“What’s New” Medical Policy Updates August 2021

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of July that will become **effective September 15, 2021** (unless otherwise specified). The Plan uses medical policies as guidelines for coverage decisions made within the insured individuals written benefit documents. Coverage may vary by line of business and providers and members are encouraged to verify benefit questions regarding eligibility before applying the terms of the policy.

MP001 Neuromuscular Electrical Stim – (Revised) – Add Indication; Add Exclusions

INDICATIONS:
Commercial and Non-Medicare Business Segments

Neuromuscular electrical stimulation (NMES)

- Disuse muscle atrophy, where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse are causing atrophy including but not limited to:
  - Previous casting or splinting
  - Contracture due to scarring of soft tissue as in burn lesions
  - Hip replacement surgery (until physical therapy begins)
  - Major knee surgery (when there is a failure to respond to physical therapy)

Requires pre-certification through the Plan’s Medical Management Department. Equipment must be obtained through an approved Durable Medical Equipment vendor(s). Coverage for these items is subject to the terms, conditions and limitations of the Durable Medical Equipment benefits as outlined in the applicable benefit document.

All requests for approval of neuromuscular stimulation outside the context of disuse atrophy including, but not limited to post-operative protocol, or extended use beyond one month, will require review and approval by a Plan Medical Director or designee.

Functional Electrical Stimulation (FES):

Functional neuromuscular stimulation (FNS)/functional electrical stimulation (FES) (e.g, Parastep® Ambulation System) may be considered medically necessary to enable members with spinal cord injury to ambulate when all of the following criteria are met:

- Intact lower (both muscle and peripheral nerve) motor units at L1 and below: and
- Sufficient muscle/joint stability and control to maintain an independent upright posture and weight bearing for a minimum of 3 minutes; and
- Documentation of sensory perception of electrical stimulation sufficient for muscle contraction and a brisk muscle contraction to FES; and
- There is a minimum of 6 months post recovery of spinal cord injury and restorative surgery; and
- The member can transfer independently and has sufficient hand and finger function to manipulate controls; and
- The member demonstrates the motivation, commitment and cognitive ability to use such device for walking.

~~**Additional indication for**~~ **For Medicare Business Segment:**

EXCLUSIONS:
NMES is considered **experimental, investigational and unproven** for the following applications and is **NOT COVERED**:

- As a muscle strengthening regimen in healthy individuals
- For use in the treatment of scoliosis
- For reduction of spasticity or to facilitate voluntary motor control in cerebral palsy, or other upper motor neuron disorders
- Treatment of denervated muscles
- Treatment of pain

The Plan does **NOT** provide coverage for the use of NMES as a treatment for idiopathic facial palsy (Bell's palsy) because it is considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

~~The Plan does **NOT** provide coverage for the use of MEDex unit (combined NMES and TENS), and RS4i (combined NMES and interferential therapy) or similar equipment as a treatment for any indication because it is considered **experimental, investigational or unproven.** Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies~~

The Plan does **NOT** provide coverage for the use of FES including but not limited to RT300 FES cycle ergometer used for upper limb paralysis or hemiplegia because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does **NOT** provide coverage for the use of robotic lower body exoskeleton suits (e.g., the ReWalk, Ekso system, etc) because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

MP048 Surgical and Minimally Invasive Therapies for the Treatment of BPH – (Revised) – Add Cross Reference; Add Exclusion

Endourethral prosthesis (e.g., Urolume® urethral stent) is considered medically necessary to treat obstruction secondary to BPH in men at least 60 years of age or older, or men under 60 years of age who are poor surgical candidates.

See also: MP093 Cystourethroscopy, with Insertion of Urethral Stent

EXCLUSIONS:

The Plan does **NOT** provide coverage for Prostatic arterial embolization (PAE) for the treatment of BPH hypertrophy because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

MP280 Whole Exome and Whole Genome Sequencing – (Revised) – Revise Title; Add Information; Add Exclusions

DESCRIPTION:

Whole exome sequencing is a strategy to selectively sequence the coding regions of the genome. Exons are short, functionally important sequences of DNA which represent the coding regions of genes. In the human genome there are about 180,000 exons which represents about 1% of the human genome. The goal of this approach is to focus on the 1% of the genome that corresponds to functional variation responsible for both Mendelian and common diseases, rather than examining DNA sequence from the whole genome, the majority of which has not yet been linked to clinically relevant information.

Whole genome sequencing is the process of determining the entirety, or nearly the entirety, of the DNA sequence of an organism's genome. This entails sequencing all of an organism's chromosomal DNA as well as DNA contained in the mitochondria.

LIMITATIONS:

Whole Genome Sequencing (WGS) - REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

WGS is an evolving technology, but currently has limited application outside of a research setting. Consideration of requests for WGS will be done on a "per-case" basis.

EXCLUSIONS: The Plan does NOT provide coverage for the use of whole exome sequencing for indications other than those listed above because it is considered experimental, investigational or unproven. There is currently insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of WES/WGS ~~this modality~~ on health outcomes when compared to established tests or technologies for the following applications:

- Preimplantation genetic testing in embryos
- Prenatal genetic diagnosis and/or screening
- Evaluation of fetal demise

The Plan does **NOT** provide coverage for the use of WES/WGS for diagnosis or prognosis of cancer because it is considered experimental, investigational or unproven. There is currently insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of WES/WGS on health outcomes when compared to established molecular profiling tests or technologies.

MP323 Molecular Profiling of Malignant Tumors to Identify Targeted Therapies – (Revised) – Add Indications

FoundationOne, Foundation One CDx, Memorial Sloan Kettering Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT), or Target Now Molecular Profiling Service Caris Diagnostics) - (Commercial and Medicare Business Segments)

Molecular profiling to identify targeted therapies utilizing one of the following tests: **FoundationOne, Foundation One CDx, Memorial Sloan Kettering Integrated Mutation Profiling of Actionable Cancer Targets (MSK-IMPACT), or ~~Target Now Molecular Profiling Service~~ MI Profile and MI Tumor Seek(Caris Diagnostics)** will be considered medically necessary when **all of the following** criteria are met:

FoundationOne Liquid CDx: (Commercial and Medicare Business Segments)

Guardant360 CDx: (Commercial)

OncoType MAP PanCancer Tissue Test (Commercial and Medicare)

OncoType MAP PanCancer Tissue Test is considered medically necessary for any the following indications when criteria are met:

- The member is diagnosed with an unresectable or metastatic solid tumor(s); and
- The test is used to assess tumor mutation burden and identify candidates for checkpoint inhibition immunotherapy;

and

- The member has progressed following prior treatment

MP324 Genetic Testing for Non-Cancer Heritable Disease Carrier Status – (Revised) – Add Indications

Marfan Syndrome Loeys-Dietz Syndrome, Ehlers-Danlos Syndrome

Genetic testing may be considered medically necessary when:

- There is a known family pathogenic variant; **or**
- The member presents with signs and symptoms consistent with Marfan syndrome Loeys-Dietz Syndrome, or Ehlers-Danlos Syndrome but a definitive diagnosis cannot be established.

And

- Targeted mutation testing limited to 1 or more of the following is planned: FBN1, MYH11, ACTA2, COL3A1, SLC2A10, SMAD3, MYLK, TGFBR1, and TGFBR2

EXCLUSIONS:

Direct-to-consumer genetic testing, or "home testing" kits, are NOT COVERED.

Genetic testing for the diagnosis or risk assessment of Alzheimer's disease is considered experimental, investigational or unproven and therefore NOT COVERED. There is insufficient published peer reviewed medical literature to support the efficacy of genetic testing in Alzheimer's disease.

Whole Genome Sequencing (WGS) - REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

Whole Genome Sequencing (WGS) is an evolving technology, but currently has limited application outside of a research setting and is generally considered to be unproven for the purposes of screening and evaluating genetic disorders. There is currently insufficient evidence to support the efficacy is using WGS for routine evaluations. Consideration of requests for WGS will be done on a "per-case" basis.

MP343 Percutaneous Electrical Nerve Field Stimulation (PENFS) for Treatment of Functional Abdominal Pain – (NEW)

DESCRIPTION: Percutaneous Electrical Nerve Field Stimulation (PENFS) has been proposed as a treatment of functional abdominal pain secondary to inflammatory bowel disease in children and adolescents. The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to auricular branches of cranial nerves V, VII, IX and X, and the occipital nerves identified by transillumination. Once the desired neurovascular bundles are visualized by transillumination, the electrode needle is secured and implanted percutaneously with gentle pressure. The four-needle electrode array, attached to the white wire, is placed on the ventral side of the ear lobe.

EXCLUSIONS:

The Plan does **NOT** provide coverage for Percutaneous Electrical Nerve Field Stimulation (PENFS) for treatment of functional abdominal pain because it is considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established treatments or technologies.

MP346 Intraoperative Neurophysiologic Monitoring – (NEW)

DESCRIPTION:
Intraoperative neurophysiologic monitoring (IONM) is a technique used to reduce the risk of neurological deficits after operations that involve the nervous system. IONM makes use of recordings of electrical potentials from the nervous system during surgical operations. The use of IONM offers a possibility to detect injuries before they become so severe they cause permanent deficits after the operation, and is normally performed by technologists supervised by a physiologist, or a neurologist acting within the scope of their license/certification. According to a guideline by the American Academy of Neurology (AAN) " it is expected that a specifically trained technologist preferably with credentials from the American Board of Neurophysiologic Monitoring (ABNM) or the American Board of Registration of Electrodiagnostic Technologists (ABRET), will be in continuous attendance in the operating room, with either the physical or electronic capacity for real-time communication with the supervising physician. Although credentialing varies among professional organizations, the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) and AAN provide guidance that the monitoring technologist should be under the direct supervision of a clinical neurophysiologist." (AAN, 2008; AANEM, 2008).

INDICATIONS:
Intraoperative neurophysiological monitoring (IONM) with an FDA approved technique and device is considered medically necessary when:

- IONM is performed by either a physician trained in clinical neurophysiology or a trained technologist practicing within the scope of their license/certification and working under the direct supervision of a physician trained in neurophysiology; and

- IONM is interpreted by a physician trained in clinical neurophysiology (other than the operating surgeon or anesthesiologist) who is either physically in attendance in the operating room or present via a real-time remote mechanism for all electroneurodiagnostic (END) monitoring situations and is immediately available to interpret the recording and advise the surgeon; and

- IONM is conducted and interpreted real-time (either on-site or at a remote location) and continuously communicated to the surgical team; and

- There is significant risk of nerve or spinal cord injury during a surgical procedure

LIMITATIONS:
Train of four monitoring is considered integral to intraoperative monitoring and/or administration of anesthesia.

Baseline electrodiagnostic studies prior to surgery is limited to once per operative session. Use of the following baseline testing modalities alone or in combination is dependent upon surgical procedure and/or surgical site:

- Sensory Evoked potentials (i.e., somatosensory [SSEP], auditory brainstem evoked responses [ABR], visual evoked potentials [VEP])
- Motor evoked potentials (MEP)
- Electromyography (EMG), free-running or stimulus-triggered
- Electroencephalogram (EEG)

EXCLUSIONS:

- Non-FDA approved techniques
- Outside of hospital/ASC settings

The following policies have been reviewed with no change to the policy section. Additional references or background information was added to support the current policy.

MP005 Medical Policy Process
MP010 Blepharoplasty
MP063 Acupuncture
MP100 Electrical Bioimpedance
MP125 Cranial Remodeling Orthotic
MP137 Vibroacoustic Therapy
MP227 Spaced Retrieval Testing
MP240 Dermal Injections for Treatment of Facial LDS
MP241 Non-invasive Measurement of Advanced Glycation Endproducts
MP266 Magnetoencephalography and Magnetic Source Imaging
MP299 Measurement of Serum Antibodies to Infliximab and Adalimumab
MP309 Computerized Dynamic Posturography
MP336 Genetic Testing for Inherited Thrombophilia/ Hypercoagulability
MP338 COVID19 Antibody Testing