"What's New" Medical Policy Updates April 2019

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of March that will become **effective May 15, 2019** (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) – (Added Exclusion)

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 Micro-current Stimulation Devices (MENS) including, but not limited to use in the treatment of migraine headache, fibromyalgia, anxiety, depression, insomnia, cognitive dysfunction and other pain disorders 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 Electromyographic impulse generated muscle stimulator (biofeedback device) as a treatment for any indication 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 horizontal therapy as a treatment for any indication 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 FES of the upper extremities (e.g., NESS H200 Handmaster NMS1 System) to improve muscle strength, treat atrophy or reduce spasticity due to traumatic brain injury, stroke, spinal cord injury or upper motor neuron disorders 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.

MP078 Sexual Dysfunction Therapies – (Revised) – (Added Exclusions)

EXCLUSIONS:

For group and non-group members, sexual dysfunction services, devices and equipment are excluded and are not covered per the applicable benefit document section titled "Exclusions" unless explicitly provided under the terms of a Rider and listed on the current face sheet.

Clitoral stimulation devices (e.g., Eros clitoral stimulation device). There is insufficient peer reviewed literature to support the efficacy of this treatment at this time. The device is considered **investigational** and is **NOT COVERED**.

Penile revascularization surgery is considered **investigational** and is **NOT COVERED.** There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

Extracorporeal shock wave therapy (ESWT) for treatment of erectile dysfunction is considered investigational and is **NOT COVERED**. There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

Stem cell therapy) for treatment of erectile dysfunction is considered investigational and is **NOT COVERED**. There is insufficient evidence in the published, peer-reviewed medical literature to support the safety and efficacy of this procedure.

MP324 Genetic Testing for Non-Cancer Heritable Disease Carrier Status – (NEW)

DESCRIPTION: Genetic testing for the purposes of carrier status screening is performed to identify genetic risk that may impact reproductive decision-making. Individuals identified as being "carriers" are typically not affected by the condition but have an increased risk of having a child with a genetic condition. Genetic testing for carrier screening may be available for autosomal recessive genetic conditions, X chromosome-linked conditions, and certain other chromosomal abnormalities.

GENERAL INDICATIONS:

Genetic testing for inheritable diseases, offered in a setting with appropriately trained health care professionals who can provide pre- and post-test counseling, and performed by a qualified laboratory, is considered to be medically necessary when:

- Based on family history, pedigree analysis, risk factors, and / or signs or symptoms, there is a reasonable expectation that a genetically inherited condition exists; and
- The testing methodology is considered a proven method for the identification of a genetically-linked disease; and
- The test results will guide disease treatment decisions or prevention strategies**.**

INDICATIONS:

Tay-Sachs disease:

Genetic testing of the HEXA gene may be considered medically necessary when one or more of the following criteria are met:

- Symptomatic member with clinical features suggestive of TSD or variants and abnormal HEX A or HEX B enzymatic testing, but after conventional studies a definitive diagnosis remains uncertain.

- To detect a pseudodeficiency allele in an asymptomatic member with abnormal HEX A or HEX B enzymatic testing
- Member with a first or second-degree relative with a confirmed TSD or variant
- Members with reproductive partners with chronic or adult-onset HEXA or HEXB deficiency with the intention to reproduce
- Members who are pregnant or whose reproductive partner is pregnant or planning a pregnancy when one or more of the following criteria apply:
    - At least one of the couple is of Ashkenazi Jewish origin
    - At least one of the couple is of Cajun or Acadian origin
    - At least one of the couple is of French-Canadian origin
    - At least one of the couple is affected with or is a known carrier of Tay-Sachs disease
    - There is a positive family history of Tay-Sachs disease

Cystic Fibrosis

Genetic testing of the CFTR gene may be considered medically necessary when one or more of the following criteria are met:

- Member with a negative sweat test who exhibit symptoms of CF
- Male members with congenital bilateral absence of the vas deferens
- Infant members with symptoms consistent with CF who are too young to accomplish a sweat chloride test
- Members who are pregnant or whose reproductive partner is pregnant or are planning a pregnancy

Hemoglobinopathies (Sickle Cell Anemia, Alpha/beta thalassemia)

Genetic testing may be considered medically necessary when one or more of the following criteria are met:

- Family history of hemoglobinopathy with known mutation
- Hemoglobinopathy is suspected after complete blood count and hemoglobin analysis and the member has origins in a high-risk group (eg, African American, African, Asian, Middle eastern, Carribbean, or Mediterranean **decent)**

Ashkenazi Jewish Carrier Screening Panel

(Canavan Disease, Fabry Disease, Gaucher Disease, Bloom syndrome, Maple Syrup Urine disease, Cystic Fibrosis, Glycogen Storage disease type 1, Familial Dysautonomia, Franconi Anemia, Mucolipidosis IV, Friederich Ataxia, Niemann-Pick Disease, Tay-Sachs Disease, Tuberous Sclerosis)

Panel testing may be considered medically necessary when the following criteria are met:

- The member is planning a pregnancy or currently pregnant; and
- At least one partner of a couple is of Ashkenazi Jewish heritage (NOTE: If only one partner of a couple is Ashkenazi Jewish, testing should start in that person when possible.)

Single Ashkenazi Jewish Genetic Diseases Carrier Screening Tests

Single gene carrier screening may be considered medically necessary when:

- The member has a family history of one of the conditions listed in the panel; OR
- The member's partner is a known carrier or affected with any of the conditions listed in the panel

Duchenne muscular dystrophy/Becker muscular dystrophy

Genetic testing may be considered medically necessary when one or more of the following criteria are met:

- In a male member with signs and symptoms of a dystrophinopathy in order to confirm the diagnosis and direct treatment.
- For at-risk female member relatives defined as first- and second-degree female relatives and include the proband's mother, female siblings of the proband, female offspring of the proband, the proband's maternal grandmother, maternal aunts and their offspring.

Fragile X syndrome

Genetic testing may be considered medically necessary when one or more of the following criteria are met:

- Members of either sex with intellectual disability, developmental delay or autism spectrum disorder
- Members seeking reproductive counseling who have a family history of fragile X syndrome or a family history of undiagnosed intellectual disability
- Prenatal testing of fetuses in pregnant members who are known carriers
- Affected members who have had a positive cytogenetic fragile X test result who are seeking further counseling related to the risk of carrier status

Neurofibromatosis type 1 and 2

Genetic testing for neurofibromatosis type 1 may be considered medically necessary when the diagnosis is clinically suspected due to signs of disease, but a definitive diagnosis cannot be made without genetic testing.

The member must meet one of the following:

- A first-, second- or third-degree relative has a known NF mutation; or
- A first-, second- or third-degree relative has been diagnosed with neurofibromatosis but whose genetic status is unavailable

Or

The member meets at least two of the following criteria:

- six or more light brown spots on the skin ("cafe-au-lait" spots), measuring more than 5 mm in diameter in children or more than 15 mm across in adolescents and adults;
- two or more neurofibromas, or one plexiform neurofibroma (a neurofibroma that involves many nerves);
- freckling in the area of the armpit or the groin;
- two or more growths on the iris of the eye (Lisch nodules or iris hamartomas);
- a tumor on the optic nerve (optic nerve glioma);
- abnormal development of the spine (scoliosis), the temple (sphenoid) bone of the skull or the tibia;
- a parent, sibling or child with NF1

Genetic testing for neurofibromatosis type 2 is medically necessary when the diagnosis is clinically suspected due to signs of disease, but a definitive diagnosis cannot be made without genetic testing. The member must meet one of the following criteria:

- Members with a first degree relative with NF2 (i.e., affected parent, sibling or offspring)
- Multiple spinal tumors (schwannomas, meningiomas)
- Cutaneous schwannomas
- Sporadic vestibular schwannoma less than 30 years of age, or spinal tumor or meningioma less than 20 years of age
- Unilateral vestibular schwannoma in those less than 20 years of age

Cerebral autosomal dominant arteriopathy with subcortical infarcts and leukoencephalopathy (CADASIL);

Genetic testing to confirm the diagnosis of CADASIL syndrome may be considered medically necessary when:

- Clinical signs, symptoms and imaging results indicate the pre-test probability of CADASIL is moderate to high (total score of 14)*; or
- The diagnosis of CADASIL is inconclusive following alternate methods of testing, including MRI and skin biopsy

Features	***Points***
Migraine	*1*
Migraine with aura	*3*
Psychiatric disturbance	*1*
Transient ischemic attack/stroke	*1 (2 if <50yo)*
Subcortical infarcts	*2*
Cognitive decline	*3*
LE (leukoencephalopathy)	*3*
LE extended to temporal pole	*1*
LE extended to external capsule	*5*

Pooled Frequency of Clinical and Radiologic Features (Pescini et al., 2012)

Charcot-Marie-Tooth:

Genetic Testing for Charcot-Marie-Tooth (CMT) disease is medically necessary when the member has clinical features of CMT and a definitive diagnosis remains uncertain after history, physical examination, genetic counseling and completion of nerve conduction studies and/or electromyography.

- If nerve conduction studies of ulnar/median nerve indicate demyelinating neuropathy (velocity <38 m/s), test for the most commonly identified CMT subtype: CMT1A (PMP22 duplication).
- If the result is negative, multi-gene panel testing of genes GJB1 (CMTX1), MPZ (CMT1B), MFN2 (CMT2A2), LITAF (CMT1C), EGR2 (CMT1D), PMP22 sequencing (CMT1E), GARS (CMT2D), NEFL (CMT2E/1F), GDAP1 (CMT2H/2K) and SH3TC2 (CMT4C).
- If nerve conduction studies of ulnar/median nerve indicate axonal neuropathy (velocity >38 m/s), multi-gene panel testing of genes GJB1 (CMTX1), MPZ (CMT1B), LITAF (CMT1C), EGR2 (CMT1D), PMP22 sequencing (CMT1E), MFN2 (CMT2A2), GARS CMT2D), NEFL (CMT2E/1F), GDAP1 (CMT2H/2K) and SH3TC2 (CMT4C)

Alpha-1-antitrypsin deficiency:

Genetic testing for alpha-1 antitrypsin deficiency may be considered medically necessary when the member meets either criteria 1 or 2, and 3:

1. alpha-1 antitrypsin deficiency is suspected in member presenting with clinical factors such as:
   - Early-onset emphysema (45 years or younger); or
   - Emphysema without history of risk factors (smoking, occupational exposure, etc.); or
   - Emphysema with prominent basilar hyperlucency; or
   - Bronchiectasis of unknown etiology; or
   - liver disease of unknown etiology; or
   - Anti-proteinase 3-positive vasculitis; or
   - Necrotizing panniculitis

   Or;

2. Member is at risk due to a first-degree relative with alpha-1 antitrypsin deficiency

   AND

3. Member has a serum alpha-1 antitrypsin level in the range of severe deficiency

Phenotype	**AAT Blood Level**
MM	20–53 µM | 150–350 Mg/dL
MZ	12–28 µM | 90–210 Mg/dL
SS	13–27 µM | 100–210 Mg/dL
SZ	10–16 µM | 75–120 Mg/dL
ZZ	2.5–7 µM | 20–45 Mg/dL
NULLNULL	0 µM | 0 Mg/dL

Neimann – Pick Disease:

Genetic testing for SMPD1 and NPC1 gene may be considered medically necessary in either of the following populations:

- Symptomatic members with clinical features suggestive of NPD and abnormal biochemical testing, but a definitive diagnosis remains uncertain after completion of conventional studies.
- First- or second-degree relative members with the capacity and desire to reproduce once the mutations have been identified in the proband.

Primary Dystonia Type 1:

Genetic testing for DYT1 gene sequence variants may be considered medically necessary in either of the following populations:

- Members with documented onset of primary dystonia at or before age 30 years
- Members with documented onset of primary dystonia at age 30 years or later with a relative who developed dystonia at 30 years or younger

Prader-Willi Syndrome

Genetic testing may be considered medically necessary in symptomatic pediatric members for diagnosis of Prader-Willi syndrome or in symptomatic adult members when all of the following criteria are met:

- Documented history of hypotonia and poor suck
- Global developmental delay

Angelman Syndrome

Genetic testing to confirm the absence of maternally expressed gene(s) located on chromosome 15 within bands q11.2 to q13 may be considered medically necessary in symptomatic pediatric members for diagnosis of Angelman Syndrome or in symptomatic adult members when all of the following criteria are met:

- Documentation of absence of major birth defects with normal head circumference
- Evidence of developmental delay by age 6 to 12 months
- Delayed progression and attainment of developmental milestones without overall loss of skills
- Normal metabolic, hematologic and chemical laboratory studies
- Normal brain structure as evidenced by CT or MRI
- Absent or severely impaired speech
- Balance disorder with ataxia or tremulous movement of limbs
- Documentation of behavioral characteristics such as inappropriate happy demeanor, frequent and inappropriate laughter or smiling, short attention span, excitability, hand-flapping, or hypermotor activity

Gaucher disease

Genetic testing may be considered medically necessary as follows:

Diagnostic Testing for Symptomatic members:

- Glucosylceramidase enzyme activity in peripheral blood leukocytes is 0 - 15% of normal activity, and
    - bone changes including osteopenia, focal lytic or sclerotic bone lesions or osteonecrosis; or
    - Liver/spleen enlargement and anemia or thrombocytopenia; or
    - Primary neurologic disease including one or more of the following:
        - cognitive impairment,
        - pyramidal signs (e.g., spasticity, hyperactive reflexes)
        - bulbar signs (e.g., dysphagia, dysarthria, dysphonia, etc)
        - eye movement disorders,
        - seizures

Diagnostic Testing for members who are Asymptomatic Carriers:

- a mutation is detected by targeted mutation analysis, and
- Glucosylceramidase enzyme activity in peripheral blood leukocytes is 0-15% of normal activity,

Testing for Members with Family History or Partners of Carriers:

- 1st, 2nd, or 3rd degree biologic relative with confirmed Gaucher diagnosis, or
- the member has the intention to reproduce with a partner who is monoallelic or biallelic for GBA mutation

Huntington's disease

Genetic testing related to Huntington's disease may be considered medically necessary for:

a) Confirmatory testing in members with clear symptoms and positive family history; or
b) Diagnostic testing in members with no family history of the disease, but who exhibit symptoms consistent with Huntington's disease such as:
    - Involuntary jerking movements
    - Impaired gait, posture and balance
    - Dystonia
    - Cognitive disorders

Rett syndrome:

Genetic testing may be considered medically necessary when:

- The member meets the clinical diagnostic criteria for Rett syndrome; and
- Gene testing is necessary to confirm diagnosis due to clinical uncertainty

Spinal Muscular Atrophy:

Genetic testing may be considered medically necessary for the indications of:

Diagnostic testing in members with:

- hypotonia and weakness (symmetrical but proximal greater than distal); and
- abnormal deep tendon reflexes (severely decreased or absent)

Carrier testing:

- Members with a family history of SMA or disease suspicious for SMA; or
- Member with a blood relative who is a known carrier or diagnosed with SMA and has a known SMA mutation; or
- Member who is pregnant or is planning a pregnancy
- Members whose reproductive partner has a known carrier status

Prenatal testing in members who are pregnant and both partners are known carriers

EXCLUSIONS:

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

MP326 Biomarker Testing for Rheumatoid Arthritis – (NEW)

DESCRIPTION: Assessment of disease activity is an important component of management of rheumatoid arthritis. Disease activity is determined using a combination of physical exam, radiologic findings, and serum biomarkers that result in a disease activity score. The current standards include Disease Activity Score with 28 joints (DAS28), Clinical Disease Activity Index, Patient Activity Scale, Patient Activity Scale II, Simplified Disease Activity Index, and the Routine Assessment of Patient Index Data 3.

The Vectra DA test is a commercially available test using 12 serum biomarkers to report a disease activity score that ranges from 1 (low disease activity) to 100 (high disease activity). Proponents describe it as an adjunct to other disease activity measures, to identify patients at high risk of progression. This testing would then guide a more aggressive treatment strategy.

INDICATIONS:

FOR MEDICARE BUSINESS SEGMENT:
Palmetto GBA, the Medicare contractor in California, has issued a coverage decision for the Vectra DA test. Per CMS rules, since all Vectra DA tests are processed out of the Crescendo Bioscience Laboratory in California, the test will be covered for Medicare patients in the United States.

EXCLUSIONS:
Unless otherwise noted, the Plan does **NOT** provide coverage for Vectra DA 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 test on health outcomes when compared to established measures of disease activity.

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.

MP025 Transcatheter Closure Devices
MP034 Foot Orthotics
MP066 ESWT
MP068 Reduction Mammaplasty
MP075 Tissue Engineered Skin Substitutes
MP090 Inj. Bulking Agents/Incontinence
MP094 Unilateral Pallidotomy
MP106 Ultrasound/ Pregnancy
MP112 Wireless Capsule Endoscopy
MP113 Electrical Stim Wound Healing
MP158 Continuous Passive Motion
MP172 MicroVas Vascular Treatment System
MP176 Meniett Device
MP179 Photodynamic Therapy for Esophageal and Lung Cancer
MP189 Computer Aided Detection Technology
MP196 Convection-Enhanced Drug Delivery
MP209 Medical Error Never Events
MP319 Percutaneous Left Atrial Appendage Occlusion
MP320 Absorbable Hydrogel Spacer