

Artificial Intervertebral Disc: Cervical Spine

A. BCNEPA will not provide coverage for artificial intervertebral discs for treatment of disorders of the cervical spine, including degenerative disc disease as they are considered investigational.

Artificial Intervertebral Disc: Lumbar Spine

B. BCNEPA will not provide coverage for artificial intervertebral discs of the lumbar spine as they are considered investigational.

Automated Percutaneous and Endoscopic Discectomy

C. BCNEPA will not provide coverage for automated percutaneous discectomy or endoscopic discectomy as a technique of intervertebral disc decompression in patients with back pain related to disc herniation in the lumbar, thoracic, or cervical spine as this is considered investigational.

Axial Lumbosacral Interbody Fusion

D. BCNEPA will not provide coverage for axial lumbosacral interbody fusion (axial LIF) as this is considered investigational.
Biometric Bone Void Filler

E. BCNEPA will not provide coverage for biometric bone void fillers (e.g., Integra, Allomatrix, Opteform, Trinity Evolution, Vitoss, Wellgraft PE II) when administered during arthroscopic knee surgery as this is considered investigational.

Bronchial Thermoplasty

F. BCNEPA will not provide coverage for bronchial thermoplasty for the treatment of asthma as this is considered investigational.

Computer-Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure

G. BCNEPA will not provide coverage for computer assisted surgery for orthopedic procedure of the pelvis and appendicular skeleton as this is considered investigational.

Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

H. BCNEPA will not provide coverage for laser discectomy and radiofrequency coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain as these are considered investigational.

Dynamic Spine Stabilization

I. BCNEPA will not provide coverage for dynamic spine stabilization for the treatment of degenerative spine disorders, either as an adjunct to spinal fusion surgery, or an alternative to fusion as this is considered investigational. (The Dynesys® Dynamic Stabilization System by Zimmer, Inc. is an example of such a device.)

Electromagnetic Navigation Bronchoscopy

J. BCNEPA will not provide coverage for electromagnetic navigation bronchoscopy for the following applications as they are considered investigational:

1. Electromagnetic navigation bronchoscopy for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes; or
2. Electromagnetic navigation bronchoscopy for the placement of fiducial markers.

Endobronchial Valves

K. BCNEPA will not provide coverage for endobronchial valves for the following conditions as they are considered investigational:

1. As a treatment of prolonged air leaks; and
2. As a treatment for patients with COPD or emphysema.
Facet Arthroplasty

L. BCNEPA will not provide coverage for total facet arthroplasty as this is considered investigational.

Handheld Radiofrequency Spectroscopy for Intraoperative Assessment of Surgical Margins during Breast-Conserving Surgery

M. BCNEPA will not provide coverage for handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery as this is considered investigational.

Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

N. BCNEPA will not provide coverage for image-guided minimally invasive lumbar decompression as this is considered investigational.

Injectable Bulking Agents for the Treatment of Fecal Incontinence

O. BCNEPA will not provide coverage for the use of perianal bulking agents to treat fecal incontinence as this is considered investigational.

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

P. BCNEPA will not provide coverage for interspinous distraction devices as a treatment of neurogenic intermittent claudication as this is considered investigational.

Q. BCNEPA will not provide coverage for the use of an interlaminar stabilization device following decompressive surgery as this is considered investigational.

Interspinous Fixation (Fusion) Devices

R. BCNEPA will not provide coverage for interspinous fixation (fusion) devices for any indication, including but not limited to use in combination with interbody fusion, or alone for decompression in patients with spinal stenosis as this is considered investigational.

Magnetic Esophageal Ring to Treat Gastroesophageal Reflux Disease (GERD)

S. BCNEPA will not provide coverage for an implantable magnetic esophageal ring to treat gastroesophageal reflux disease (GERD) as this is considered investigational.

Nerve Graft in Association with Radical Prostatectomy

T. BCNEPA will not provide coverage for unilateral or bilateral nerve graft in patients who have undergone resection of one or both neurovascular bundles as part of a radical prostatectomy as this is considered investigational.
Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty and Percutaneous Intradiscal Radiofrequency Annuloplasty

U. BCNEPA will not provide coverage for percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biaxoplasty) for the treatment of chronic discogenic back pain as this is considered investigational.

Percutaneous Tenotomy of the Elbow

V. BCNEPA will not provide coverage for percutaneous tenotomy of the elbow for the treatment of epicondylitis, tennis elbow, or golfer’s elbow as this is considered investigational.

Plugs for Fistula Repair

W. BCNEPA will not provide coverage for biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material for all indications including, but not limited to, repair of anal and rectal fistulas as this is considered investigational.

Saturation Biopsy for Diagnosis and Staging of Prostate Cancer

X. BCNEPA will not provide coverage for saturation biopsy in the diagnosis, staging, and management of prostate cancer as this is considered investigational.

Subtalar Arthroereisis

Y. BCNEPA will not provide coverage for subtalar arthroereisis as this is considered investigational.

Surgical Deactivation of Headache Trigger Sites

Z. BCNEPA will not provide coverage for surgical deactivation of trigger sites for the treatment of migraine and non-migraine headache as this is considered investigational.

Surgical Ventricular Restoration

AA. BCNEPA will not provide coverage for surgical ventricular restoration for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm as this is considered investigational.

Treatment of Sacroiliac Joint Pain

BB. BCNEPA will not provide coverage for the use of fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint as it is considered investigational, including but not limited to percutaneous and minimally invasive techniques [Si-FIX Sacroiliac Joint Fusion System (Medtronic), IFUSE Implant System (SI Bone), Simmetry Sacroiliac Joint Fusion System (Zyga Technologies) SI-LOK (Globus Medical)].
Vertical Expandable Prosthetic Titanium Rib

CC. BCNEPA will not provide coverage for the use of the vertical expandable prosthetic titanium rib except in the treatment of progressive thoracic insufficiency syndrome due to rib and/or chest wall defects in infants/children between 6 months of age and skeletal maturity; as all other indications are 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).
The five character codes included in the Blue Cross of Northeastern Pennsylvania’s Medical Policy are obtained from Current Procedural Terminology (CPT®), copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures.

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CPT is a registered trademark of the American Medical Association.

- 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.

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