

“What’s New” Medical Policy Updates February 2017

Listed below are the recent changes made to policies within the Geisinger Health Plan Medical Policy Portfolio during the month of December/January that will become **effective March 15, 2017** (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.

MP20 Transplant Services - REVISED – (Edited language)

INDICATIONS: REQUIRES PRIOR MEDICAL DIRECTOR AUTHORIZATION (except corneal transplant)

Treatment guidelines for transplant and related follow-up are continuously changing due to rapid advances and research. Approved transplant services are covered according to the individual contract language. Except for corneal transplants, ~~the Plan~~ **Geisinger Health Plan (GHP)** requires prior authorization for services related to transplants and follow-up treatment. The following transplants are considered for coverage when appropriate criteria, as determined by **GHP** ~~the Plan~~ medical director and the current contracted transplant management vendor, are met. In order to assess the medical necessity of the transplant, adequate information must be submitted to **GHP** ~~the plan~~. Please see the appropriate attachment as listed below for the required information:

- Heart (~~Attachment 1~~)
- Heart & Lung (~~Attachment 2~~)
- Lung & Lobar Lung (~~Attachment 3~~)
- Liver (~~Attachment 4~~)
- Renal (~~Attachment 5~~)
- Renal & Pancreas/ Solitary Pancreas (after a successful Kidney) (~~Attachment 6~~)
- Small Bowel (~~Attachment 7~~)
- Small Bowel/Liver and Multi-visceral (~~Attachment 8~~)

For Medicare and Medicaid Business Segment

~~The Plan~~ **GHP** covers all medically necessary and non-investigational/experimental organ and tissue transplants, as covered by Medicare. When Medically Necessary, the following transplants are covered: Kidney (cadaver and living donor), kidney/pancreas, cornea, heart, heart/lung, single lung, double lung, liver (cadaver and living donor), liver/pancreas, small bowel, pancreas/small bowel, bone marrow, stem cell, pancreas, liver/small bowel transplants, and multivisceral transplants.

For Medicaid Business Segment:

GHP covers all medically necessary and non-investigational/experimental organ and tissue transplants, as approved by the PA Dept. of Human Services.

MP38 Oral Health - REVISED – (Edited Member Language)

• Impacted Wisdom Teeth

~~For insured individuals~~ **members** in which applicable benefit documents include the Impacted Wisdom Tooth rider, the benefit is limited to those services that are expressly outlined in the applicable benefit document.

• Temporomandibular Joint (TMJ) Dysfunction

~~Insured individuals~~ **members** with orthotic benefits have coverage for occlusal splints, mandibular occlusal repositioning appliances or bite planes/splints.

Coverage is subject to the limitations of the insured individual's applicable benefit document specific to the orthotic benefit.

- **Fluoride gel tray**

Although Fluoride Gel Trays are generally considered a dental service and are excluded, in some instances coverage may be extended to insured individuals members receiving radiotherapy for head and neck cancer.

Hospital/ambulatory surgical center services - REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR OR DESIGNEE

The Plan considers the following indications on a "per case" basis as being medically necessary for deep sedation or general anesthesia to perform an oral or dental surgery procedure:

- When deemed medically necessary for insured individuals members aged 7 years or younger; or
- insured individuals members who require multiple procedures in more than one quadrant of the mouth and there is an inability to perform the necessary services in a staged, "in-office" procedure or over multiple visits ; or
- insured individuals members who require complex procedures that have a documented failure of at least one attempt to perform the required procedure in an office setting (**NOTE: This criteria not applicable to Medicaid Business Segment**); or
- the insured individual member has a medical condition that precludes the use of in-office anesthesia methods or in whom in-office anesthesia methods are ineffective (due to acute local infection, anatomic variation or allergy); or

MP55 Mastectomy for Gynecomastia - REVISED – (Added Language)

~~For product lines in which gynecomastia surgery is not specifically excluded, prior Medical Director or designee authorization must be obtained. Determinations of coverage will be based on specific criteria listed below.~~

REQUIRES PRIOR AUTHORIZATION BY A PLAN MEDICAL DIRECTOR or Designee CRITERIA:

For those product lines in which surgical treatment of gynecomastia is not specifically excluded, the following criteria will be used to determine eligibility for coverage. All must be met:

- Member is of age 18 years or older or puberty is substantially completed
- Gynecomastia meets ASPS Grade II, III, or IV definition (see Definitions Section)
- Condition is present for no less than 2 years and contributing factors have been treated for at least 6 months
- Excess breast tissue is glandular and not fatty, confirmed by mammogram and/or tissue histology
- Other causes including obesity (BMI greater than or equal to 35) or reversible drug therapy have been ruled out
- The member must be excluded from, or failed treatment of, an underlying hormone disorder
- Excessive breast development is not due to non-covered therapies or illicit drug use

Mastectomy for gynecomastia is considered medically necessary, regardless of age, when there is a clinically concern that a breast mass may represent breast carcinoma.

MP64 Breast Reconstruction - REVISED – (Edited Indications)

- Prosthesis (either implanted or external) and treatment of physical complications at all stages of the mastectomy including lymphedema

- Removal and replacement of a ruptured breast implant (either silicone or saline) is reconstructive for implants inserted following mastectomy.
- Lymphedema treatments considered medically necessary include:
 - Complex Decongestive Physiotherapy
 - Lymphedema pumps
 - Compression lymphedema sleeves (not applicable to Medicare beneficiaries)
- Reconstructive breast surgery in insured individuals **members** with congenital absence or significant deformity secondary to Poland syndrome

MP73 Deep Brain Stimulation - **REVISED – (Edited Criteria)**

DESCRIPTION:

Unilateral **or bilateral** deep brain stimulation of the thalamus, or bilateral stimulation of the globus pallidus or sub-thalamic nucleus refers to a neurosurgical procedure where a device is implanted in the brain for the control of tremors in selected members who have been diagnosed with essential tremor or Parkinsonian tremor. The device consists of a pacemaker-like chest unit that transmits mild electrical pulses through a wire to a lead that is stereotactically implanted in the thalamus or selected surrounding structures. This procedure, being reversible, is an alternative to permanent neuroablative procedures such as thalamotomy and pallidotomy in patients with significant functional disability and who are refractory to maximized pharmacological management.

INDICATIONS:

- Essential tremor
- Parkinson's disease **tremor or complicated motor fluctuation** ~~induced tremor~~
- Intractable primary dystonia, including generalized and/or segmental dystonia, hemidystonia and cervical dystonia when used in accordance with the Humanitarian Device Exemption specifications of the U.S. Food and Drug Administration

CRITERIA FOR COVERAGE: Requires Prior Authorization by a Plan Medical Director or designee
 Authorization **Note:** This requirement only applies to initial placement, and not to revision(s) and replacement(s) after implantation.

Essential Tremor: **unilateral or bilateral deep brain stimulation of the ventral intermediate (Vim) nucleus is considered medically necessary when all of the following criteria are met:**

- Diagnosis of disabling essential tremor refractory to pharmacotherapy
- The tremor constitutes a significant functional disability **as evidenced by a standardized scale (e.g., Fahn-Tolosa-Marin Clinical Tremor Rating Scale*, TETRAS**, or equivalent scale) or discussion of their ADL or iADL limitations with their physician.**

*<https://www.yumpu.com/en/document/view/11254127/fahn-tolosa-marin-tremor-rating-scale>

** https://www.bcm.edu/neurology/pdf/poster_other_TETRAS.pdf

Parkinson's Disease: **unilateral or bilateral deep brain stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) is considered medically necessary when all of the following criteria are met:**

- History of clearly documented Parkinson's disease, **diagnosed using the UK Parkinson's disease brain bank criteria** that has responded to ~~Sinemet® or dopamine agonists~~ **pharmacologic therapy** in the past, **and**
- ~~● A minimal score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale when the patient has been without medication for approximately 12 hours; and~~
- ~~● The tremor constitutes a significant functional disability.~~
- **Having symptoms of parkinsonism for at least four years, and**
- One of the following:

- Disabling motor fluctuations despite optimized **medical/pharmacologic therapy** doses of Sinemet®/dopamine agonists; or
- Disabling tremor despite **optimized** medical/**pharmacologic** therapy.

Primary Dystonia **unilateral or bilateral deep brain stimulation of the internal globus pallidus (GPI) or the subthalamic nucleus (STN) is considered medically necessary when all of the following criteria are met:**

- Chronic, intractable primary dystonia, including generalized and/or segmental dystonia, hemidystonia, **or** ~~and~~ cervical dystonia (torticollis); and
- ~~The tremor constitutes a significant functional disability.~~
- ~~Insured individual~~ **Member** is 7 years of age or older; and
- Medical documentation that the condition is refractory to pharmacotherapy

NOTE: Services related to component reimplantation or replacement in insured individuals members previously approved for the implantation, or members having had the implantation prior to enrollment in the Plan, and who otherwise meet criteria for coverage, do not require prior authorization.

CONTRAINDICATIONS:

- Independent diagnoses that could explain the failure to respond to medical treatment
- Mental impairment, (~~advanced dementia or severe depression~~) **moderate to severe cognitive impairment** or ~~severe~~ **uncontrolled** depression
- Focal lesions of the basal ganglia (lacunae or space occupying lesion) or at the target site.
- **Surgical risk is unacceptable due to comorbid conditions**

EXCLUSIONS:

The Plan does **NOT** provide coverage for Deep brain stimulation for control of tremor induced by any diagnosis other than those listed above 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 list of such diagnosis includes, but is not limited to:

- | | |
|---|--------------------------------------|
| • Trauma | • Multiple Sclerosis |
| • Neurological Degenerative Disorders | • Metabolic Disorders |
| • Infectious Disease | • Drug Induced Movement Disorders |
| • Obsessive Compulsive Disorder | • Tourette's Syndrome |
| • Tardive dyskinesia | • Neuropsychiatric conditions |
| • Cerebral palsy | • Chronic pain |
| • Chronic Intractable Cluster Headaches | |
| • Post-traumatic tremor | |

MP098 Genetic Testing Related to Colorectal Cancer - REVISED – (Edited Criteria; Added Exclusion)

Fecal DNA Testing: (e.g., Cologuard,) **DOES NOT REQUIRE PRIOR AUTHORIZATION** a noninvasive, multitarget fecal DNA test for the qualitative detection of colorectal neoplasia-associated DNA markers in addition to the presence of occult hemoglobin in stool is covered **as a preventive screening methodology** once every 3 years **according to the following criteria** ~~when all of the following criteria are met:~~

EXCLUSIONS:

The Epi proColon test is considered **experimental, investigational, or unproven** and is **NOT COVERED**. 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 tests or technologies.

MP99 Breast Implant Removal - REVISED – (Edited Member Language)

INDICATIONS:

For ~~insured individuals~~ **members** who have undergone cosmetic breast augmentation unrelated to reconstruction following cancer surgery, removal of breast implants is considered medically necessary for any of the following indications:

- Breast cancer (new onset) or chest wall tumors in proximity to the implant; or
- Intra- or extra-capsular rupture of silicone gel implant; or
- Implants with contracture that interferes with mammography; or
- Implants with contracture associated with pain (Baker Class III or IV)*; or
- Implants complicated by persistent or recurrent local or systemic infection secondary to the breast implant and refractory to medical management, including antibiotics
- Erosion of the implant through the skin or scar

For ~~insured individuals~~ **members** who have undergone reconstruction following a medically necessary mastectomy (due to malignancy or prophylactic mastectomy), removal of implants will be considered medically necessary for the following indications:

EXCLUSIONS:

Removal of ruptured saline –filled breast implant in ~~insured individuals~~ **members** who have undergone cosmetic breast augmentation (not related to breast cancer or prophylactic mastectomy) is considered **cosmetic** and **NOT COVERED**.

MP108 Work Hardening/Conditioning - REVISED – (Edited

Functional Capacity Assessment is a comprehensive, objective testing of a person's abilities in work related functional tasks. At times, it is used as a preliminary test to determine functional status and capabilities prior to beginning a Work Hardening Program. Functional capacity assessment examinations are limited to those situations in which the following criteria are met:

- The ~~insured individual~~ **member** is determined to be medically stable; and
- The evaluation is designed to determine return to work capabilities following a defined injury or following a medically necessary rehabilitation **period**; and
- The evaluation is structured to **address** ~~answer~~ a specific questions or questions about the ~~worker's~~ **member's** performance abilities. The ~~answer to the question(s)~~ must be addressed in the evaluation report; and
- Reported results must be compared to meaningful standardized norms; and
- The Functional Capacity ~~Performance~~ **performance assessment** must be performed by a qualified provider. For the purposes of this policy, a qualified provider is defined as a licensed PT/OT who is able to show evidence of education, training and competencies specific to the delivery of Functional Capacity Assessments

MP170 Gene Expression Profiling for Breast Cancer Treatment - REVISED – (Added Exclusions)

EXCLUSIONS:

Unless coverage is mandated, the Plan does NOT provide coverage for any other assays of genetic expression in breast tumor tissue (e.g. MammaPrint®, Blueprint™, TargetPrint®, **Mammostrat® Breast Cancer Test**, the **Breast Cancer IndexSM**, **BreastOncPx™**, **NexCourse® Breast IHC4**, **BreastPRS™** and the Rotterdam Signature 76-Panel) because they are considered experimental, investigational or unproven.

MP205 Advanced Molecular Topographic Genotyping - REVISED – (Added Genotyping test)

INDICATIONS: FOR MEDICARE AND MEDICAID BUSINESS SEGMENT:

***REQUIRES PRIOR MEDICAL DIRECTOR or DESIGNEE AUTHORIZATION**

Consideration for coverage is limited to the Medicare Business Segment, in compliance with CMS directives.

The Plan considers the use of advanced molecular topographic genotyping (including but not limited to RedPath Pathfinder TG, **PancraGen™**) medically necessary for pancreatic cyst/mass when ALL of the following criteria are met:

For the Non-Medicare Business Segment, the Plan does NOT provide coverage for advanced molecular topographic genotyping (including but not limited to RedPath Pathfinder TG, **PancraGen™) because it is considered experimental, investigational or unproven.**

MP230 Outpatient Pulmonary Rehabilitation - REVISED – (Edited Member Language)

Maintenance Therapy - *Maintenance therapy* consists of activities that preserve the patient's present level of function and prevent regression of that function. Maintenance begins when the therapeutic goals of a treatment plan have been achieved or when no additional functional progress is apparent or expected to occur.

Pulmonary Rehabilitation – Pulmonary Rehabilitation (PR) is an evidence-based, multidisciplinary and comprehensive intervention for ~~insured individuals~~ **members** with chronic respiratory diseases who are symptomatic and have decreased daily activities. The goal of PR is to:

- Restore the patient to the highest possible level of independent function
- Educate the patient and significant others about the disease, treatment options and coping strategies
- Encourage patients to be actively involved in providing for their own healthcare and to be more independent in activities of daily living (ADL).

Coverage for outpatient pulmonary rehabilitation will be approved up to 36 visits per benefit period. If coverage for pulmonary rehabilitation is available, the following conditions of coverage apply.

The Plan covers a comprehensive, individualized program of outpatient pulmonary rehabilitation as medically necessary for ~~insured individuals~~ **members** with a documented diagnosis of moderate to severe chronic obstructive pulmonary disease (COPD), either emphysema or chronic bronchitis, **or other chronic pulmonary diseases that meet the following criteria. Pulmonary rehabilitation** is considered *medically necessary* when **ALL** of the following exist:

- Activities of daily living (ADL) are currently limited by breathing difficulty
- Moderate to severe lung function impairment by pulmonary function tests: FEV1 at values 25-60% of prediction
- No other medical/psychological limitations (e.g. congestive heart failure, substance abuse, significant liver dysfunction, metastatic cancer, disabling stroke, dementia, organic brain syndrome)
- The ~~insured individual~~ **members** has stopped smoking for a minimum of 3 months (if applicable) prior to the requested therapy

2. Signature of the ~~insured individual~~ **members** attending physician and therapist

Therapy in ~~insured individuals~~ **members** who are asymptomatic or without any documented clinical condition is considered not medically necessary.

MP233 Injectable Blood Products for Orthopedic Conditions - REVISED – (Added CMS CES Provision)

FOR MEDICARE BUSINESS SEGMENT:

Per Decision Memo CAG-00190R3, CMS covers autologous platelet-rich plasma (PRP) only for patients who have chronic non-healing diabetic, pressure, and/or venous wounds and when the beneficiary is enrolled in a clinical research study that addresses the following questions using validated and reliable methods of evaluation.

The clinical research study must meet specified requirements to assess the effect of PRP for the treatment of chronic non-healing diabetic, pressure, and/or venous wounds.

A listing of approved studies can be found at:

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Autologous-Platelet-rich-Plasma-PRP.html>

MP247 Nutritional Supplements - REVISED – (Edited Criteria)

Commercial Business Segments: (Coverage may vary by individual TPA)

Enteral nutrition (including administration, supplies and formula) ~~when ordered by a registered dietitian, gastroenterologist or bariatrician~~ may be considered medically necessary in members with:

Medicaid Business Segment:

Amino acid-based Elemental formula may be considered to be medically necessary in members ~~age 5 years~~ **age 21 years** and younger when all of the following criteria are met:

LIMITATION:

Standard formula for newborns or infants is not considered to be medically necessary and is therefore not covered. Standard infant formula for normal infants or for infants with medical illness or disability is considered to be non-medical in nature, as nutrition is a normal need for all infants. ~~Formula, including some special or prescription formulas for premature infants or infants with allergies can be obtained through Pennsylvania WIC up to the age of 5 years. The WIC program must be the primary provider of enteral products if patient is WIC eligible. GHP Family will only approve coverage of enteral product requirements in excess of WIC's maximum quantities as set by the United States Department of Agriculture.~~

MP251 Percutaneous Heart Valve Replacement - REVISED – (Added Exclusion)

EXCLUSIONS:

With the exception of mandated for coverage by CMS under a Coverage with Evidence Development (CED) program, the Plan does **NOT** provide coverage for percutaneous transcatheter closure of paravalvular leaks because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of these procedures on health outcomes when compared to established procedures or technologies.

<http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257>

MP262 Microarray Based Gene Expression Testing for Cancer of Unknown Origin - REVISED – (Added Exclusion)

EXCLUSIONS:

Unless mandated coverage exists, the Plan does **NOT** provide coverage for the use of microarray-based expression testing for cancer of unknown origin, including but not limited to Pathwork® Tissue of Origin Test, Pathwork TOO Frozen Array; CancerTYPE ID® Test, Rosetta Cancer Origin test; miRview®; ProOnc TumorSourceDX™, **DecisionDX-G-CIMP** to evaluate the site of origin of a tumor of unknown primary, and to distinguish a primary from a metastatic tumor 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 tests or technologies.

MP265 Proteomic Serum Analysis - REVISED – (Added VeriStrat)**DESCRIPTION:**

VeriStrat (Biodesix Inc) test uses mass spectrometry and a proprietary algorithm to analyze pretreatment plasma or serum to predict the benefit of single-agent chemotherapy or EGFR Tyrosine Kinase Inhibitor treatment in patients with non-small cell lung cancer with an unknown or wild-type variant of EGFR, or to identify patients with particularly aggressive disease. The NCCN recommends that proteomic testing be conducted in patients with NSCLC and wild-type or unknown EGFR status, and that a “poor” assignment indicates that the patient should not be treated with erlotinib in the second-line setting

INDICATIONS:**VeriStrat®**

Proteomic testing (VeriStrat®) is considered medically necessary for members with advanced non-small cell lung cancer (NSCLC) when ALL of the following criteria are met:

- The tumor is wild-type EGFR or the EGFR status is unknown;
- The member has failed first-line systemic chemotherapy; AND
- The test results will assist in informing whether to proceed with erlotinib (Tarceva®) therapy.

Medicare Business Segment:

In compliance with Novitas LCD (A52986) (L35396) the OVA1 proteomic assay will be covered according to the FDA label. OVA1 is intended only for members, 18 years and older, who are already selected for surgery because of their pelvic mass. It is not intended for ovarian cancer screening or for a definitive diagnosis of ovarian cancer.

In compliance with Novitas LCD (A52986) the VeriStrat proteomic assay will be covered to predict the benefit of single-agent chemotherapy or EGFR Tyrosine Kinase Inhibitor treatment in patients with non-small cell lung cancer with an unknown or wild-type variant of EGFR, or to identify patients with particularly aggressive disease..

EXCLUSIONS:

Any use of VeriStrat® serum proteomic testing except as noted above is considered experimental/investigational or unproven and **NOT COVERED**.

MP287 Shift Care - REVISED – (Edited Criteria)**Skilled Nursing Care in Home or Outside of Home**

In accordance with PA Code § 1249.53 skilled nursing care is considered medically necessary. ~~Private duty nursing~~ Shift skilled nursing is considered medically necessary when ordered by the member's attending physician ~~the need for skilled nursing services or home health aide services involving continuous monitoring and observation of a member and~~ **ALL** of the following criteria are met:

The services are performed by a registered nurse or licensed practical nurse; and

The services are reasonable and necessary for the treatment of an illness or injury and is:

- consistent with the member's medical needs as determined by the attending physician
- consistent with accepted standards of medical practice

The skilled nursing care includes, but is not limited to, any of the following:

- Observation and evaluation
- Teaching/training the member or the member's family to provide care such as:
 - Giving injections
 - Irrigation of a catheter
 - Applying wound dressings involving prescription medication and using aseptic techniques
 - Proper use of medications
- Insertion of sterile catheters
- Bladder training
- Administering injections
- Administering enteral and intravenous total parenteral nutrition
- Treating decubitus ulcers and other skin disorders

LIMITATIONS:

- Activities such as, but not limited to, the administration of eye drops, topical ointments, applying creams, and bathing the skin do not constitute skilled care. Each request for this type of service will be evaluated on an individual basis for determination of medical necessity.
- Skilled nursing is provided in the home in order to meet the skilled needs of the member, not for the convenience of the family/caregiver.
- Skilled nursing is not covered once the member is 21 years of age
- PH-MCOs cannot require a minimum number of specified hours [e.g., four (4) continuous hours] be medically necessary in order to authorize services. Each request submitted must be reviewed for medical necessity on its own merit and an appropriate decision rendered.
- A request may not be denied because the service will be provided in a location outside of the child's home, such as, but not limited to, a school setting. Each request submitted must be reviewed for medical necessity on its own merit and an appropriate decision rendered.
- A request may not be denied because the PH-MCO believes that the service should be covered as part of a child's Individualized Education Program (IEP) or Section 504 Plan.. Each request submitted must be reviewed for medical necessity on its own merit and an appropriate decision rendered.

Home Health Aide in Home or Outside of Home

In accordance with PA Code § 1249.54, home health aide service is considered medically necessary when ALL of the following criteria are met:

- The home health aide service is provided in conjunction with skilled care or, when personal care services are medically necessary; and
- There is documentation of communication between the home health aide and a supervisory nurse regarding the member, at least every two weeks; and
- The assignment of home health aide services is made in accordance with a written treatment plan established by the member's attending physician which indicates a need for personal care services, and the specific services to be furnished by the home health aide is determined by a registered nurse. If skilled care is not required, the member's attending physician must certify that the personal care services are medically necessary.

Personal care services that may be performed by a home health aide include, but are not limited to, assisting the member with:

- Bathing and personal hygiene;
- Ambulation and transfer;
- Exercise;
- Administering medications ordered by a physician that are ordinarily self-administered;
- Retraining the member in necessary self-help skills;

LIMITATIONS:

Domestic and/or housekeeping services that are unrelated to the member's care such as, but not limited to, vacuuming, dusting, floor mopping, kitchen and bathroom maintenance, washing, mending and ironing clothes, child care do not constitute home health aide services

1. ~~Member is under 21 years of age or under; and~~
2. ~~Member requires frequent medical intervention/observation; and~~
3. ~~Member requires more continuous skilled nursing care than can be provided by a home health skilled nursing visit including, but not limited to:~~
 - ~~Member is ventilator dependent~~
 - ~~Member is being weaned from a ventilator~~
 - ~~Members with tracheostomy and respiratory compromise requiring frequent suctioning~~
 - ~~Member requires feeding and/or medication via a nasogastric tube and insertion and removal of the nasogastric tube is required and is associated with complex medical problems~~
4. ~~Member has medical needs that require complex nursing assessments and interventions that are in response to acute episodes of medical instability~~

In order to consider medical necessity for private duty nursing, sufficient information must be submitted for review. Necessary information includes the following:

- ~~Clinical history and the anticipated plan of care.~~
- ~~Skilled nursing needs, including frequency and duration, that require private duty care.~~
- ~~Ability and availability of family or other caregivers to be trained to care for the member to provide services including but not limited to: routine tube feedings, bladder catheterization, tracheostomy care, routine maintenance of colostomies and ileostomies, and assistance with activities of daily living such as bathing, eating, dressing and personal hygiene. (Refer to Limitation section).~~
- ~~Parent/caregiver work schedules indicating hours/days of the week at work. Work schedules must be provided for home-based business arrangements.~~
- ~~Additional information may be required based upon the specifics of the case.~~

Note: ~~Medically necessary in-home or outside the home nursing or home health aide services cannot be denied on the basis that the member has a family member, live-in caregiver, or other person that is able and available to provide the level or extent of care that the member needs, given the caregivers work schedule or other responsibilities, including other responsibilities in the home. Additionally, these services may not be denied on the basis that the prescribed services are limited to the provision of ADL's, or could be performed by a personal care assistant or other person, or that the member needs but is not receiving a higher level of care.~~

PROCESS: Please refer to Medical Management Procedure MM16_1222

Note: ~~A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15- Experimental Investigational or Unproven Services or Treatment.~~

MP312 Routine Care in Clinical Trials – NEW POLICY

DESCRIPTION: Routine care during participation in an approved clinical trial is defined as being those items and services that are consistent with the coverage typically provided to a qualified member who is not otherwise enrolled in a clinical trial. Coverage is consistent with Centers for Medicare & Medicaid Services policy and Patient Protection and Affordable Care Act requirements.

INDICATIONS: The routine care while a member is participating in a qualifying Phase II, III, or IV clinical trial for the treatment of cancer or another life-threatening disease or condition is covered.

Qualifying clinical trials are defined as those:

- Funded by National Institutes of Health (NIH), National Cancer Institute (NCI), The Center for Disease Control and Prevention (CDC), The Agency for Health Care Research and Quality (AHRQ), The Centers for Medicare & Medicaid Services (CMS), Department of Defense (DOD), Veterans Administration (VA) or supported by centers and/or cooperative groups which are funded by one of those agencies; or
- Conducted under an Investigational New Drug (IND) application reviewed by the Food and Drug Administration (FDA) (e.g., drugs that have not been approved for marketing by the FDA, or FDA-approved drugs being tested for uses that are not approved by the FDA); or
- Meet the criteria for exemption from IND regulations

Routine costs in clinical trials include those items and services that:

- are typically considered to be conventional care; and
- are required for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service and the prevention of complications; and
- are needed for necessary care for the diagnosis or treatment of complications.

EXCLUSIONS: Costs which are not routine care costs, including, but not limited to, the following:

- The investigational item, device, drug or service;
- Services, drugs or items specifically excluded in the member's benefit plan document;
- Products and services provided by the research sponsors free of charge for any person enrolled in the trial;
- Services that are provided for the sole purpose of data collection and analysis, and not used in the direct clinical management of the patient;
- Any service that is inconsistent with generally accepted and established standards of care for the treatment of a particular diagnosis;
- Travel and transportation expenses;
- Lodging;
- Meals

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.

MP60 Lung Volume Reduction

MP77 Noninv Mech tx for Back Pain

MP83 Contact Lenses

MP123 HDR Temp Brachytherapy

MP186 Hip Resurfacing

MP191 Mindstreams Cognitive Health Assessment

MP210 Endometrial Ablation

MP224 Topical Oxygenation

MP225 Circulating Tumor Cell Testing

MP272 PCA3 Assay (Progenesa)

MP258 Hyperhidrosis
MP157 Prothrombin Time Home Testing
MP144 Vitamin B12 Injection Therapy
MP17 Ambulance Transport
MP293 Intrathecal Infusion Pump
MP298 Intrathecal Infusion Pump for Anti-Spasmodic Medications
MP06 Nocturnal Enuresis Alarm
MP19 Laser Tx of Cutaneous Lesions
MP95 Craniosacral Therapy
MP119 Therapeutic Listening
MP126 Massage Therapy
MP130 Automated Amb. BP
MP138 Lysis Epidural Adhesions
MP142 Anodyne Infrared Therapy
MP149 Pulsed Electrical Stimulation for Osteoarthritis
MP155 Cooling Devices
MP169 Retinal Prosthesis
MP168 Non-invasive Testing for Heart Transplant Rejection
MP190 Xstop Interspinous Process Decompression System
MP276 Hearing Aids
MP182 Transcranial Magnetic Stimulation