

List of Investigational Procedures

Initial Date: August 2004 Revised: April, 2021

This list is subject to the terms in the IMPORTANT NOTICE at the end of this document

Disclaimer

This list is subject to member evidence of coverage guidelines. For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions on this list, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this list. For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to using this list. Refer to the CMS website at https://www.cms.gov/ for additional information.

Definition

Health Net considers as Experimental or Investigational if it meets any of the following:

- It is currently the subject of active and credible evaluation (e.g., clinical trials or research) to determine:
 - clinical efficacy,
 - \circ $\;$ the rapeutic value or beneficial effects on health outcomes, or
 - \circ benefits beyond any established medical based alternative.
- It is the subject of an active and credible evaluation and does not have final clearance from applicable governmental regulatory bodies (such as the US Food and Drug Administration "FDA") and unrestricted market approval for use in the treatment of a specified medical condition or the condition for which authorization of the Service is requested.
- The most recent peer-reviewed scientific studies published or accepted for publication by nationally recognized medical journals do not conclude, or are inconclusive in finding, that the Service is safe and effective for the treatment if the condition for which authorization of the Service is requested.

Α

Acoustic heart sound recording, computer analysis and interpretation Acoustic rhinometry

Active Specific Immunotherapy with Therapeutic Melanoma Vaccines Aerosolized Anti-infective Treatment for Sinusitis (AdhesENT) AMPLIFY Recombinant Human Bone Morphogenetic Protein (rhBMP-2) Matrix

Angiotensin Receptor 1 (AGTR1) c.*86A>C (1166A>C, A1166C) Polymorphism testing for evaluation of hypertension in symptomatic patients Angiotensin Receptor 1 (AGTR1) c.*86A>C (1166A>C, A1166C) Polymorphism testing for evaluation of hypertension risk in asymptomatic individuals Anticonvulsants in the treatment of posttraumatic stress disorder Applied Kinesiology Apostherapy as a medical program for the treatment of various orthopedic conditions ARISk Autism Risk Assessment Test Aromatherapy Art Therapy ATI Neurostimulation System for Electrical Stimulation of the Sphenopalatine Ganglion for Headache Autologous serum eyedrops for initial treatment of dry eye syndrome Automated whole breast ultrasound (e.g., somo-v Automated Breast Ultrasound System) as a screening tool Axial lumbar interbody fusion (AxiaLIF)

В

BeScreened CRC test Biochemical markers of Alzheimer's disease Bioimpedance for assessment of lymphedema Biomagnetic Therapy, Bioelectromagnetic Therapy Biomet Signature System Blood-brain barrier disruption for treatment of malignant brain tumors Blood product injections for tendonopathies Brachytherapy of the femoralpopliteal arterial system Bracing for the treatment of asymptomatic pectus carinatum (e.g., T-Joe brace, WPC compressor) Breast Elastography BreastNextNext-Gen Cancer Panel BREVAGen

С

Cancell (Entelev) CancerIntercept Carbogen therapy Cardiac Contractility Modulation Therapy Carotid Artery Intimal-Medial Thickness Cautery-Assisted Palatal Stiffening (CAPSO) Cefaly device for migraines Cellular therapy Chronic Intermittent Intravenous Insulin Therapy (CIIIT), (also know as hepatic activation therapy, metabolic activation therapy, pulse insulin therapy, and pulsatile intravenous insulin therapy) CO2 laser for the treatment of breast cancer Collagen and Procollagen analysis for screening, diagnosis or management of any disease affecting bone formation or resorption Collagen nerve conduit Comprehensive Sequence Analysis for Epilepsy and Seizure Disorders (i.e. EpiSEEK, Invitae) Computer-Aided Semen Analysis (CASA) for the Diagnosis of Male Infertility Computerized Dynamic Posturography Conexa Reconstructive Matrix

Confocal Microendoscopy (e.g. Cell-viZio, image enhanced endoscopy) Continuous Rotation Therapy for Patients with Acute Respiratory Distress Syndrome (e.g. RotoRest bed, Effica bed) CorMatrix pericardial patch Corneal hysteresis determination by air impulse stimulation (e.g. ocular response analyzer) Cranial electrotherapy stimulation (Alpha Stim 100, Alpha Stim SCS) Craniosacral therapy

Cryoablation of sural nerve

Cunningham Panel (Moleculera Labs)

Current Perception Threshold Testing/Sensory Nerve Conduction Threshold Custom (personalized) knee replacement

D

Digital Mole Mapping Devices for annular repair (e.g., Xclose Tissue Repair System) DNA banking/storage Dry needle stimulation Ductal Lavage for Breast Cancer Dune Margin Probe Dynamic spinal visualization (not medically necessary)

Ε

Early CDT-Lung Risk Assessment Test (Oncimmune) Electrical impedance scan of the breast Electromagnetic navigational bronchoscopy Electromagnetic therapy in healing of pressure sores Electrocardiographic Body Surface Mapping Electrothermal coagulation of knee, wrist, ankle and elbow joints (thermal shrinkage) ENDURAGen Enzyme-potentiated desensitization E-tegrity Test for Evaluation of Uterine Receptivity eVox system (Evoke Neuroscience) Exhaled Breath Condensate pH Testing for Asthma Management Extracorporeal liver assist device (ELAD) Extracorporeal shock wave therapy (ESWT) for Peyronie's disease

F

Fecal analysis for diagnosis of intestinal dysbiosis Functional anesthetic discography

G

Galvanic stimulation devices Gene expression profiling for cancers of unknown origin Genetic Testing for Capillary Malformation-Arteriovenous Malformation Syndrome (CMAVM) Genetic testing for classic Ehlers-Danlos Syndrome (EDS) Genetic testing for Generalized Epilepsy with Febrile Seizures Plus (unless for Dravet Syndrome) Genetic testing for isolated autosomal dominant thrombocytopenia. Genetic testing for narcolepsy Genetic testing for Oculofaciocardiodental (OFCD) Syndrome (Syndromic Microphthalmia 2; MCOPS2)

Genetic Testing for Parkinson Disease

Genetic testing for Nonsyndromic Peripheral Pulmonary Stenosis; PPS for Nonsyndromic Peripheral Pulmonary Stenosis

Genetic testing for SCN9A-Related Inherited Erythromelalgia

Genetic testing for sequence variants and deletions/duplications in the COL2A1,

COL11A1, COL11A2, COL9A1, and COL9A2 gene in individuals with a suspected diagnosis of Stickler syndrome, and to detect the presence or absence of a familial variant in an at-risk asymptomatic relative of an individual with Stickler syndrome. Gene Testing for von Willebrand Disease

GenoType IL-1 testing for periodontal disease

Genotyping for statin associated myopathy (ie SLCO1B1)

Gerson Therapy (Metabolic Therapy, Kelley's treatment, Gonzalez treatment, Issels whole body therapy)

Η

Hair analysis (except for diagnosis of heavy metal poisoning) Healthy Weight DNA Insight Hellerwork HemiCap patello-femoral resurfacing system (Knee joint patello-femoral resurfacing prosthesis) Hepatic dialysis High powered therapeutic laser therapy for pain (K-Laser) Hippotherapy (Equestrian Therapy) Histamine desensitization therapy for headaches

Hivamat Therapy

Home monitoring of pulmonary function unless post lung transplant

H-Wave electrical stimulation device for home use

Hydrodiscectomy (e.g., Spinejet HydroSurgery system)

Ι

IBD sqi Diagnostic Test for Inflammatory Bowel Disease ileoinguinal nerve entrapment Ilizarov technique for the treatment of short stature (cosmetic) Immunoaugmentive therapy Infrared light therapy (Anodyne Therapy) for treatment of pain or neuropathy intraepithelial lesions (HSIL) with anal carcinoma Injection snoreplasty for the treatment of obstructive sleep apnea Interferential current therapy, interferential stimulation Interspinous Process Decompression System (X-Stop, Coflex Interlaminar Stabilization Device) ImmuKnow Iontophoresis for Epicondylitis Insulin-like growth factor receptor (IGF-IR) for cancer treatment Interstitial hyperthermia for malignant brain tumor Intravascular near infrared spectroscpy (e.g LipiScan Coronary Imaging System, InfraReDx) Intravenous Vitamin C injection for treatment of cancer

J

JaundiceChip Resequencing Array



Κ

Live Blood Cell Analysis

Lokomat (Hocoma AG) Driven Gait Orthosis (DGO) for Use in Children with Cerebral Palsy

Laser ablation (Interstitial Laser Coagulation) for treatment of localized breast cancer Laser photocoagulation for macular drusen

Laser prostatectomy for prostate cancer

Laser treatment of onychomycosis

Laser vitreolysis for treatment of vitreous floaters of the eye

Low Level Laser therapy for pain

Low pressure pulse generator (Meniett Pressure Therapy)

Μ

Macula Risk PGx Test

MAKOplasty Total Hip Arthroplasty using the Robotic Arm Interactive Orthopedic System

MAKOplasty Partial Knee Resurfacing using the Robotic Arm Interactive Orthopedic System

Megavitamin Therapy

Micra Leadless Pacemaker

Micronutrient Panel Testing

MicroVas

Microwave thermotherapy for breast cancer

MindStreams Cognitive Health Assessment for Assessing Mild Cognitive Impairment

MitoMet Mitochondrial/MetabolicMicroarray Analysis

Monochromatic infrared energy (MIRE) therapy

MRI guided ultrasound ablation of uterine fibroids

MtDNA testing for mitochondrial dysfunction (e.g., mtSEEK)

Multifunction Cardiogram

myPath Melanoma test

Ν

NanoKnife System for Irreversible Electroporation Treatment of Pancreatic and Liver Cancer

Neural Therapy

Ness H200 (neuroprosthetic and rehabilitation system)

Neutralizing antibody testing in multiple sclerosis

NeuraGen Nerve Guide (Integra LifeSciences Corp.) for Repair of Severed Peripheral Nerves of the Upper Extremity

NeuroTrax Testing

NexCourse CRC for evaluation of colorectal cancer

Non-contact normothermic wound therapy (NNWT) - also known as non-contact radiant heat bandage devices or Warm-Up Active Wound Therapy

Noninvasive Peripheral Arterial Tonometry

NPDX ASD ADM Panel I for autism spectrum disorders NutrEval test

0

Ocular Blood flow analyzer Optical Coherence Tomography for Coronary Artery Plaque Characterization and Stent Evaluation for assessment of intracoronary plaques and stents Optiwave Refractive Analysis (ORA) system OrthAdapt Bioimplant

Ρ

Paraspinal surface electromyography Percutaneous sacroplasty Permacol Biologic Implant Physiologic recording of tremor using accelerometer(s) and gyroscope(s), (including frequency and amplitude including interpretation and report Pillar Palatal Implant System for treatment of obstructive sleep apnea Placement alpha miroglobulin-1-rapid immunoassay for detection of rupture of fetal membranes (e.g., AmniSure) Plasma kinetic vaporization of prostate (also known as bipolar vaporization) Prolotherapy Prometheus Liver Support System Proteomic-based testing of serum (e.g. OvaCheck, OvaSure, OVA1, ROMA) for the detection of ovarian cancer P Stim auricular stimulation Pudendal Nerve Block for Treatment of Pudendal Neuralgia Pulsed radiofrequency

Q

Quantitative Sensory Thermal Testing (QST)

R

Radiofrequency ablation of breast tumors Radiofrequency ablation for the treatment of complex regional pain syndrome Radiofrequency Discectomy Radiofrequency lesioning for plantar facsiitis Radiofrequency stimulation devices for wound care (e.g., Provant Wound Closure System, MicroVas Vascular Treatment System) Reflexology Reiki (Energy Healing, Biofield Therapeutics, Palm Healing, Tenohira) Revici's Guided Chemotherapy Rhinomanometry Rolfing (Structural Integration) Rubenfeld Synergy Method (RSM)

S

Saliva tests:

- Estriol hormone level to predict pre-term labor
- Hormone levels for menopause and aging (e.g., cortisol, DHEA, estradiol, estriol, estrone, progesterone, testosterone)

ScoliScore Adolescent Idiopathic Scoliosis (AIS) Prognostic Test SensiGene Fetal RhD Genotyping Septin 9 (SEPT9) Methylation Analysis' for Colorectal Cancer

Signal-Averaged Electrocardiography

Single Nucleotide Polymorphism (SNP) Testing for Breast Cancer Risk Assessment Skin Autofluorescence (AFR) to Aid in Assessing Diabetes-Related Complications SLE-key for biomarkers for systemic lupus erythematosus SpeechEasv fluency device Sperm Hyaluronan binding assay Staggered Spondaic Word Test Stealth System for spinal surgery (e.g. Medtronic StealthStation) Subtalar Implant for Pes Planus Suit Therapy for cerebral palsy Supraorbital nerve stimulation for treatment of headache Sural nerve graft with radical prostatectomy Surgical deactivation of refractory migraine headache Surgical Decompression for treatment of diabetic neuropathy (not medically necessary) Surgical Repair of athletic pubalgia Surgical Ventricular Restoration for Heart Failure Sympathetic therapy

Т

TenoGlide tendon protector sheet (Tendon Wrap tendon protector) for the management and protection of tendon injuries or for any other indications Thermal shrinkage of knee, wrist, ankle and elbow joints

Thermography

T-Joe Bracing System for asymptomatic pectus carinatum

Tinnitus maskers

Tinnitus retraining therapy

TMR device for chronic pain

Topaz microdebrider for musculoskeletal conditions

Transmeatal laser irradiation for treatment of tinnitus

Trufuse Facet Fusion for Spinal Instability (not medically necessary)

Trumatch personalized knee replacement

U

Ultrasound for evaluation of paranasal sinuses

Ultrasound guidance for podiatry and other joint injections

Ultrasound of the carotid and/or femoral artery(s) to assess risk for coronary artery disease

Unicondylar Interpositional Spacer

Urinary Cross-Linked N-Telopeptide of Type I Collagen Biomarker for Diagnosis of Osteoporosis and Fracture Risk Assessment

V

Vacuum therapy for treatment of female sexual dysfunction Vascular surgery as treatments for refractory migraine headache Vectra DA VersaJet Hydrosurgery System for treatment of burns Vertebral Axial Decompression (VAX-D) Vertical Auto Profile cholesterol test (VAP) Vestibular autorotation test Vestibular evoked myogenic potential (VEMP) testing Vision therapy for the treatment of learning disabilities and mild traumatic brain injury, including:

• Training glasses

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Prism glasses

• Tinted or colored lens VitalStim therapy

W

Whole Body CT Scan for screening Whole body DEXA for body composition studies Whole body hyperthermia Willow Curve



Xpresys Lung Test



General Purpose.

Health Net's Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.

The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, new or revised policies require prior notice or posting on the website before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.

Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, new or revised policies require prior notice or website posting before an amendment is deemed effective.

No Medical Advice.

The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.

The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.

The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and

requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. Coverage decisions are the result of the terms and conditions of the Member's benefit contract. The Policies do not replace or amend the Member's contract. If there is a discrepancy between the Policies and the Member's contract, the Member's contract shall govern.

Policy Limitation: Legal and Regulatory Mandates and Requirements.

The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Policy Limitations: Medicare and Medicaid.

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.