Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Medical Necessity Guidelines:

Noncovered Investigational Services

*Effective October 1, 2026**

Prior Authorization Required If REQUIRED, submit supporting clinical documentation (electronically recommended or by fax)	Yes ☒ No ☐
Notification Required	Yes ☐ No ☒

Applies to:

- Harvard Pilgrim Health Care Commercial products
- Tufts Health Plan Commercial products
- Tufts Health Direct
- Tufts Health Together
- Tufts Health RITogether
- Tufts Health One Care

We recommend submitting prior authorization electronically. If you opt to submit prior authorization requests via fax, please refer to this reference chart for the appropriate fax number (varies by product).
For details on all our products, please visit the Our Plans page on our provider website. For additional Prior Authorization and Notification details on other lines of business not listed on our Medical Necessity Guidelines page, please also reference our Prior Authorization Resources page.

*For the purposes of this document, this date refers to the date when the list was updated with the addition or deletion of items/services. Please see specific item to determine when that item was placed on noncovered status.

According to the The Plan Evidence of Coverage (EOC), a treatment or procedure is considered investigative or unproven if reliable evidence shows that the treatment is "under study to determine its safety, efficacy, toxicity, maximum tolerated dose, or its efficacy as compared with a standard means of treatment or diagnosis". The Plan restricts coverage to those devices, treatments, or procedures for which the safety and efficacy have been proven, or where the clinical evidence is such that the treatment is at least as beneficial as any established evidence-based alternatives. Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered investigational (unproven) and therefore not medically necessary and is excluded from coverage.

To determine whether a device, medical treatment, supply or procedure is proven safe and effective the following hierarchy of reliable evidence is used:

1. Published formal technology assessments and/or high quality meta analyses
2. Well-designed randomized studies published in credible, peer-reviewed literature
3. High quality case-control or cohort studies
4. Historical control studies, or case reports and/or case series
5. Reports of expert opinion from national professional medical societies or national medical policy organizations

With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the referred medical and scientific literature shall be considered reliable evidence. Specifically, not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included is the fact that a provider or a number of

providers have elected to adopt a device, medical treatment, or procedure as their personal treatment or procedure of choice or standard of practice.

Policy and Coverage Criteria:

The plan considers the services listed below and the following CPT/HCPCS codes, List of Investigational and Unproven Codes as experimental/investigational and therefore not covered (this is not an all-inclusive list)

****NOTE:** Genetic and molecular diagnostic testing for Tufts Health Public Plan and Harvard Pilgrim Commercial Members is managed by Carelon Medical Benefits Management. For Tufts Health Public Plan and Harvard Pilgrim Commercial Members Refer to Medical Necessity Guidelines: Genetic and Molecular Diagnostic Testing for Harvard Pilgrim Commercial, Tufts Health Direct, Tufts Health Together, Tufts Health RITogether, and Tufts Health One Care

- Abiliti Gastric Stimulation
- ABRx Antibiotic Resistance Panel (Diatherix Laboratories)
- AccuBoost for breast cancer (Non-invasive image-guided breast brachytherapy)
- Acoustic heart sound recording, computer analysis only
- Acoustic heart sound recording, computer analysis with interpretation and report
- Acoustic heart sound recording, interpretation and report only
- Active Specific Immunotherapy with Therapeutic Melanoma Vaccines
- Agile Patency Capsule (except when used for 'patency capsule' trial before a planned video capsule when the request is suspected Crohn's disease)
- AlloSure (CareDX Inc.)
- Alpha-Stim for Treatment of Chronic Pain
- AlzoSure Predict- Alzheimer's Early Prediction Bloodtest
- Amniotic Allografts for Tendon and Ligament Injuries
- Amniotic fluid epidural injections in the management of patients with LBP
- Amniotic membrane tissue (e.g. tissue graft, injection) for treatment of orthopedic conditions (e.g. spinal, tendon/ligament injury/inflammation, osteoarthritis, cartilage restoration)
- Amplatzer Cardiac Plug (ACP) and Amplatzer Amulet devices in left atrial appendage closure to reduce risk of stroke in adult patients with NVAF
- AmpliChip™ Cytochrome P450 (CYP450) Test for pharmacogenic assay of medication sensitivity
- Ancillary Hyaluronic-Hyaluronidase testing for bladder cancer screening and detection
- Angiotensin Receptor 1 (AGTR1) c.*86A>C (1166A>C, A1166C) Polymorphism Testing for Essential Hypertension
- Anora Miscarriage Test for Miscarriage, (Natera)
- Anoscopy, with delivery of thermal energy to the muscle of the anal canal (eg, for fecal incontinence)
- Anser VDZ® Test (Prometheus Laboratories) for monitoring vedolizumab treatment of Crohn's disease
- Anterior Scoliosis Correction (ASC)
- Antiprothrombin (phospholipid cofactor) antibody, each Ig class
- Apollo Overstitch™ Endoscopic Suturing System for bariatric applications
- Apple Watch Irregular Rhythm Notification Feature (Apple Inc.) for Detection of Atrial Fibrillation
- AQUACEL Ag Advantage (ConvaTec) for Wound Care
- ARISK™ Autism Risk Assessment Test
- ArthroFLEX Decellularized Dermal Allograft
- Arthrographic Hydrodilation for Adhesive Capsulitis
- Arthroscopic Microdiscectomy (AMD)
- Aspire Assist Aspire Bariatrics
- Asynchronous texting including but not limited to depression and anxiety.
- ATI Neurostimulation System (Autonomic Technologies Inc.) for Electrical Stimulation of the Sphenopalatine Ganglion (SPG) for Headache
- Autism and Intellectual Disability NGS Panel
- Autism NGS Panel (Fulgent Diagnostics)
- AutismNext
- Autologous micro-fragmented adipose tissue (MFAT) injection for treatment of degenerative joint disease
- Autologous Serum Eye Drops
- Autologous Stem Cell Transplantation (ASCT) for Crohn's Disease (CD)
- Autosomal Dominant Hereditary Spastic Paraplegia (AD-HSP)
- Autosomal Dominant Thrombocytopenia (Prevention Genetics)
- Axone Sequencing Genome Testing
- BBDRisk Dx (Silbiotech Inc.)
- Bilateral Frontoparietal Polymicrogyria (BFPP)
- BioCartilage for orthopedic indications

- BioDDryFlex® human amniotic allograft
- BioDFence® G3 human amniotic allograft
- Bioidentical Hormone Replacement Therapy for Menopause (BHRT)
- Bioimpedance Spectroscopy
- Bioness H200 Wireless Hand Rehabilitation System (Bioness) in Patients with Traumatic Brain Injury
- BioZorb 3D Bioabsorbable Marker (Focal Therapeutics)
- Bladder EpiCheck
- Bleeding Disorders NextGen Sequencing (NGS) Panel (Prevention Genetics)
- Blood-Based Genetic Testing for Colorectal Cancer Screening
- Blood Test for Amyloid Plaques associated with Alzheimer's Disease
- Blueprints Molecular Subtyping Profile for Breast Cancer
- Bone Marrow Failure Region of Interest (Claritis Genomics)
- Bone substitute injection for subchondral bone cysts
- BostonSight Prosthetic - C466Replacement of the Ocular Surface Ecosystem (PROSE) Treatment for Dry Eye Disease
- Bovine Collagen Implants for the Treatment of Rotator Cuff Injuries (REGENETEN bioinductive implant)
- BRCAvantage Plus (BRCA1, BRCA2, TP53, STK11, PTEN, CDH1, PALB2)
- Breast Cancer Focus Panel (Fulgent Genetics)
- Breast Ovarian Cancer NGS Panel (Fulgent Diagnostics)
- Breast/GYN Cancer Panel (GeneDx)
- BreastTrue High Risk Panel for Hereditary Breast Cancer, (Pathway Genomics Corp.)
- BrightSeq Beacon Assay Gene Panel Test
- BROCA Cancer Risk Prenatal Test
- Burst -frequency spinal cord stimulation
- CancerIntercept Detect
- CancerIntercept Monitor
- CancerNext Next-Gen Cancer Panel (Ambry Genetics Corp.)
- CancerPlex (KEW Inc.)
- Capillary Malformation-Arteriovenous Malformation Syndrome (CMAVM)
- Carbon monoxide, expired gas analysis (e.g., ETCOc/hemolysis breath test)
- Cartilage transfer surgery (OATS and mosaicplasty) for joints other than knee and ankle
- Cartiva synthetic cartilage implant
- CASR DNA Sequencing Test (Athena Diagnostics)
- Catheter based thrombectomy procedure- The JETi system
- Catheter lavage of mammary duct(s) for collection of cytology specimen(s), in high risk individuals (GAIL risk scoring or prior personal history of breast cancer), each breast; single duct
- Catheter lavage of mammary duct(s) for collection of cytology specimen(s), in high risk individuals (GAIL risk scoring or prior personal history of breast cancer), each breast; each additional duct
- C-Brace Orthotronic Mobility System (Ottobock)
- Charcot-Marie-Tooth Neuropathy, Type 1 (CMT1, CMT2,) CMTX
- CHEK2-related cancer test:The CHEK2-related cancer test may diagnose a personal and/or family
- history suggestive of hereditary breast and/or colon cancer
- Chemokine CC Motif Receptor 5 (CCR5) CCR5-Δ32 Polymorphism
- Chiropractic Biophysics (CBP) for Segmented Somatic Dysfunction of Spinal Regions
- Chromosomal Microarray Analysis Mitochondrial/Metabolic (MitoMet®) Testing
- "CJ" User Volume Adjustable Socket
- Coagulation Factor Deficiency NextGen Sequencing (NGS) Panel (Prevention Genetics)
- Coated VICRYL* Plus Antibacterial (polyglactin 910) Suture
- COLMOL (OSU Wexner Medical Center Clinical Laboratories)
- ColoSense
- ColoNext™ for Hereditary Colorectal Cancer
- ColonSentry (Innovative Diagnostic Laboratory)
- Color Hereditary Cancer Test (30 genes)
- Color Test (Color Genomics)
- Combination Heat/Ice Devices for Use After Knee Surgery
- Combined Cardiac Panel (GeneDx)
- COMPASS; COMPASS is an assessment of bone marrow and/or blood workups that uses several technologies to provide results to a team of experts
- Complement Factor H (CFH) p.Tyr402His and Age-Related Maculopathy Susceptibility 2 (ARMS2) p.Ala69Ser Polymorphism Testing for Susceptibility to Age-Related Macular Degeneration (AMD)
- Comprehensive Brain Malformations Panel (GeneDX)
- Comprehensive Epilepsy Evaluation NGS Panel

- Comprehensive Non-Specific Intellectual Disability Panel
- Comprehensive Personalized Medicine Panel, (Alpha-Genomix Laboratories)
- Computer-Assisted Semen Analysis (CASA) for Infertility
- Computerized Neurocognitive Testing (CNT), e.g. ImPACT™, for Sports-Related Head Injury
- Conductive Keratoplasty for Treatment of Keratoconus
- Congenital Disorders of Glycosylation (CDG) Panel by Massively Parallel Sequencing (BCM-MitomeNGS) (Baylor Miraca Genetics Laboratories)
- Constant Therapy
- Coolief Cooled Radiofrequency (RF) System (Halyard Health) for Knee and Hip Pain
- Corneal incisions in the donor cornea created using a laser, in preparation for penetrating or lamellar keratoplasty (List separately in addition to code for primary procedure)Coronary Artery Calcium Scoring to Assess the Risk of Coronary Artery Disease in Asymptomatic Adults
- Cranial electrical stimulation (CES) for the treatment of migraine/headaches
- Cranial electrical stimulation (CES) for treatment of chronic pain (e.g. fibromyalgia, chronic pain from SCI)
- Craniosacral Therapy
- Craniosynostosis NGS Panel and/or HDT array (Connective Tissue Gene Tests)
- Cunningham Panel (Moleculera Labs)
- CureSight for Amblyopia in Children
- Cxbladder, (Pacific Edge Ltd), (e.g., Cxbladder Triage, Cxbladder Detect, and Cxbladder Monitor)
- CYP2C19 Genotyping to Predict Response to Voriconazole
- CYP2C19 Pharmacogenomic Genotyping to Direct Clopidogrel Therapy for Secondary Prevention in Patients with a History of Stroke and/or Transient Ischemic Attack (TIA)
- CYP2C19 Pharmacogenomic Genotyping to Direct Clopidogrel Therapy in Adult Patients Undergoing Percutaneous Coronary Intervention (PCI)
- CYP2D6 Genotyping to Guide Dosing with Eliglustat Tartrate (Cerdelga) in Gaucher Disease Type 1
- CYP3A4 Genotyping for Ivacaftor Metabolism and Toxicity
- Cytochrome P450 (CYP450) Genotyping to Predict Response to Antidepressant and Antipsychotic Medications
- DCISionRT (PreludeDx)
- Decipher Prostate Biopsy (Decipher Biosciences)
- Decipher Prostate Cancer Classifier
- Decipher® Prostate Cancer Test (GenomeDx Biosciences)
- Decision Dx Melanoma
- DecisionDx-GBM (Castle Biosciences Inc.)
- deCODE ProstateCancer™ (deCODE diagnostics)
- DecodEX Microbial Genetic Identification; NGS) test for the identification and relative abundance of microbial pathogens in a patient sample
- DeNovo NT Natural Tissue Graft (Zimmer Inc.) for Articular Cartilage Repair
- dermaPACE system (Sanuwave Inc) extracorporeal shock-wave system for treatment of chronic full thickness diabetic foot ulcers
- Destruction of localized lesion of choroids (e.g., choroidal neovascularization), transpupillary thermotherapy
- Destruction of macular drusen, photocoagulation
- Destruction/reduction of malignant breast tumor including breast carcinoma cells in the margins, microwave phased array thermotherapy, disposable catheter with combined temperature monitoring probe and microwave sensor, externally applied microwave energy, including interstitial placement of sensor
- devACT Clinical Management Panel
- Developmental Relationship-Based Intervention for Autism (DRBI)
- devSEEK Sequence Analysis for Neurodevelopmental Disorders
- DGAT1 Single Gene (Fulgent Diagnostics)
- Diabetes Sentry Nocturnal Hypoglycemia Alarm
- Digital Fluoroscopic Grid System (HipGrid) for Total Hip Arthroplasty
- Discseel
- DNA Polymerase Gamma (POLG) - Related Disorders
- Dry Needling
- Dual energy x-ray absorptiometry (DEXA), body composition study, one or more sites
- Ear Popper™
- EDX110 nitrous oxide emitting dressing
- Ehlers-Danlos Syndrome (EDS) Classic Type
- ELANE (ELA2) Gene Testing for ELANE –related Neutropenia
- Electric cell signaling treatment (EST) (Sanexas neoGEN-Series System)
- Electrical impedance scan of the breast, bilateral (risk assessment device for breast cancer)
- Electromagnetic Hearing Aids
- Electronic analysis of implanted peripheral subcutaneous field stimulation pulse generator, with reprogramming when performed

- Embrace 2: Physiological Signal Based Seizure Monitoring System
- Embryonic Stem Cell Transplants
- EndoBarrier Endoluminal Liner
- Endolumenal Functional Lumen Imaging Probe (EndoFLIP; Medtronic Inc.)
- Endometrial Cancer Panel (GeneDx)
- Endoscopic Laser Assisted discectomy for cervical disc herniation
- Endoscopic Sleeve Gastroplasty
- Envisia Genomic Classifier (Veracyte)
- EpiMonitor (Empatica) System for Detection of Seizures
- Epilepsy and Seizure Disorders Panel (Emory Genetics Laboratory)
- Epilepsy NGS Panel (Fulgent Diagnostics)
- epiSEEK Comprehensive Sequence Analysis for Epilepsy and Seizure Disorders (Courtagen Life Sciences Inc.)
- ERCC1 Expression Analysis (Genzyme Genetics)
- Erector spinae block for treatment of chronic pain
- EsophyX® (transoral incisionless fundoplication)
- Esteem Totally Implantable Hearing System for Treatment of Moderate to Severe Sensioneural Hearing Loss in Adults
- E-tegrity® Test (Hologic Inc.; distributed by Sepal Reproductive Devices) for Evaluation of Uterine Receptivity
- eXciteOSA
- Expanded Non-Invasive Prenatal Testing (NIPT) Panels
- Extracorporeal Magnetic Stimulation for Urinary Incontinence
- Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
- Extracranial vein Angioplasty for Treatment of Multiple Sclerosis
- External Beam Radiation Therapy for Treatment of Dupuytren's Contracture
- EyeBOX to aid in diagnosis of concussion
- Factor V (F5) HR2 Haplotype Testing for thrombophilia
- Factor V Leiden (FVL) Testing for Oral Contraceptive Use
- Factor VII (F7) p.Arg353Gln Polymorphism Testing (Quest Diagnostics Inc.)
- Factor XI Deficiency
- Factor XIIIA1 (F13A1) p.Val34Leu Polymorphism Testing
- FHNext
- FiberNet® autologous fibrin and platelet system
- Fibrinogen-Beta (FGB) c.-455G>A Polymorphism Testing (Rosalind Franklin University – Clinical Immunology Laboratory)
- FM/a Test (EpicGenetics, Inc.) For Diagnosis of Fibromyalgia
- Focal and Segmental Glomerulosclerosis (FSGS) Evaluation (Athena Diagnostics®)
- Forkhead Box Protein G1 (FOXG1) for Congenital Variant Form of Rett
- FoundationOne Heme
- FoundationOne Liquid (Foundation Medicine)
- Freedom Spinal Cord Stimulator (SCS) System
- Full Sense Bariatric Device from BFKW LLC
- GammaTileTM Therapy for the Treatment of Recurrent Intracranial Tumors
- Ganglion Impar Block or Radiofrequency Thermocoagulation for the Treatment of Chronic Coccydynia
- Gastric Plication Surgery
- Gastric Vest System (ReShape)
- Generalized Epilepsy with Febrile Seizures Plus (GEFS+)
- GeneStrat (Biodesix) for all indications
- Genetic Testing for Alpha-Mannosidosis (MAN2B1 gene)
- Genetic testing for autism spectrum disorder (ASD) (e.g. for primary diagnosis of ASD, to aid in the evaluation of syndromic or complex ASD, to aid in the evaluation of idiopathic ASD)
- Genetic testing for Factor V Leiden in Women with Unexplained Recurrent Pregnancy loss
- Genetic Testing for Familial Hemiplegic Migraine (FHM)
- Genetic Testing for Family Members of Individuals with Brugada Syndrome
- Genetic Testing for FGFR-Related Craniosynostosis
- Genetic Testing for Fragile X-Associated Primary Ovarian Insufficiency
- Genetic Testing for Individuals Clinically Diagnosed with Brugada Syndrome
- Genetic testing for Inflammatory Bowel Disease
- Genetic Testing for Ki67 (MK167) Proliferation Marker Testing in DCIS and Breast Cancer
- Genetic Testing for Narcolepsy
- Genetic Testing for: Alzheimer's Disease (Athena Labs)
- Genetic Testing for: Friedreich Ataxia (FRDA) for Movement Disorders
- Genetic Testing for: Melanoma, CDKN2A (various manufacturers including Myriad)
- Genetic Testing in Patients with or Suspected of Congenital and/or Prelingual Nonsyndromic Hearing Loss (e.g., OtoSCOPE®)
- Genicular Nerve Blocks for Knee Pain

- Genomic Microarray Testing for Hematological Oncology Indications
- genTrue (True Health Diagnostics)
- GI Microbial Assay Plus (GI-MAP, Diagnostic Solutions Laboratory) for Evaluation of Gastrointestinal Microbiome
- Global Metabolomic
- Assisted Pathway Screen (Baylor Miraca Genetics Laboratories)
- Glucose Transporter Type 1 (Glut-1) Deficiency Syndrome
- Glutaric Acidemia Type I via the GCDH Gene (PreventionGenetics)
- gMS® DX (Glycominds Ltd.) to Aid in the Diagnosis of Multiple Sclerosis
- GPS Cancer (NantHealth)
- Guardant Reveal
- Guardant Shield
- H/I™ (HOXB13:IL17BR) Gene Expression Ratio (AviaraDx Inc.)
- Healthy Weight DNA Insight (Pathway Genomics)
- Hematopoietic Stem Cell for autoimmune disorders
- Hematopoietic Stem Cell for ovarian cancer
- Hematopoietic Stem Cell for renal cell carcinoma
- Hereditary Hemochromatosis Panel (Invitae Corp.)
- Hereditary Thrombophilia Panel (Invitae Corp.)
- High power laser therapy for musculoskeletal disorders
- High/Moderate Risk Panel, (GeneDX Inc.)
- HipGrid with PhantomMSK for use in total hip arthroplasty
- HIRREM (High-resolution, relational, resonance-based, electroencephalic mirroring) for Post-Concussion Syndrome
- HistoSonics Image guided sonic beam therapy system
- Home Electrical Stimulation Devices, such as:
    - NESS H200; NESS L300; NESS L300 Plus
    - Bionicare Knee System
    - WalkAide
    - Odstock Dropped Foot Stimulator (ODFS) Pace
- HPA-1a (PLA1 Platelet Antigen) Genotyping (PLA2 Polymorphism Detection)
- Human Platelet Antigen 1 Genotype (Quest Diagnostics)
- Hydrodissection in the treatment of neuropathic pain
- Hyper-IgE Syndromes Panel
- IBD sgi Diagnostic Test, (Prometheus Inc.)
- iGene Cancer Panel, (ApolloGen Molecular Diagnostics Laboratory)
- Image-Guided Intranasal Sphenopalatine Ganglion (SPG) Block for Treatment of Migraine Headaches
- ImPACT™ Concussion Management Test
- In vitro chemosensitivity testing for prediction of response to chemotherapy (i.e., ChemoFx® Assay by Precision Therapeutics)
- Inert gas rebreathing for cardiac output measurement during exercise
- Inert gas rebreathing for cardiac output measurement; during rest
- Infantile Epilepsy Panel
- Injectable Amniotic Tissue–Derived Allografts for Treatment of Chronic Plantar Fasciitis
- Insulia® Diabetes Management Companion (voluntis) for management of diabetes mellitus
- Intellectual Disability NGS Panel (Fulgent)
- Intellijoint Hip System (Intellijoint Surgical)
- Intense Pulsed Light Therapy for the Treatment of Dry Eye Disease
- Interleukin 28B (IL28B) Testing for Predict Response to Treatment of Hepatitis C with Interferons and Ribaviri
- Intragastric Balloons for Treatment of Obesity (e.g. ReShape Integrated Dual Balloon System, Orbera Intragastric Balloon System)
- Intravenous Vitamin C for the Treatment of Cancer
- InVisionFirst-Lung (Invita)
- Invitae Aortopathy Comprehensive Panel (Invitae Corp.)
- Invitae Breast Cancer High-Risk Panel
- Invitae Comprehensive Neuromuscular Disorders Panel
- Iontophoretic Drug Delivery for the Treatment of Axillary Hyperhidrosis
- Iontophoretic Drug Delivery for the Treatment of Primary Palmoplantar Hyperhidrosis
- iovera° system for the treatment of knee pain- Ablation, percutaneous, cryoablation, includes imaging guidance
- JACO Assistive Robotic Arm device for patients with neuromuscular diseases
- JaundiceChip Resequencing Array (Cincinnati Children's Hosptal Molecular Genetics Laboratory)
- Juvederm for Vocal Cord Paralysis
- Kabuki Syndrome
- Know Error System (Diagnostic ID, LLC)

- LactoTYPE, (Prometheus)
- Lantrida-allogeneic pancreatic islet cellular therapy
- Laparoscopy, surgical, implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
- Laparoscopy, surgical, revision or removal of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
- Laparotomy, implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
- Laparotomy, revision or removal of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
- Lariat Suture Delivery Device in left atrial appendage closure to reduce the risk of stroke in adult patients with NVAF
- Laser Interstitial Thermal Therapy (LITT), (e.g. NeuroBlate System)
- LDEX® U400 BIS Extracellular Fluid Analysis
- Left ventricular filling pressure, indirect measurement by computerized calibration of the arterial waveform response to Valsalva measurement
- Lenire BiModal Neuromodulation
- LipiScan Dynamic Meibomian Imager for the evaluation of meibomian gland dysfunction
- Lipoprotein Subclass Quantification Using NMR LipoProfile® Test (LipoScience Inc.) for Atherosclerosis /Coronary Heart Disease (CHD)
- Lipoprotein, direct measurement, intermediate density lipoproteins (IDL) (remnant lipoproteins)
- Lokomat driven gait orthosis (DGO)
- Low-Intensity Extracorporeal Shockwave Therapy for Treatment of E.D
- Luminopia ONE for Treatment of -Amblyopia in Children
- LUKE Arm (Mobius Bionics LLC)
- lysoSEEK Sequence Analysis for Lysosomal Storage Disorders
- Macula Risk PGx (ArcticDx Inc.)
- Macular Translocation Surgery
- Magnetically controlled growing rods (MCGRs) for the treatment of early-onset scoliosis (EOS) in children
- Mammostrat® (Clarient Inc.)
- Medicinal honey wound care dressings (i.e., Medihoney™)
- Medtronic METRx™ Microdiscectomy System for lumbar disc herniation
- MelanoSITE™ FISH Test
- Meniett Low-Pressure Pulse Generator for Treatment of Meniere's Disease
- Mesenchymal Stem cell therapy for treatment of orthopedic indications
- MI Profile test
- MI TumorSeek (Caris Life Sciences)
- Microcephaly NGS Panel
- Microcephaly Panel (Gene DX)
- Microcephaly Sequencing Panel
- Microcurrent electrical therapy (MET) for the treatment of musculoskeletal pain and the treatment of postoperative pain
- Microsurgery (e.g., transplanting lymph node(s) for preventing lymphedema, during surgery, for breast cancer
- Microwave thermal ablation of tumors
- Migraine Headaches - Surgical Treatment
- Mild® Minimally Invasive Lumbar Decompression for Lumbar Spinal Stenosis
- Mindstreams® Cognitive Health Assessment (e.g., NeuroTrax®
- Minimal Residual Disease (MRD) Tests
- Minimally Invasive Deformity Correction (MID-C) system for the treatment of adolescent idiopathic scoliosis
- Minimally invasive sacroiliac joint (SIJ) fusion with cylindrical threaded implants
- miraDry® (Miramar Labs®, Inc.) for the treatment of hyperhidrosis
- MIRE Therapy (Monochromatic Infrared Energy) for Peripheral Neuropathy
- Misha Knee System
- MitoSwab test
- MNG Transcriptome™
- Molecular Intelligence (Caris Life Sciences)
- Monarch external Trigeminal Nerve Stimulation (eTNS) System (NeuroSigma Inc.) for the treatment of attention-deficit/hyperactivity disorder (ADHD)
- Monogram Biosciences PhenoSense GT Plus Integrase
- MRI-Guided Laser Ablation using Visualase (Visualase Inc.) for Treatment of Seizures
- mtSEEK Whole Mitochondrial Genome Analysis (Courtagen Life Sciences Inc.)
- Multi cancer early detection test- Galleri
- Myeloma Prognostic Risk Signature (MyPRS Plus) Test for Myeloma (Signal Genetics LLC)
- Myoelectric orthosis — a custom orthosis that uses myoelectric signals to control brace function, providing assistive motion for joint function
- MyoPro upper extremity orthosis for all indications including muscle weakness, neurological disorders or neuro-muscular damage from conditions including, spinal cord injury, traumatic brain injury, amyotrophic lateral sclerosis, multiple sclerosis and other upper limb neuromuscular disorders

- myPath Melanoma (Castle)
- MyRiskTM
- Natera Miscarriage Test (Natera)
- Near-infrared guidance for vascular access requiring real-time digital visualization of subcutaneous vasculature for evaluation of potential access sites and vessel patency
- Nebulized antibiotic therapy (Except for the treatment of cystic fibrosis)
- Nerivio/remote electrical neuromodulation (REN)
- Neuroblastoma RAS Viral Oncogene (NRAS) for prediction of Treatment Response in Colorectal Cancer
- Neurodevelopment – Expanded (Ambry Genetics)
- NexCourse CRC (Genoptix Medical Laboratory)
- Next-Generation Sequencing (NGS) for Identification of Microbial Pathogens in Infections
- Next-Generation Sequencing (NGS) for Microbial Pathogens in Infection Outbreak Surveillance or Response
- NGS Epilepsy/Seizure Panel (Greenwood Genetic Center)
- NLRP3 Exon 3 Sequencing (GeneDx)
- NOD2/CARD15 gene testing for Crohn's Disease
- Noninvasive Cardiac Radioablation for Ventricular Tachycardia
- Noninvasive methods to assess skin cholesterol (e.g., PREVU™ Point of Care Skin Test)
- Nonsyndromic Peripheral Pulmonary Stenosis, PPS (Laboratory for Molecular Medicine)
- Norditropin for Female Infertility
- NuclearMitoDX(formerly MitoNucleomeDx) (MEDomics)
- nuSEEK Comprehensive Sequence Analysis of Nuclear Mitochondrial Exome (Courtagen Life Sciences Inc.)
- Occipital nerve stimulation (ONS) for treatment of cluster headache
- Oculofaciocardiodental (OFCD) Syndrome (Syndromic Microphthalmia 2; MCOPS2)
- Oculopharyngeal Muscular Dystrophy (OPMD) (Athena Diagnostics Inc.)
- Office based minimally invasive joint arthroscopy (e.g. mi-eye 2, VisionScope®)
- OmniSeq Comprehensive (OmniSeq), OmniSeq Advanced (OmniSeq)
- Oncofocus (Oncologica)
- OncoGeneDx
- Oncopanel (DFCI)
- Oncotype DX AR-V7 Nucleus Detect Test
- Oncotype MAP™ Pan-Cancer Tissue (formerly Paradigm Cancer Diagnostic (PCDx))
- OncoVue® (InterGenetics Inc.) for Breast Cancer Risk Assessment
- One Touch Via disposable insulin delivery system
- Optic Atrophy Evaluation (OPA1) (Athena Diagnostics)
- AposTherapy System for the treatment of pain and loss of function associated with osteoarthritis of the knee, Apos Therapy System
- Osseointegrated Prostheses
- OvaNext Next-Gen Cancer Panel
- Ovarian Cancer Focus Panel (Fulgent Diagnostics)
- OvaSure™ (LabCorp)
- PancNext Next-Gen Cancer Panel (Ambry Genetics Corp.)
- Pancreatic Cancer Panel (GeneDX, Inc.)
- Panexia (Myriad Genetics Inc.)
- PAP-NAP
- Partial HPRT Deficiency (Kelley-Seegmiller Syndrome)
- Pathfinder TG®; Topographic Genotyping (RedPath)
- PAULA's Test (Protein Assays Utilizing Lung Cancer Analytes; Genesys Biolabs) for Early Detection of Lung Cancer
- PCR Tests for UTI Panels
- Pediatric Neurology Region of Interest Trio (Claritas Genomics Inc.)
- Percepta Genomic Sequencing Classifier (GSC)
- Percutaneous Cervical Disc Decompression for Cervical Herniation
- Percutaneous mechanical thrombectomy for acute limb ischemia with AngioJet® Rheolytic Thrombectomy system (Possis Medical, Inc)
- Percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation), including imaging guidance, when performed, cervical, thoracic or lumbar - for trial, including removal at the conclusion of trial period, or for permanent implantation, with implantation of a pulse generator.
- Revision or removal of related pulse generator and/or electrodes, including imaging guidance, when performed, including addition of new electrodes, when performed
- Percutaneous Transcatheter Coil Embolization for Pelvic Congestion Syndrome (PCS)
- PGxOneTM Plus (Admera Health)
- Pharmacogenetic testing for single-gene variants in the CYP2D6, CYP3A4, CYP3A5, ABCB1, and UGT2B7 genes for general opioid prescribing

- Pharmacogenic testing for Warfarin responsiveness
- Phenylalanine Hydroxylase (PAH) Deficiency (Including Phenylketonuria [PKU])
- Plasma proteins predict conversion to dementia from prodromal disease
- Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G (Quest Diagnostics)
- Platelet Rich Plasma (PRP) for bone healing and fusion
- Polymerase Chain Reaction (PCR) Testing for Onychomycosis
- Pontocerebellar Hypoplasia Panel (GeneDx)
- Positional adaptive spinal cord stimulation
- Powered Exoskeletal Mobility Device, (e.g. Rewalk)
- Prenatal Genetic Testing for Autism Spectrum Disorder
- Pre-Ovar KRAS-Variant Test
- PreTRM (Sera Prognostics)
- Preventest (GeneID Advanced Molecular Diagnostics LLC)
- Previstage™ GCC Colorectal Cancer Staging Test
- Previvo uterine embryo lavage catheter
- PRI-MUS™ (Prostate Risk Identification for Micro-Ultrasound) for diagnosis of prostate cancer
- Proove Opioid Risk test
- Prospera (Natera)
- Prostate Core Mitomic Test (Mitomics Inc.)
- ProstateNext
- Prostatic Artery Embolization for BPH
- Proteus® Ingestible Event Marker (IEM)
- Provent Sleep Apnea Therapy
- Proveri Prostate Cancer Assay (PPCA) (Proveri Inc.)
- PTEN Gene Expression Testing in Non-Small Cell Lung Cancer (NSCLC)
- Pulsed radiofrequency treatment of chronic shoulder pain
- Pulsed radiofrequency treatment of complex regional pain syndrome of the lumbar region
- Radiofrequency Ablation of the Sural Nerve for Ankle Pain specialty
- Radiofrequency Ablation of Cluneal Nerves for Treatment of Chronic Lower Back Pain
- Radiofrequency Nerve Ablation for Treatment of Plantar Fasciitis
- Radiofrequency Neurotomy for Headaches
- Rapid Heme Panel (Dana Farber Cancer Institute/Brigham and Women's Hospital)
- ReActiv8 Restorative Neurostimulation System
- Relieva Balloon Sinuplasty (Acclarent Inc.) for Chronic Sinusitis in children
- RenalNext Next-Generation Sequencing (NGS) Panel (Ambry Genetics Corp.)
- ResponseDX: Colon® for Colorectal Cancer Treatment
- ReStore Soft Exo-SuitTM
- Retinal Dystrophy Panel (Blueprint Genetics)
- Rhinophototherapy, intranasal application of ultraviolet and visible light, bilateral
- RightMed Comprehensive Test
- Riscover Hereditary Cancer Test
- Robotic Rehabilitation of Upper Extremities in Patients with Degenerative Neurological Conditions
- RosettaGX Reveal (Rosetta Genomics Ltd.)
- Saethre-Chotzen Syndrome (TWIST) Sequencing and MLPA (Greenwood Genetic Center)
- Sclerotherapy for re-anastomosis after bariatric surgery
- ScoliScore Adolescent Idiopathic Scoliosis (AIS) Prognostic Test (Transgenomic Inc.)
- SelectMDx for Prostate Cancer (MDxHealth Inc.)
- Sensigene
- SensiGene Fetal RHD Genotyping for Rh Incompatibility (Sequenom Center for Molecular Medicine)
- SensiGene Fetal Sex Determination Testing (Sequenom Center for Molecular Medicine)
- Serological Assay for the Diagnosis and management of inflammatory bowel disease
- Serum autoantibody tests for diagnosis of autoimmune epilepsy (Athena Diagnostics)
- Signatera ctDNA test
- Single anastomosis duodenal switch
- Single Nucleotide Polymorphism (SNP) Testing for Breast Cancer Risk Assessment
- Single-pulse transcranial magnetic stimulation [sTMS] device for treatment of acute migraines
- Skeletal dysplasia ciliopathy NGS panel (Connective Tissue Gene Tests)
- SLCO1B1 Pharmacogenomic Genotyping for Statin Dosing or Selection
- SNaPshot Genetic Testing Panel
- SoundBite Hearing System (Sonitus Medical, Inc.)
- Spectroscopy, expired gas analysis

- Speculoscopy
- Speculoscopy, with directed sampling
- SPiN Thoracic Navigation System®
- STA2R SureGene Test for Antipsychotic and Antidepressant Response
- StabiLink MIS Interlaminar Spinal Fixation System for Spinal Fusion
- Stereotactic placement of infusion catheter(s) in the brain for delivery of therapeutic agent(s), including computerized stereotactic planning and burr hole(s)
- Stereotaxis Niobe Magnetic Navigation System (Stereotaxis Inc.) for Percutaneous Coronary Intervention in Coronary Artery Disease
- Stickler Syndrome
- Stretta Procedure (Mederi Therapeutics) for Gastroesophageal Reflux Disease (GERD)>(Stretta Radiofrequency Endoscopic Anti-reflux Procedure) (e.g., Stretta, Esophyx)
- Subchondral calcium phosphate (SCP) injections, knee
- SYMGENE68 NGS Cancer Panel, (CellNetix Pathology & Laboratories LLC)
- Syn-One
- Syndromic Autism Panel (NGS)
- TargetNow® Molecular Profiling Test (Caris™Life Sciences)
- Telcare Glucose Monitor
- Tempus HRD
- Tenex Health Tx Procedure for tendon pain. Include Percutaneous ultrasonic tenotomy
- TenJet for treatment of plantar fasciitis
- The Genecept Assay
- The Morning Repositioner (SomnoMed) to Restore Proper Mandibular Alignment After Use of Overnight Sleep Apnea Appliance
- The ProMark Proteomic Prognostic Test
- The TransPyloric Shuttle (BAROnova Inc.)
- The Use of Information Communication Technology (ICT) to Improve Treatment Adherence in Patients with Diabetes
- TheraSEEK Sequence Analysis for Functional Disorders (Courtagen Life Sciences Inc.)
- Thermal Shrinkage
- Thyroid Hormone Receptor Beta (THRB) Gene Testing
- Tinnitus Treatment/Rehabilitation (e.g., Neuromonics® and other programs)
- Tissue of Origin Test (ResponseDX; Response Genetics Inc.)
- Topaz® MicroDebrider (ArthroCare Corp.) for Treatment of Tendon Disorders of the Lower Extremities
- Topoisomerase II Alpha (TOP2A) Testing
- ToxProtectTM (Genotox Laboratories)
- TP63-Related Disorders (GeneDx Inc.)
- Transcranial Direct Current Stimulation
- Transcription Factor 4 (TCF4) Testing for Pitt-Hopkins Syndrome (PTHS)
- Transcutaneous Electrical Nerve Stimulation for Knee Osteoarthritis
- Transmembrane Activator and CAML Interactor (TACI) Gene, Full Gene Analysis (Mayo Medical Laboratories)
- Transoral Gastric Volume Reduction (TVGR)
- Transpalatal Advancement Pharyngoplasty for Sleep Apnea
- Transvascular Autonomic Modulation (TVAM)
- Treatment(s) for incontinence, pulsed magnetic neuromodulation, per day
- TreatmentMAP (Molecular Health)
- Urinalysis infectious agent detection, semi-quantitative analysis of volatile compounds
- Urinary Microsatellite Analysis
- Urine based ancillary tests designed to detect molecular changes (Tests may include, but are not limited to surviving, telomerase; Ancillary UroVysion™ aka FISH testing)
- UroCuff (SRS Medical) Evaluation of Lower Urinary Tract Symptoms
- Use of Anser IFX and Anser ADA to Monitor Treatment in Patients with Inflammatory Bowel Disease
- Use of Anti-Infliximab Antibody Levels to monitor treatment in patients with Inflammatory Bowel Disease (IBD)
- Use of Fractional CO2 laser therapy (e.g. Monalisa Touch®), radiofrequency technology (e.g. THERMIva®), and ER YAG laser therapy for vaginal rejuvenation and vaginal tightening
- USGI Primary Obesity Surgery Endolumenal (POSE)
- Vercise Directional Deep Brain Stimulation (DBS) System (Boston Scientific) for Parkinson's Disease
- Vertebral Motion Analysis for Assessment of Spinal Instability
- Vestibular Evoked Myogenic Potential (VEMP) Auditory Testing
- Video Head Impulse testing (vHIT) for evaluation of vestibular disorders
- VistaSeq Hereditary Cancer Panel
- Vivally-wearable, non-invasive bladder control therapy device
- Vizilite Oral Screening System
- Von Willebrand Factor (VWF)

- Whole Body Vibration for Promotion of Bone Growth in Postmenopausal Women
- Whole Exome Sequencing for Cancer Indications
- Wide-Area Transepithelial Sampling (WATS 3D) Biopsy for the Detection of Barrett's Esophagus or Esophageal
- Dysplasia
- Wireless capsule for measuring gastric emptying (SmartPill GI Monitoring System®)
- X-linked Charcot-Marie-Tooth Neuropathy, Type 1 (CMT1, CMT2,) CMTX
- X-Linked Intellectual Disability (XLID) Multigene Panels
- Xenotransplant

Approval And Revision History

Reviewed by the Medical Affairs Medical Policy Committee on September 24, 2007.

Subsequent endorsement date(s) and changes made:

- January 18, 2023: Reviewed by MPAC, investigational items updated, added and removed
- February 15, 2023: Reviewed by MPAC investigational items updated
- April 3, 2023: Investigational items added/removed
- April 19, 2023: Reviewed by MPAC, investigational items updated
- May 17, 2023: Reviewed by MPAC, investigational items update/removed
- June 6, 2023:Investigational items updated/removed
- June 21, 2023: Reviewed by MPAC, investigational items updated
- July 1, 2023: Coding updated
- August 16, 2023: Reviewed by MPAC, investigationa items updated, effective November 1, 2023
- September 20, 2023: Reviewed by MPAC, investigational items updated,
- October 18, 2023: Reviewed by MPAC, investigational items updated/added or removed. Point32Health integrated policy, effective January 1, 2024
- November 16, 2023: Reviewed by MPAC, investigational items updated/removed/added, effective December 1, 2023
- December 13, 2023: Investigational items updated
- January 17, 2024: Reviewed by MPAC, investigational items updated/removed
- January 19, 2024: Coding updated, per AMA HCPCS® ,and CPT® effective January 1, 2024
- February 9, 2024: Investigational item added
- February 26, 2024: Investigational items updated
- March 29, 2024: Coding updated, per AMA HCPCS® and CPT®, effective April 1, 2024
- April 24, 2024: Reviewed by MPAC, investigational items updated/removed, effective May 1, 2024
- May 15, 2024: Reviewed by MPAC, investigational tiem added, effective September 1, 2024
- May 24, 2024: Coding updated
- June 20, 2024: Reviewed by MPAC, investigational items updated, including items for One Care, effective August 1, 2024
- July 18, 2024: Coding updated, per AMA HCPCS® and CPT®, effective July 1, 2024
- August 30, 2024 Reviewed by MPAC, investigational items updated
- September 26, 2024: Coding updated, per AMA HCPCS® and CPT®, effective October 1, 2024
- October 17, 2024, Investigational item removed
- November 4, 2024: Reviewed by MPAC, investigational items updated/removed
- November 21, 2024: Reviewed by MPAC, investigational items updated/added, effective January 1, 2025
- December 18, 2024: Reviewed by MPAC, investigational items added/removed, effective January 1, 2025
- January 8, 2025: Investigational items updated
- January 9, 2025: Coding updated per AMA AMA HCPCS® and CPT®, effective January 1, 2025
- January 14, 2025: Administrative update
- February 10, 2025: Administrative update
- February 19, 2025: Reviewed by MPAC, investigational items updated, effective April 1, 2025
- March 19, 2025: Reviewed by MPAC, investigational items added/removed, effective June 1, 2025
- April 2, 2025: Coding updated per AMA HCPCS® and CPT®, for April 1, 2025
- April 14, 2025: Investigational item updated
- April 16, 2025: Reviewed by MPAC, investigational item updated.
- April 22, 2025: Investigational items updated
- May 21, 2025: Reviewed by MPAC, investigational items updated
- May 23, 2025: Investigational item updated
- May 30, 2025: Coding updated per AMA HCPCS® and CPT®, for July 1, 2025
- June 18, 2025: Reviewed by MPAC, investigational items updated, effective August 1, 2025
- July 22, 2025: Investigational items updated, and template updated, language for Carelink removed
- August 20, 2025: Reviewed by MPAC, investigational items updated, effective September 1, 2025
- August 25, 2025: Fax number for Senior Care Options, Tufts Medicare Preferred HMO and Tufts Medicare Preferred PPO updated

- Septermber 29, 2025: Coding updated per AMA HCPCS® and CPT®, effective October 1, 2025
- October 8, 2025: Investigational item updated
- October 15, 2025: Reviewed by MPAC, investigational items updated and removed, effective November 1, 2025
- November 19, 2025: Investigational items added, effective December 1, 2025
- December 1, 2025: Investigational items updated
- December 17, 2025: Reviewed by MPAC, investigational item added, effective February 1, 2026
- January 1, 2026: Coding updated per AMA HCPCS® and CPT®, effective January 1, 2026
- January 23, 2026: Coding updated.
- February 2, 2026: Investigational item removed
- February 4, 2026: Investigational item updated
- March 18, 2026 Reviewed by MPAC, investigational items removed/updated, effective 5/1/26
- April 8, 2026: Coding updated per AMA HCPCS® and CPT®, effective, April 1, 2026
- April 23, 2026: Coding updated
- May 20, 2026: Reviewed by MPAC, investigational items removed, effective July 1, 2026
- May 27, 2026: Administrative updates, template updated
- July 15, Reviewed by MPAC, investigational items removed/updated, effective September 1, 2026
- July 20, 2026: Coding updated per AMA HCPCS® and CPT®, effective July 1, 2026
- July 23, 2026: Administrative update
- August 19, 2026: Reviewed by MPAC, investigational items added/updated/removed, effective October 1, 2026

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.