



BlueCross BlueShield of Vermont

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Investigational Services and Procedures Corporate Medical Policy

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Description

The following is an attempt to outline current services and procedures considered to be investigational by Blue Cross Blue Shield of Vermont for purposes of transparency and ease of use for practitioners.

Definition of Investigational

“Experimental or investigational services” means health care items or services that are either not generally accepted by informed health care providers in the United States as effective in treating the condition, illness or diagnosis for which their use is proposed, or are not proven by medical or scientific evidence to be effective in treating the condition, illness or diagnosis for which their use is proposed.

Technologies are assessed using the following criteria. Any technology that **fails to meet ALL** of the following criteria is considered to be “Investigational”:

1. The technology must have final approval from the appropriate governmental regulatory bodies.

- This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration or any other federal governmental body with authority to regulate the use of the technology.
- Any approval that is granted as an interim step in the U.S. Food and Drug Administration’s or any other federal governmental body’s regulatory process is not sufficient.
- The indications for which the technology is approved need not be the same as those which the Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policy Committee is evaluating.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

- The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
- The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.

3. The technology must improve the net health outcome.

- The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.

4. The technology must be as beneficial as any established alternatives.

- The technology should improve the net health outcome as much as, or more than, established alternatives.

5. The improvement must be attainable outside the investigational settings.

- When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria #3 and #4.

In reviewing the above criteria, the BCBSVT Medical Policy Committee will consider physician specialty society recommendations, the view of prudent medical practitioners practicing in relevant clinical areas and any other relevant factors.

Policy

The following is a list of current services and procedures grouped by discipline and/or function which are considered investigational and therefore not covered:

Cardiology/Cardiothoracic Surgery

- The use of the Presage® ST2 Assay to evaluate the prognosis of patients diagnosed with chronic heart failure.
- The use of the Presage® ST2 Assay to guide management (pharmacological, device-based, exercise, etc.) of patients diagnosed with chronic heart failure.
- The use of the Presage® ST2 Assay in the post cardiac transplantation period, including but not limited to predicting prognosis and predicting acute cellular rejection.
- The measurement of volatile organic compounds with the Heartsbreath test to assist in the detection of grade 3 heart transplant rejection.
- The use of peripheral blood genetic profiling tests in the management of patients after heart transplantation, including but not limited to the detection of acute heart transplant rejection or heart transplant graft dysfunction.
- Enhanced external counterpulsation for all indications including but not limited to, treatment of chronic stable angina pectoris, heart failure, erectile dysfunction, or ischemic stroke.

- Cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk, are considered investigational.
- Electrocardiographic body surface mapping for the diagnosis or management of cardiac disorders, including acute coronary syndrome.
- Gene expression testing to predict coronary artery disease (CAD) for all indications, including but not limited to prediction of the likelihood of CAD in stable, nondiabetic patients.
- Use of baroreflex stimulation implanted devices.
- Genetic testing for dilated cardiomyopathy.
- Surgical ventricular restoration for the treatment of ischemic dilated cardiomyopathy or postinfarction left ventricular aneurysm.
- The use of ultrafiltration in patients with heart failure.
- The use of computed tomography (CT) to detect coronary artery calcification (CAC).
- Myocardial sympathetic innervation imaging with 123Iodine meta-iodobenzylguanidine (MIBG) for patients with heart failure.
- Progenitor cell therapy as a treatment of damaged myocardium, including but not limited to skeletal myoblasts or hematopoietic stem cells.
- Infusion of growth factors (ie, granulocyte colony stimulating factor [G-CSF]) as a technique to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium.
- The use of percutaneous left atrial appendage closure devices for the prevention of stroke in atrial fibrillation.
- In the ambulatory care and outpatient setting, 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 .
- Radiofrequency ablation of the renal sympathetic nerves for the treatment of resistant hypertension.
- The use of genetic testing for the LPA rs3798220 allele (LPA-Aspirin Genotype) in patients who are being considered for treatment with aspirin to reduce the risk of cardiovascular events.
- The use of genotyping for 9p21 single nucleotide polymorphisms (SNPs) for all clinical uses, including but not limited to identification of patients who may be at increased risk of cardiovascular disease or its manifestations (eg, MI, ischemic stroke, peripheral arterial disease, coronary artery calcification), or identification of patients who may be at increased risk for aneurysmal disease (AAAs, intracranial aneurysms, polypoidal choroidal vasculopathy).
- Measurement of novel lipid and nonlipid risk factors (ie, apolipoprotein B, apolipoprotein AI, apolipoprotein E, B-type natriuretic peptide, cystatin C, fibrinogen, leptin, LDL subclass, HDL subclass, lipoprotein[a]) as an adjunct to LDL cholesterol in the risk assessment and management of cardiovascular disease.
- KIF6 genotyping for predicting cardiovascular risk and/or the effectiveness of statin therapy.
- Optical coherence tomography in all situations, including but not limited to, risk stratification of intracoronary atherosclerotic plaques and follow-up evaluation of stenting.

- The use of implantable sinus stents for postoperative treatment following endoscopic sinus surgery.
- Use of baroreflex stimulation implanted devices.

Dermatology

- Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, as a technique to evaluate or serially monitor pigmented skin lesions.
- Computer-based optical imaging devices, eg, multispectral digital skin lesion analysis as a technique to evaluate or serially monitor pigmented skin lesions.
- Dermatoscopy and computer-based optical imaging devices for defining peripheral margins of skin lesions suspected of malignancy prior to surgical excision.
- Nonpharmacologic treatment of rosacea, including but not limited to laser and light therapy, dermabrasion, chemical peels, surgical debulking and electrosurgery.
- Electronic brachytherapy for the treatment of nonmelanoma skin cancer.
- Genetic testing for mutations associated with familial cutaneous malignant melanoma or associated with susceptibility to cutaneous malignant melanoma.
- Melanoma vaccines.
- Topical hyperbaric oxygen therapy.
- Laser treatment of onychomycosis.
- Electrical stimulation for the treatment of wounds, including but not limited to low-intensity direct current, high-voltage pulsed current, alternating current, and transcutaneous electrical nerve stimulation.
- Electrical stimulation performed by the patient in the home setting for the treatment of wounds.
- Electromagnetic therapy for the treatment of wounds.
- Noncontact ultrasound treatment for wounds.

Endocrinology

- Measurement of bone turnover markers in the diagnosis and management of osteoporosis.
- Measurement of bone turnover markers in the management of patients with conditions associated with high rates of bone turnover, including but not limited to Paget disease, primary hyperparathyroidism and renal osteodystrophy.
- Mutation analysis in fine-needle aspirates of the thyroid.
- The use of a gene expression classifier in fine-needle aspirates of the thyroid that are cytologically considered to be indeterminate, atypical or suspicious for malignancy.
- Chronic intermittent intravenous insulin therapy.
- Allogeneic islet transplantation.

Gastroenterology

- Implantable magnetic esophageal ring to treat gastroesophageal reflux disease.

- Gastric electrical stimulation for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiology.
- Gastric electrical stimulation for the treatment of obesity.
- 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.
- Peroral endoscopic myotomy as a treatment for esophageal achalasia.
- Measurement of antibodies to infliximab in a patient receiving treatment with infliximab, either alone or as a combination test which includes the measurement of serum infliximab levels.
- Measurement of antibodies to adalimumab in a patient receiving treatment with adalimumab, either alone or as a combination test which includes the measurement of serum adalimumab levels.
- Transoral incisionless fundoplication (TIF) (ie, Esophyx®) as a treatment of gastroesophageal reflux disease.
- Transesophageal radiofrequency to create submucosal thermal lesions of the gastroesophageal junction (ie, Stretta® procedure) as a treatment of gastroesophageal reflux disease.
- Endoscopic submucosal implantation of a prosthesis or injection of a bulking agent (eg, polymethylmethacrylate beads, zirconium oxide spheres) as a treatment of gastroesophageal reflux disease.
- Fecal calprotectin testing in the diagnosis and management of intestinal conditions, including the diagnosis and management of inflammatory bowel disease.
- Transanal radiofrequency therapy as a treatment of fecal incontinence.
- Chromoendoscopy as an adjunct to diagnostic or surveillance colonoscopy
- Virtual chromoendoscopy as an adjunct to diagnostic or surveillance colonoscopy.
- Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for fecal incontinence.
- Use of confocal laser endomicroscopy.
- Hydrogen/methane breath testing (CPT: 91065).
- DNA analysis of stool samples as a screening technique for colorectal cancer in both patients with average to moderate risk and in patients considered at high risk for colorectal cancer.
- Fecal analysis of the following components as a diagnostic test for the evaluation of intestinal dysbiosis, irritable bowel syndrome, malabsorption, or small intestinal overgrowth of bacteria:
 - Triglycerides
 - Chymotrypsin
 - Iso-butyrate, iso-valerate, and n-valerate
 - Meat and vegetable fibers
 - Long-chain fatty acids
 - Cholesterol
 - Total short-chain fatty acids
 - Levels of Lactobacilli, bifidobacteria, and E. coli and other “potential pathogens,” including Aeromonas, B. cereus, Campylobacter,

- Citrobacter, Klebsiella, Proteus, Pseudomonas, Salmonella, Shigella, S. aureus, and Vibrio
 - Identification and quantitation of fecal yeast (including Candida albicans, Candida tropicalis, Rhodotorula, and Geotrichum)
 - N-butyrate-glucuronidase
 - pH
 - Short-chain fatty acid distribution (adequate amount and proportions of the different short-chain fatty acids reflect the basic status of intestinal metabolism)
 - Fecal secretory IgA
- Molecular testing using the PathFinderTG® system for all indications including the evaluation of pancreatic cyst fluid, suspected or known gliomas, and Barrett esophagus.
- Evaluation of AFP-L3 biomarkers in the screening, diagnosis, or monitoring of patients with suspected or known hepatocellular cancer.
- Electromagnetic navigation bronchoscopy for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes.
- Electromagnetic navigation bronchoscopy for the placement of fiducial markers.
- An implantable magnetic esophageal ring to treat gastroesophageal reflux disease.
- Use of wireless pressure sensors in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair.
- Vagus nerve stimulation as a treatment of conditions including but not limited to heart failure, fibromyalgia, depression, essential tremor, obesity, headaches, tinnitus, and traumatic brain injury.
- Nonimplantable vagus nerve stimulation devices.

General, Colon & Rectal Surgery

- Embolization of the ovarian vein and internal iliac veins as a treatment of pelvic congestion syndrome.
- Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery.
- Biosynthetic fistula plugs, including plugs made of porcine small intestine submucosa or of synthetic material, including, but not limited to, repair of anal and rectal fistulas.
- Intra-abdominal vagal nerve blocking therapy in all situations, including but not limited to the treatment of obesity.
- Surgical deactivation of trigger sites for the treatment of migraine and nonmigraine headache.
- Composite tissue allotransplantation of the hand and/or face.
- Preoperative or intraoperative sentinel lymph node detection using handheld or mounted mobile gamma cameras.
- The use of autologous fat grafting to the breast, with or without adipose-derived stem cells.
- Cryosurgical ablation of either primary or metastatic tumors in the liver.
- Gastric bypass using a Billroth II type of anastomosis, popularized as the mini-gastric bypass

- Biliopancreatic bypass without duodenal switch
- Long-limb gastric bypass procedure (i.e., >150 cm)
- Endoscopic procedures (e.g., insertion of the StomaphyX™ device) as a primary bariatric procedure or as a revision procedure, i.e., to treat weight gain after bariatric surgery to remedy large gastric stoma or large gastric pouches
- Bariatric surgery as a cure for type 2 diabetes mellitus
- Handheld radiofrequency spectroscopy for intraoperative assessment of surgical margins during breast-conserving surgery.

Genetic, Serum Biomarker Tests, Panel and Screening Tests

- Methylenetetrahydrofolate reductase (MTHFR) (NADPH)
- PCR-based direct detection of *B burgdorferi* in urine samples.
- Serum biomarker tests for multiple sclerosis.
- Intracellular micronutrient panel testing.
- 23andme.
- Measurement of bone turnover markers in the diagnosis and management of osteoporosis.
- Measurement of bone turnover markers in the management of patients with conditions associated with high rates of bone turnover, including but not limited to Paget disease, primary hyperparathyroidism and renal osteodystrophy.
- Cardiovascular risk panels, consisting of multiple individual biomarkers intended to assess cardiac risk (other than simple lipid panels).
- Evaluation of AFP-L3 biomarkers in the screening, diagnosis, or monitoring of patients with suspected or known hepatocellular cancer.
- Multi-target polymerase chain reaction (PCR) testing for diagnosis of bacterial vaginosis.
- Serum biomarker panel testing with proprietary algorithms and/or index scores for the diagnosis of systemic lupus erythematosus.
- Measurement of human epididymis protein 4 (HE4).
- Measurement of direct-acting antiviral drug metabolite levels for the purpose of monitoring adherence to treatment for hepatitis C infection.

Neurology

- Genetic testing for the diagnosis or risk assessment of Alzheimer disease. Genetic testing includes, but is not limited to, testing for the apolipoprotein E epsilon 4 allele (APOE), presenilin genes (PSEN), amyloid-beta precursor protein (APP), or triggering receptor expressed on myeloid cells 2 (TREM2).
- CT-based perfusion imaging of the brain for all indications including the diagnosis and management of acute cerebral ischemia (stroke).
- Dopamine transporter imaging with single-photon emission computed tomography (DAT-SPECT), including but not limited to, aiding in the diagnosis of patients with clinically uncertain parkinsonian syndromes, essential tremor, or dementia with Lewy bodies, and for the monitoring of disease progression.
- Measurement of cerebrospinal fluid biomarkers of Alzheimer disease, including but not limited to tau protein, amyloid-beta peptides, or neural thread proteins.

- Measurement of urinary biomarkers of Alzheimer disease, including but not limited to neural thread proteins.
- Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.
- Automated nerve conduction tests.
- Serum biomarker tests for multiple sclerosis.
- 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.
- Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES).
- Electrical stimulation of auricular acupuncture points.
- Percutaneous electrical neurostimulation or neuromodulation.
- Peripheral subcutaneous field stimulation.
- Minimally invasive ablation procedures, RFA, and cryoablation for treatment of peripheral neuromas.
- 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.
- Surgical deactivation of trigger sites for the treatment of migraine and non-migraine headache.
- Occipital nerve stimulation for all indications.
- Autonomic Response Testing (A.R.T.), a method of muscle testing.

Obstetrics & Gynecology

- Multitarget polymerase chain reaction (PCR) testing for diagnosis of bacterial vaginosis.
- Laparoscopic uterine nerve ablation (LUNA) and laparoscopic presacral neurectomy (LPSN) as techniques to treat primary or secondary dysmenorrhea.
- Fetal RHD genotyping using maternal plasma.
- Laparoscopic and percutaneous techniques of myolysis as a treatment of uterine fibroids.
- Embolization of the ovarian vein and internal iliac veins as a treatment of pelvic congestion syndrome.
- Injection of micronized amniotic membrane.
- Injection of amniotic fluid.

Oncology/Hematology

- Bevacizumab for treatment of advanced adenocarcinoma of the pancreas.
- Intracellular micronutrient panel testing.
- Whole exome sequencing and whole genome sequencing for the diagnosis of genetic disorders.
- Measurement of HE4.
- Testing for 1 or more single nucleotide polymorphisms (SNPs) to predict an individual's risk of breast cancer.

- The OncoVue® and BREVAGenplus® breast cancer risk tests for all indications, including but not limited to use as a method of estimating individual patient risk for developing breast cancer.
- Genetic testing for CHEK2 mutations in patients with breast cancer or for cancer risk assessment in patients with or without a family history of breast cancer.
- Detection and quantification of circulating tumor cells in the management of patients with cancer.
- The use of proteomic testing, including but not limited to the VeriStrat assay, for all uses in the management of non-small-cell lung cancer.
- Use of tests utilizing systems pathology that include cellular and biologic features of a tumor, including use in predicting risk of recurrence in patients with prostate cancer.
- MGMT promoter methylation testing for prognostic value or as a predictive biomarker for response to treatment with alkylating agents.
- Genetic testing for PALB2 mutations in patients with breast or pancreatic cancer or for cancer risk assessment in patients with or without a family history of breast or pancreatic cancer.
- The use of positron emission tomography scans to determine early response to treatment (PET scans done during a planned course of chemotherapy and/or radiation therapy) in patients with cancer.
- NRAS mutation analysis to predict nonresponse to anti-EGFR monoclonal antibodies cetuximab and panitumumab in the treatment of metastatic colorectal cancer.
- BRAF mutation analysis to predict nonresponse to anti-EGFR monoclonal antibodies cetuximab and panitumumab in the treatment of metastatic colorectal cancer.
- My5-FU™ testing or other types of assays for determining 5-fluorouracil area under the curve in order to adjust 5-FU dose for colorectal cancer patients or other cancer patients.
- TheraGuide® testing for genetic mutations in dipyrimidine dehydrogenase (DPYD) or thymidylate synthase (TYMS) to guide 5-FU dosing and/or treatment choice in patients with cancer.
- The assessment of HER2 status by quantitative total HER2 protein expression and HER2 homodimer measurement.
- Gene expression profiling to evaluate the site of origin of a tumor of unknown primary, or to distinguish a primary from a metastatic tumor.
- All uses of the OVA1 and ROMA tests, including but not limited to:
 - preoperative evaluation of adnexal masses to triage for malignancy, or
 - screening for ovarian cancer, or
 - selecting patients for surgery for an adnexal mass, or
 - evaluation of patients with clinical or radiologic evidence of malignancy, or
 - evaluation of patients with nonspecific signs or symptoms suggesting possible malignancy, or
 - postoperative testing and monitoring to assess surgical outcome and/or to detect recurrent malignant disease following treatment.

- Microarray-based gene expression profile testing for multiple myeloma for all indications.
- Adoptive immunotherapy for all indications including using adoptive cellular therapy for the administration of cytotoxic T lymphocytes, cytokine-induced killer cells, lymphokine-activated killer cells, tumor-infiltrating lymphocytes, antigen-loaded autologous dendritic cells, or genetically engineered T cells.
- In vitro chemosensitivity assays, including, but not limited to, the Histoculture Drug Response Assay, a fluorescent cytoprint assay, the ChemoFx assay, or the CorrectChemo assay.
- In vitro chemoresistance assays, including, but not limited to, Extreme Drug Resistance assays.
- Genotyping to determine cytochrome p450 2D6 (CYP2D6) genetic polymorphisms for the purpose of managing treatment with tamoxifen for women at high risk for or with breast cancer.
- Autologous or allogeneic hematopoietic stem-cell transplantation as a treatment of autoimmune diseases, including, but not limited to, the following:
 - Multiple sclerosis
 - Juvenile idiopathic and rheumatoid arthritis
 - Systemic lupus erythematosus
 - Systemic sclerosis/scleroderma
 - Type 1 diabetes mellitus
 - Chronic inflammatory demyelinating polyneuropathy.
- Use of the immune cell function assay to monitor and predict immune function after solid organ transplantation.
- Use of the immune cell function assay to monitor and predict immune function after hematopoietic stem cell transplantation.
- Intracavitary balloon catheter brain brachytherapy, alone or as part of a multimodality treatment regimen, for primary, recurrent, or metastatic malignant brain tumors.
- Microwave ablation of primary and metastatic tumors.
- Autologous or allogeneic hematopoietic stem-cell transplantation to treat epithelial ovarian cancer.
- Gene expression analysis and protein biomarker to guide management of prostate cancer.
- The following genetic and protein biomarkers for the diagnosis of prostate cancer:
 - Kallikrein markers (eg, 4Kscore™ Test)
 - Metabolomic profiles (eg, Prostarix™)
 - □PCA3 testing
 - □TMPRSS fusion genes
 - Candidate gene panels
 - Mitochondrial DNA mutation testing (eg, Prostate Core Mitomics Test™)
 - Gene hypermethylation testing (eg, ConfirmMDx®)
 - Single nucleotide polymorphisms (SNPs) testing for cancer risk assessment of prostate cancer.
- Donor lymphocyte infusion following allogeneic HSCT that was originally considered investigational for the treatment of a hematologic malignancy.

- Donor lymphocyte infusion as a treatment of nonhematologic malignancies following a prior allogeneic HSCT.
- Genetic modification of donor lymphocytes.
- Intracavitary balloon catheter brain brachytherapy, alone or as part of a multimodality treatment regimen, for primary or recurrent malignant brain tumors.
- Intracavitary balloon catheter brain brachytherapy, alone or as part of a multimodality treatment regimen, for metastasis to the brain from primary solid tumors outside the brain.
- Gene expression profiling for uveal melanoma.

Ophthalmology

- Intraocular placement of a radiation source for the treatment of choroidal neovascularization
- Intraocular proton beam therapy for the treatment of choroidal neovascularization
- Stereotactic radiation therapy for the treatment of choroidal neovascularization
- Retinal prostheses.
- Gene expression profiling for uveal melanoma.
- Genetic testing for macular degeneration.
- Eyelid thermal pulsation therapy to treat dry eye syndrome.
- Scanning computerized ophthalmic (eg, OCT) imaging of the anterior eye segment.
- Corneal collagen cross-linking for all indications.
- Intraocular placement of a radiation source for the treatment of choroidal neovascularization.
- Intraocular proton beam therapy for the treatment of choroidal neovascularization.
- Stereotactic radiation therapy for the treatment of choroidal neovascularization.

Orthopedics/Podiatry/Sports Medicine

- Total facet arthroplasty.
- Semi-invasive electrical stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion.
- Invasive, semi-invasive, and noninvasive electrical stimulation as an adjunct to cervical fusion surgery and for failed cervical spine fusion.
- Laser treatment of onychomycosis.
- Injection of micronized amniotic membrane for all indications.
- Injection of amniotic fluid for all indications.
- Artificial intervertebral discs of the lumbar spine.
- Mesenchymal stem cell therapy for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue.
- Allograft bone products containing viable stem cells, including but not limited to demineralized bone matrix (DBM) with stem cells.
- Allograft or synthetic bone graft substitutes that must be combined with autologous blood or bone marrow.

- Interspinous distraction devices as a treatment of neurogenic intermittent claudication.
- Use of custom implants or patient-specific instrumentation (eg, cutting guides) for joint arthroplasty, including but not limited to use in unicompartmental or total knee arthroplasty.
- Use of an interlaminar stabilization device following decompressive surgery.
- Axial lumbosacral interbody fusion (axial LIF).
- Subtalar arthroereisis.
- Alcohol injections for treatment of Morton neuroma.
- Automated percutaneous discectomy as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.
- Endoscopic discectomy as a technique of intervertebral disc decompression in patients with back pain and/or radiculopathy related to disc herniation in the lumbar, thoracic, or cervical spine.
- Combination active cooling and compression (cryopneumatic) devices.
- Screening for vertebral fractures using dual-energy x-ray absorptiometry (DXA or DEXA).
- 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 (lateral epicondylitis), Achilles tendinitis, and patellar tendinitis; spasticity; stress fractures; delayed union and nonunion of fractures; and avascular necrosis of the femoral head.
- Laser discectomy and radiofrequency coblation (disc nucleoplasty) as techniques of disc decompression and treatment of associated pain.
- Surgical treatment of athletic pubalgia (also known as Gilmore groin, osteitis pubis, pubic inguinal pain syndrome, inguinal disruption, slap shot gut, sportsmen groin, footballers groin injury complex, hockey groin syndrome, athletic hernia, sports hernia, or core muscle injury).
- Percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain.
- Allograft bone products containing viable stem cells, including but not limited to demineralized bone matrix (DBM) with stem cells.
- Regenerative Injection Treatments (RIT, Prolotherapy) Use of platelet-rich plasma for all orthopedic indications. This includes, but is not limited to, use in the following situations:
 - Primary use (injection) for the following conditions:
 - Achilles tendinopathy
 - Lateral epicondylitis
 - Osteochondral lesions
 - Osteoarthritis
 - Plantar fasciitis
 - Adjunctive use in the following surgical procedures:
 - ACL reconstruction
 - Hip fracture
 - Long-bone nonunion
 - Patellar tendon repair

- Rotator cuff repair
 - Spinal fusion
 - Subacromial decompression surgery
- Neural therapy for all indications.
- Image-guided minimally invasive lumbar decompression.
- DNA-based prognostic testing for adolescent idiopathic scoliosis.
- Arthrography of the sacroiliac joint.
- Radiofrequency denervation of the sacroiliac joint.
- Vertebral axial decompression.
- Total facet arthroplasty.
- Interspinous fixation (fusion) devices including but not limited to use:
 - in combination with interbody fusion, or
 - alone for decompression in patients with spinal stenosis.
- The use of dynamic spinal visualization.
- Intravenous infusion of anesthetics (eg, ketamine or lidocaine) for the treatment of chronic pain, including, but not limited to chronic neuropathic pain, chronic daily headache, and fibromyalgia.
- Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities.

Otolaryngology

- Transtympanic micropressure applications as a treatment of Meniere disease
- The use of implantable sinus stents for postoperative treatment following endoscopic sinus surgery
- Treatment of tinnitus with tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, tinnitus coping therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, sound therapy, or botulinum toxin A injections .
- Use of a catheter-based inflatable device (balloon ostial dilation) in the treatment of sinusitis.
- Semi-implantable and fully implantable middle ear hearing aids.
- Uvulectomy for the treatment of obstructive sleep apnea and other sleep related breathing disorders.
- Partial glossectomy for the treatment of obstructive sleep apnea and other sleep related breathing disorders.
- Radiofrequency volumetric tissue reduction of the tongue base or palatal tissues.
- Tongue base suspension procedures, including but not limited to the Repose™.
- Laser-assisted palatoplasty (LAUP) or volumetric tissue reduction.
- Palatal stiffening procedures, including but not limited to the following:
 - Cautery-assisted palatal stiffening operation (CAPSO)
 - Injection of sclerosing agent
 - Implantation of palatal implants (also known as the pillar procedure.
- Nasal surgery employing any technique, including nasal valve surgery, septoplasty, turbinectomy, polypectomy and laser or radiofrequency ablation (volumetric tissue reduction) of the nasal turbinates for the treatment of obstructive sleep apnea and other sleep related breathing disorders.
- Penetrating electrode auditory brainstem implant (PABI).

Physical Medicine/Pain Management/Chiropractic

- Spinal manipulation (and manipulation of other joints, eg, hip joint, performed during the procedure) with the patient under anesthesia, spinal manipulation under joint anesthesia, and spinal manipulation after epidural anesthesia and corticosteroid injection for treatment of chronic spinal (cranial, cervical, thoracic, lumbar) pain and chronic sacroiliac and pelvic pain.
- Spinal manipulation and manipulation of other joints under anesthesia involving serial treatment sessions.
- Manipulation under anesthesia involving multiple body joints for treatment of chronic pain.
- Electromagnetic therapy for the treatment of wounds.
- The use of dynamic spinal visualization.
- Neural therapy for all indications.
- Devices using bioimpedance (bioelectrical impedance spectroscopy) for use in the diagnosis, surveillance, or treatment of patients with lymphedema, including use in subclinical secondary lymphedema.
- Peripheral subcutaneous field stimulation.
- Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities.
- Noncontact ultrasound treatment for wounds.
- Dynamic posturography.
- Intravenous infusion of anesthetics (eg, ketamine or lidocaine) for the treatment of chronic pain, including, but not limited to chronic neuropathic pain, chronic daily headache, and fibromyalgia.
- Occipital nerve stimulation for all indications.
- Paraspinal surface electromyography (SEMG) as a technique to diagnose or monitor back pain.
- Interferential current stimulation.
- Prolotherapy as a treatment of musculoskeletal pain.
- Percutaneous electrical neurostimulation or neuromodulation.
- Neurofeedback.
- Aqua Massage tables.
- Applied Spinal Biomechanical Engineering.
- Atlas Orthogonal Technique.
- BioEnergetic Synchronization Technique.
- Biogeometric Integration.
- Blair Technique.
- Chiropractic Biophysics Technique, known as Chiropractic
- Biomechanics of Posture (CPB).
- Coccygeal Meningeal Stress Fixation Technique.
- Computerized radiographic mensuration analysis for assessing spinal mal-alignment.
- Cranial Manipulation.
- Craniosacral Therapy.
- Cryotherapy, cryo spa, whole body cryotherapy.
- Digital Postural Analysis.

- Digital Radiographic Measurement.
- Directional Non-force Technique.
- Dry hydrotherapy (i.e., Aquamed, Sidmar).
- Dynamic posturography.
- Emotional Freedom Technique (EFT)/tapping.
- Gait analysis.
- Kinesiology Taping.
- Paraspinal Surface Electromyography (SEMG), and Macro Electromyography.
- Gait analysis.
- Hubbard Tank.
- Iontophoresis/Phonophoresis.
- Interferential current stimulation.
- Koren Specific Technique.
- Low Level Laser Therapy/Cold Laser.
- Lumbar/Cervical Extension Machines (Med X).
- Manipulation for infant colic.
- Manipulation under Anesthesia.
- Moire Contourographic Analysis.
- Network Technique (Network chiropractic care/ Network Spinal Analysis (NSA)).
- Network Spinal Analysis software.
- Neural Organizational Technique.
- Neuro Emotional Technique.
- Neurocalometer/Nervoscope.
- Oscillating Platform Therapy (Spineforce).
- Para-Spinal Electomyography (EMG)/Surface Scanning EMG.
- Power traction equipment/devices (e.g., VAX-D, DRX 9000, SpineMED, Spina System, Lordex Decompression Unit, DRS System).
- Prolotherapy.
- Sacro-Occipital Technique.
- SCENAR Therapy.
- Sensory Integration Therapy and auditory therapy.
- Spinal manipulation under anesthesia.
- Spinalator Tables.
- Spinoscop.
- Surface EMG.
- Thermography.
- Therapeutic Magnetic Resonance (TMR).
- Treatment with crystals.
- Thermal Massage Bed, Hydro Therapy Massage.
- Upledger Technique.
- Vertebral axial decompression - (i.e. DRS System, DRX Systems, DTS, VAX-D Table, Alpha Spina System, Accuspina, Lordex Lumbar Spine System, Internal Disc Decompression (IDD)), distraction tables. (S9090)
- Whitcomb Technique.
- Whole Body Vibration Therapy.
- Whole Body Advance Exercise.
- Wobble chair.

Psychiatry

- Cranial electrotherapy stimulation (CES).
- Opioid antagonists under heavy sedation or anesthesia as a technique for opioid detoxification (ie, ultrarapid detoxification).
- Sensory integration therapy and auditory integration therapy.
- Quantitative electroencephalographic-based assessment of the theta/beta ratio as a diagnostic aid for attention deficit/hyperactivity disorder.
- Sensory integration modalities including, but not limited to, Berard Auditory integration training [AIT]; The Audio Tone Enhancer/Trainer; Digital Auditory Aerobics; Electronic Auditory Stimulation effect (EASe program); Kirby Auditory Modulation System (KAMS); SAMONAS Sound Therapy; Tomatis Sound Therapy The LiFTTM; The Listening Program.
- Social skills training programs (except social skills training within ABA), including social skills groups and social story programs.

Pulmonology

- Endobronchial valves in all situations including, but not limited to:
 - Treatment of prolonged air leaks
 - Treatment for patients with chronic obstructive pulmonary disease (COPD) or emphysema
- Electromagnetic navigation bronchoscopy for use with flexible bronchoscopy for the diagnosis of pulmonary lesions and mediastinal lymph nodes as well as for the placement of fiducial markers.
- Measurement of exhaled nitric oxide in the diagnosis and management of asthma and other respiratory disorders including but not limited to chronic obstructive pulmonary disease and chronic cough.
- Measurement of exhaled breath condensate in the diagnosis and management of asthma and other respiratory disorders including but not limited to chronic obstructive pulmonary disease and chronic cough.
- Bronchial thermoplasty for the treatment of asthma.

Radiology

- Positional (non-recumbent) magnetic resonance imaging (MRI), including its use in the evaluation of patients with cervical, thoracic, or lumbosacral back pain.
- The use of all forms of thermography.
- Dual x-ray absorptiometry (DEXA) body composition studies.
- Radioimmunoscinigraphy using indium-111 capromab pendetide (ProstaScint®).
- Navigated transcranial magnetic stimulation for all purposes, including but not limited to the preoperative evaluation of patients being considered for brain surgery, when localization of eloquent areas of the brain (eg, controlling verbal or motor function) is an important consideration in surgical planning.
- Scintimammography, breast-specific gamma imaging (BSGI), and molecular breast imaging (MBI), including but not limited to their use as an adjunct to mammography or in staging the axillary lymph nodes.
- The use of positron emission mammography (PEM) for all indications.
- Beta amyloid imaging with positron emission tomography (PET).

- The use of computer-aided evaluation (CAE) for interpretation of magnetic resonance imaging (MRI) of the breast.
- Magnetic resonance spectroscopy.

Rheumatology

- The use of a multi-biomarker disease activity score for rheumatoid arthritis (RA) (eg, Vectra DA score) in all situations.

Vascular Surgery

- Use of wireless pressure sensors in the management (intraoperative and/or postoperative) of patients having endovascular aneurysm repair.
- Ultrasonographic measurement of carotid artery intima-medial thickness (CIMT) as a technique for identifying subclinical atherosclerosis for use in the screening, diagnosis, or management of atherosclerotic disease.
- Endovascular therapy, including percutaneous transluminal angioplasty with or without stenting, for the management of extracranial vertebral artery disease.
- Treatment of peripheral arterial disease, including critical limb ischemia, with injection or infusion of cells concentrated from bone marrow aspirate.

Urology

- Saturation biopsy in the diagnosis, staging, and management of prostate cancer.
- Unilateral or bilateral nerve graft in patients who have undergone resection of one or both neurovascular bundles as part of a radical prostatectomy.
- The use of urinary tumor markers in the diagnosis of, monitoring, and/or screening for bladder cancer.
- Percutaneous tibial nerve stimulation for all indications, including but not limited to the following:
 - Urinary dysfunction, including but not limited to overactive bladder syndrome, neurogenic bladder, urinary frequency, urgency, incontinence, and retention.
 - Fecal incontinence.
- The following genetic and protein biomarkers for the diagnosis of prostate cancer:
 - Kallikrein markers (eg, 4Kscore™ Test)
 - Metabolomic profiles (eg, Prostarix™)
 - PCA3 testing
 - TMPRSS fusion genes
 - Candidate gene panels
 - Mitochondrial DNA mutation testing (eg, Prostate Core Mitomics Test™)
 - Gene hypermethylation testing (eg, ConfirmMDx®)
- Single nucleotide polymorphisms (SNPs) testing for cancer risk assessment of prostate cancer.
- Use of any focal therapy modality to treat patients with localized prostate cancer.
- Gene expression analysis and protein biomarker to guide management of prostate cancer.

- Electrical or magnetic stimulation of the pelvic floor muscles (pelvic floor stimulation) as a treatment for urinary incontinence.
- Unilateral or bilateral nerve graft in patients who have undergone resection of one or both neurovascular bundles as part of a radical prostatectomy.
- The use of autologous cellular therapy (eg, myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells), autologous fat, and autologous ear chondrocytes to treat stress urinary incontinence.
- The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence.
- The use of periurethral bulking agents to treat urge urinary incontinence.

Miscellaneous Treatments and Therapies (not all inclusive)

- Access consciousness bars
- Aromatherapy
- Arvigo Technique
- Acutonics sound therapy
- Amethyst Biomat
- Applied Kinesiology
- Auriculotherapy
- Aura Healing
- Bee sting therapy
- Bioidentical hormones
- Biomagnetic therapy
- BioMeridian testing
- Botanical medicine therapy
- Chakra therapy
- Chinese cosmology
- Chinese herbs
- Cold Laser Therapy
- Contact reflex analysis
- Cranialsacral therapy
- Crystal therapy
- Cupping
- Dark Field Microscopy
- Detoxification/Cleansing therapies
- Dry needling/trigger point dry needling (TPDN)
- Ear Candling
- Energy therapy/Medicine (Reiki, Body Talk, Brennan-style healing)
- Essential oils
- Facial rejuvenation
- First Line Therapy - therapeutic lifestyle program
- Frequency Specific Microcurrent (FMS)
- Gua Sha
- Group Acupuncture
- Healing touch
- Herbal Medicine

- Hydrotherapy/hydromassage
- Interferential electric muscle stimulation/electro-therapy
- Laser Therapy (Light Amplification by Stimulated Emission of Radiation)
- Low Level Laser Therapy
- Macrobiotic diet
- Maya Abdominal Therapy
- Mild hyperbaric oxygen treatment (mild HBOT)/community hyperbaric
- Moxibustion
- Nutrition Response Testing
- Oxidative Medicine
- Plant Spirit Medicine
- Qigong
- Reflexology
- Shiatsu
- Sound Healing
- Somatic Experience
- SRT-3 light belt
- Stone therapy
- Tuina
- Visceral manipulation
- Zero balancing

Reference Resources

Blue Cross Blue Shield Association Medical Policy Reference Manual. These policies are available upon request.

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required and benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services only (ASO) only group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

09/2016	New Policy.
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Health Care Procedure Coding System (HCPCS) codes related to chemotherapy drugs, drugs administered other than oral method, and enteral/parenteral formulas may be subject to National Drug Code (NDC) processing and pricing. The use of NDC on medical claims helps facilitate more accurate payment and better management of drug costs based on what was dispensed and may be required for payment. For more information on BCBSVT requirements for billing of NDC please refer to the provider portal <http://www.bcbsvt.com/provider-home> latest news and communications.

Approved by BCBSVT Medical Directors **Date Approved**

Joshua Plavin, MD
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Chair, Health & Payment Policy Committee

Robert Wheeler MD
Chief Medical Officer