	POLICY / PROCEDURE	No.	MP-HSOP-013-FP-01-23
	Evaluation and Determination of Pre-Authorization Services	Effective Date	12/08/2023
		Revision Letter	**AC**
		Final Approver	MPCC

1.0 Purpose

To define the manner that MMM Holdings LLC and its subsidiaries identifies and evaluates specific services requisitions and facilitate a consistent determination process for Clinical and Trained Non-Clinical personnel.

2.0 Scope

This policy applies to all departments of MMM Holdings LLC and its subsidiaries, for all policies and procedures developed as part of the Company's daily operations.

3.0 Policy

MMM Holdings LLC and its subsidiaries shall identify members who met criteria for the services that require preauthorization. Clinical Adverse Determinations are taken by a Medical Director. Administrative Adverse Determinations are taken by Registered Nurses and /or Clinical Coordinators.

4.0 Responsibilities

5.1 The Chief Clinical Operations Officer (CCOO) is ultimately responsible for overseeing the Health Services processes, and or to design it.

5.2 The Chief Medical Officer (CMO) does the oversight of the Medical Director's clinical determinations.

5.3 The Corporate Medical Director or Medical Director designee is responsible for reviewing clinical determinations.

5.4 The Pre-authorization Director is responsible for the Pre-Authorization Operational Process.

5.5 The Pre-Authorization Manager is responsible for overseeing the use of correct criteria for a pre-authorization service.

5.6 Pre-Authorization Supervisor is responsible for submitting pre-authorization operational reports to the Pre-Authorization Manager.

5.7 Pre-Authorization Registered Nurses and or Clinical Coordinators are responsible for processing requested services in the preauthorization system in accordance to the established company policies, procedures and Medicare and Medicaid (CMS) and other regulatory agencies regulations.

REGULATORY REFERENCES:

1. Chapter 1 - Medicare National Coverage Determinations Manual Chapter 1, Part 4 (Sections 220.6.13)

2. Chapter 4 - Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections

3. Chapter 7- Medicare Benefit Policy Manual Chapter 7 - Home Health Services

4. Medicare Chapter 12 Medicare Benefit Policy Manual Chapter 12 - Comprehensive Outpatient Rehabilitation Facility (CORF) Coverage

5. Medicare Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (effective August 3, 2022)

6. Medicare Chapter 20 - Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

7. MCG 27th Edition

5.0 Procedures:

Refer to HSOP-001

6.0 Document Approvals

Role	Position	Name of Approver	Approval Signature	Date Approved
Department Head	Chief Medical Officer	Dr. Rod St. Clair	Signature on file	07/26/2013
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	11/10/2015
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	01/25/2016
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	04/01/2016

Role	Position	Name of Approver	Approval Signature	Date Approved
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/19/2016
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/25/2016
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	01/30/2017
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/26/2017
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	03/06/2018
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/02/2018
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	08/19/2019
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	09/23/2019
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/15/2019
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	12/18/2019
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	01/28/2020
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/30/2020
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	05/17/2021
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	10/05/2021

Role	Position	Name of Approver	Approval Signature	Date Approved
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	06/13/2022
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	07/28/2022
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	03/07/2023
Department Head	Chief Medical Officer	Dr. Waldemar Ríos	Signature on file	05/09/2023

7.0 Medical Policy Clinical Committee Revision History

Date	Version	Comments
12/08/2023	Final	Approved by Medical Policy Clinical Committee (MPCC)

8.0 Revision History

Effective Date	Rev. Letter	Document Author	Description of Change
04-19-2012	A	Dr. Diego Rosso Liz Román Eva Rivera	Initial Release.
07-26-2013	B	Dr. Diego Rosso Liz Román Eva Rivera	Initial Release.
06-23-2013	C	Liz Román Eva Rivera	Aesthetic changes on template.
07-17-2014	D	Liz Román Eva Rivera	Minor orthographic changes
10-23-2014	E	Liz Román	Modifications ICD 9 to ICD 10 version
12-10-2014	F	Liz Román	ICD-9 elimination, also vasotherapy and Tens services were excluded.
05-21-2015	G	Liz Román	Coverage changes on certain services like Diapers, add of FP product name, addition of

Effective Date	Rev. Letter	Document Author	Description of Change
			Home Orthopedics clinical criteria
10-11-2015	H	Liz Román	Aesthetics, scope and table of contents
01-25-2016	I	Liz Román	Changes in Coagucheck contract and TU information added.
04-01-2016	J	Liz Román	Esthetics, CMS wording and table of contents change.
10-19-2016	K	Liz Román	New clinical criteria for services: esthetic and re wording changes. Myocardial Perfusion Imaging was excluded. Description of change: DME; Trapeze, Hydraulic or Mechanical Patient Lift, Custom Manual Wheelchair, Custom Motorized Wheelchair, Pneumatic Compression Devices (lymphedema and venous insufficiency), defibrillator vest K0606 and cervical traction. Procedures that were added: Cochlear Implant Devices, Biopsy of prostate, Nails debridement, removal and biopsy, BRCA, Mammaprint, Lipectomy/Panniculectomy, CORF, TAVI, Brain PET CT Scan, Molecular Pathology Process, Genoptix capitation. Medicines were also added: Cromolyn, Mucomyst, Tobramycin, Tyvaso, and Ventavis. Services that were Modified: Laser therapy for BPH, Mammoplasty reduction, Commode, BP monitor, Transportation, Blepharoplasty, semi electric bed/mattress, Cytogenetics studies and Nebulized Therapy. Changes in the name of brand.
10-25-16	L	Liz Román	New esthetic and re wording changes. The Word CT was removed from all parts where the title of Pet Brain Scan (78606) was present. CoaguChek approval period of 3 months was modified instead of 6 months. The Nebulized Therapy for non-capitated process criteria was included, again. The Mama Print cpt code was removed from all parts. Pet CT scan terminology was removed in the part of radiology reference and was substituted by the term "other related services". Reduction title Mammaplasty follows was modified: "To be Assessed by RN Only when cancer diagnosis is present, if not, with the ultimate assessment of Medical Director". Clarification of reduction mammoplasty; will not need the final assessment of

Effective Date	Rev. Letter	Document Author	Description of Change
			the Medical Director, unless the Servicing Physician is a Non-Participant Provider
01-30-2017	M	Liz Román	Formoterol Fumarate Nebulized Therapy, Unna boot, Therapeutic Shoes/Inserts, External Breast Prostheses, Mastectomy Bra, Prefabricated Knee Orthoses, Lumbo-sacral Orthoses, Breast Reconstruction Surgery, Removal of Nail Plate/Nail Bed
10-26-2017	N	Sindia Jorge	Orthotics shoes, oxygen during travel, Percutaneous Left Atrial Appendage Closure (LAAC) with Watchman device.
03-05-2018	O	Sindia Jorge	Clinical criteria are added for the Watchman procedure and Oral Device.
10-02-2018	P	Sindia Jorge	Change in titles from CCO to COO, changes in MCG 25th edition, and changes in the Transportation information, Non-Par process and LCD versions.
08-19-2019	Q	Sindia Jorge	Changes in the information for the Mamma Print.
09-23-2019	R	Sindia Jorge	Updated the LCD of some services to the current one.
10-15-2019	S	Sindia Jorge	Transportation Services information was deleted. It does not apply.
12-18-2019	T	Sindia Jorge	The criteria for the nutritional evaluation service and for the prostate biopsy procedure were eliminated. Oximetry service included in the oxygen criteria part was eliminated. Also, there was a modification in the criteria for the Oral Appliances for Obstructive Sleep Apnea.
01-28-2020	U	Sindia Jorge	Modification of the criteria for the Oral Appliances for Obstructive Sleep Apnea. References for preferred contract codes were eliminated. Criteria for Speech generating device was added.
10-30-2020	V	Sindia Jorge	Updated the LCD version numbers of some services.
05-17-2021	W	Sindia Jorge	Clinical criteria for the Blepharoplasty procedure was modified and clinical criteria was added for the Continuous Glucose Monitor service.

Effective Date	Rev. Letter	Document Author	Description of Change
10-05-2021	X	Sindia Jorge	Updated Regulatory References. Modification of the criteria for the Sclerotherapy Treatment of varicose veins of the lower extremity.
06-13-2022	Y	Sindia Jorge/ Dary Martínez	Updated the LCD version numbers of some services. Criteria for Laser Capsolutomy Surgey was added. Criteria for Formoterol therapy and preferred contract codes with Genoptix Laboratory were eliminated. Change in MCG edition. Modification of the criteria for Compression Stockings, Therapeutic (Diabetic) Shoes for Persons with Diabetes, Orthotic Shoes (this includes requests for shoes for diabetic patient and orthotics shoes, Thoracic-lumbar-sacralorthoses.
07-28-2022	Z	Sindia Jorge/Dary Martínez	Clinical Criteria for the Continuous Glucose Monitor was modified. Modification of the effective date of the medical order for the Mastectomy Bra service.
03-07-2023	AA	Sindia Jorge	Criteria for Cataract Surgery was eliminated. Updated the LCD version numbers of some services. Update the effective date of the Medicare Part C & D guide in regulatory references.
05-09-2023	AB	Sindia Jorge	Criteria for Continuous Glucose Monitor (CGM) was modified. Change in titles from COO to CCOO.
12-08-2023	AC	Liz A. Román Ana Ortiz	The following Clinical Criteria was eliminated: Unna boot, Tropism, Sterilization, Biopsy of nails, Nail debridement, Removal of nail plate/nail bed, Laser for BPH. Changes in wording: Non-Participant Process (office visits) and Attachment A - now indicates “Disclaimer”. The following criteria was modified: HBOT, Lipectomy/Panniculectomy and Brain Pet scan. Changes of Medicare reference for: MammaPrint. The Glossary was eliminated. Attachments/Forms were eliminated.

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Durable Medical Equipment & Supplies Air Pad, Air Mattress and Prevention Mattress (To be assessed by RN and Clinical Coordinator)

Medicare Reference: CGS Administrators, LLC LCD L33830

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, NPI and signature, medical order with valid date (no more than 60 days of expedition), weight and height (optional).

2. Evaluate if it is in compliance with the following: Pressure ulcer(s), members bedridden with area of pressure sore. Status post with recent Skin Graft of trunk or pelvis area (up to 60 days since surgery).

3. Requests for air pads should follow medical criteria of being confined to bed, as a preventive method to avoid development of pressure sores and/or inclined to develop pressures ulcers.

4. Request for air mattress should follow the criteria of being confined to bed, in addition of presenting one or multiple ulcers in the trunk or pelvis.

Medicare reference: LCD ID L33830 LCD

LCD Title Pressure Reducing Support Surfaces - Group 1

Group 1 Mattress codes are: E0181, E0184, E0185, E0186, E0187, E0188, E0189, E0196, E0197, E0198, E0199 y A4640

A Group 1 mattress overlay or mattress (E0181-E0189, E0196-E0199, and A4640) is covered if one of the following three criteria are met:

1. The beneficiary is completely immobile - i.e., beneficiary cannot make changes in body position without assistance, or
2. The beneficiary has limited mobility - i.e., beneficiary cannot independently make changes in body position significant enough to alleviate pressure and at least one of conditions A-D below, or
3. The beneficiary has any stage pressure ulcer on the trunk or pelvis and at least one of conditions A-D below.

Conditions for criteria 2 and 3 (in each case the medical record must document the severity of the condition sufficiently to demonstrate the medical necessity for a pressure reducing support surface):

a. Impaired nutritional status
b. Fecal or urinary incontinence
c. Altered sensory perception
d. Compromised circulatory status

When the coverage criteria for a Group 1 mattress overlay or mattress are not met, please refer case to the medical director for final assessment.

The support surface provided for the beneficiary should be one in which the beneficiary does not "bottom out". Bottoming out is the finding that an outstretched hand, placed palm up between the undersurface of the mattress overlay or mattress and the beneficiary's bony prominence (coccyx or lateral trochanter), can readily palpate the bony prominence. This bottoming out criterion should be tested with the beneficiary in the supine position with their head flat, in the supine position with their head slightly elevated (no more than 30 degrees), and in the side-lying position.

Medicare reference: LCD ID L33642

LCD Title Pressure Reducing Support Surfaces - Group 2

Group 2 Support Surface Mattress codes are: E0277, E0371, E0372 and E0373

A group 2 support surface is covered if the beneficiary meets at least one of the following three Criteria (1, 2 or 3):

1. The beneficiary has multiple stage II pressure ulcers located on the trunk or pelvis (described by the diagnosis codes listed in the table below) which have failed to improve over the past month, during which time the beneficiary has been on a comprehensive ulcer treatment program including each of the following:
    a. Use of an appropriate group 1 support surface, and
    b. Regular assessment by a nurse, physician, or other licensed healthcare practitioner, and
    c. Appropriate turning and positioning, and
    d. Appropriate wound care, and
    e. Appropriate management of moisture/incontinence, and
    f. Nutritional assessment and intervention consistent with the plan of care

2. The beneficiary has large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis (described by the diagnosis codes listed in the table below),

3. The beneficiary had a myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis within the past 60 days and has been on a group 2 or 3 support surface immediately prior to discharge from a hospital or nursing facility within the past 30 days.

If the beneficiary is on a group 2 surface, there should be a care plan established by the physician or home care nurse which includes the above elements. The support surface provided for the beneficiary should be one in which the beneficiary does not "bottom out".

When the stated coverage criteria for a group 2mattress or bed are not met, please refer case to the medical director for final assessment.

Automatic External Defibrillator (To be assessed by RN only with the final assessment of Medical Director:

Medicare Reference: CGS Administrators, LLC LCD ID L33690

A wearable defibrillator (K0606) is covered for beneficiaries if they meet **one** of the criteria described below:

1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occur during the first 48 hours of an acute myocardial infarction; or

2. Familial or inherited conditios with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or

3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or

4. A previously implanted defibrillator now requires explanation.

Semi-electric Hospital Bed/Heavy Duty/Extra Heavy Duty /Mattress Innerspring (E0271) / Foam Rubber Mattress (E0272) (To be assessed by RN and Clinical Coordinator)

Medicare Reference: CGS Administrators, LCD ID L33820

1. The beneficiary has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, or

2. The beneficiary requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, or;

3. The beneficiary requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration, or

4. The beneficiary requires traction equipment, which can only be attached to a hospital bed.

5. A semi-electric hospital bed (E0260, E0261, E0294, E0295, and E0329) is covered if the beneficiary meets one of the criteria for a fixed height bed and requires frequent changes in body position and/or has an immediate need for a change in body position.

6. A heavy duty extra wide hospital bed (E0301, E0303) is covered if the beneficiary meets one of the criteria for a fixed height hospital bed and the beneficiary's weight is more than 350 pounds but does not exceed 600 pounds.

7. An extra heavy-duty hospital bed (E0302, E0304) is covered if the beneficiary meets one of the criteria for a hospital bed and the beneficiary's weight exceeds 600 pounds.

8. If a beneficiary's condition requires a replacement innerspring mattress (E0271) or foam rubber mattress (E0272) it will be covered for a beneficiary owned hospital bed.

9. The beneficiary is completely immobile - i.e., beneficiary cannot make changes in body position without assistance.

Trapeze (To be assessed by RN or Clinical Coordinator)

Medicare reference: CGS Administrators, LCD ID L33820

Verify the following information: Name, correct member ID number, Physician's name, address, license, NPI and signature, medical order with valid date (no more than 60 days of expedition).

Trapeze equipment (E0910, E0940) is covered if the beneficiary needs this device to sit up because of a respiratory condition, to change body position for other medical reasons, or to get in or out of bed.

Heavy duty trapeze equipment (E0911, E0912) is covered if the beneficiary meets the criteria for regular trapeze equipment and the beneficiary's weight is more than 250 pounds.

Hydraulic or Mechanical Patient Lift (To be assessed by RN or Clinical Coordinator)

Medicare reference: CGS Administrators, LCD ID L33799

Verify the following information: Name, correct member ID number, Physician's name, address, license, NPI and signature, medical order with valid date (no more than 60 days of expedition).

Basic coverage:

A patient lift is covered if transfer between bed and a chair, wheelchair, or commode is required and, without the use of a lift, the beneficiary would be bed confined.

A patient lift described by codes E0630, E0635, E0639, or E0640 is covered if the basic coverage criteria are met. If the coverage criteria are not met, the lift will be denied as not reasonable and necessary.

A multi-positional heavy-duty patient transfer system (E0636, E1035, and E1036) is covered if both of the following criteria 1 and 2 are met:

1. The basic coverage criteria for a lift are met; and
2. The beneficiary requires supine positioning for transfers

Beneficiaries must not have other mobility assistive equipment, including but not limited to canes, crutches, walkers, and roll about chairs, transfer chairs, manual wheelchairs, power-operated vehicles, or power wheelchairs.

Bariatric Equipment (To be assessed by RN and Clinical Coordinator)

Refer to Specific Medicare LCD for each type of equipment and its limitations and indications including weight indicators.

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, NPI and signature, medical order with valid date (no more than 60 days of expedition).

2. Evaluate if member complies with Medicare criteria for a regular DME.

3. Documented member's weight, height and physical constitution will be taken in consideration for DME selection.

4. All bariatric DME should be evaluated by the nurse and coordinator.

5. Bariatric DME equipment that does not meet criteria will be evaluated by the medical director.

Bath Shower Chair (To be assessed by RN and Clinical Coordinator)

Service not covered by Medicare, Internal Criteria for determinations as follows:

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, NPI and signature, medical order with valid date (no more than 60 days of expedition).

2. Evaluate if complies with the following: Status post cerebrovascular accident convalescence, Vertigo, Dizziness and Giddiness, Status post amputation of extremities, progress or suddenly loss of vision and any medical condition increasing the risk of injury to the patient.

3. The Bath Shower Chair is a service out of Medicare's coverage so it will be processed as a benefit exception if it meets medical necessity. Also, to provide security and reduce potential falls.

4. The chairs can be authorized with or without back support, as ordered by physician.

Blood Glucose Monitors and Supplies (RN and Clinical Coordinator)
also includes BGM excess request process

Medicare Reference: CGS Administrators, LLC LCD ID L33822

To be eligible for coverage of home blood glucose monitors related accessories and supplies, the patient must meet all the following basic criteria:

1. Verify the following information: Name, correct ID number of members, Physician's name, address, license, NPI and signature, medical order with valid date (no more than 60 days of expedition).

2. Evaluate compliance with clinical criteria that includes diabetes diagnosis.

3. The glucose monitors and related accessories and supplies have been ordered by the physician who is treating the patient's diabetes and the treating physician maintains records reflecting the care provided including, but not limited to, evidence of medical necessity for the prescribed frequency of testing; and

4. The patient (or the patient's caregiver) has successfully completed training or is scheduled to begin training in the use of the monitor, test strips, and lancing devices; and

5. The patient (or the patient's caregiver) can use the test results to assure the patient's appropriate glycemic control; and

6. The device is designed for home use.

7. Medicare covers a daily glucose frequency monitoring for patients non-insulin dependents, and three times a day glucose frequency monitoring for those who have insulin treatment.

Continuous Glucose Monitor (To be assessed by RN)

Medicare Reference: CGS Administrators, LLC LCD ID L33822

Therapeutic CGMs and related supplies are covered by Medicare when all the following coverage criteria (1-6) are met:

1. The beneficiary has diabetes mellitus; and,

2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed.

3. The CGM is prescribed in accordance with its FDA indications for use; and,

4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:

a. The beneficiary is insulin-treated or
b. The beneficiary has a history of problematic hypoglycemia with documented evidence of at least one of the following;

- Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
- A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,

6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person or Medicare-approved telehealth or visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.

Clinical Criteria to Evaluate Brovana Nebulized Therapy (To be assessed only by RN)

This is a capitated service: criteria below for clinical knowledge only.

Medicare Reference: CGS Administrators, LLC LCD. All requisitions for this prescription must be presented to the Medical Director

What is Brovana (J7606)? It's a prescription drug called Long Acting Beta2-Agonist (LABA) used in long-acting nebulized therapy to control Chronic Obstructive Pulmonary Disease (COPD), to be used twice a day (BID).

It should not be used more than twice a day.

It should not be used in conjunction with other prescription drugs containing LABA.
This information must be obtained prior referring the requisition to the Medical Director:

1. Has the patient undergoing treatment with long acting beta2-antagonist (LABA) in form of MDI or DPI? (MDI= Metered Dose Inhaler, DPI= Dry Powder Inhaler). This information might be available at Pharmacy application or might be obtained through outbound call, to referring physician only. (Information provided by patient is not reliable, because due to possible lack of clinical knowledge, they may provide unintended wrongful information about their current prescription drugs.)

   The following are LABA (Long Acting Beta2-Antagonist) prescription drugs:

   Salmeterol: Serevent
   Formoterol: Foradil

   LABA + ICS (Long Acting Beta2-Antagonist + inhaled corticosteroid):

   Salmeterol y Fluticasicone: Advair

Formoterol y Budesonide: Simbicort
Formoterol y Mometasone: Dulera

2. Does patient have limitations for self-administration of DPI or MDI?

3. Does the patient have caregiver or relatives support to help in the drug administration?

Cromolyn Nebulized Therapy (Nasalcrom) (To be assessed by RN only with final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC ,LCD ID L33370

Verify the following information: Name, correct ID number of member, Physician's name, address signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following diagnosis:

1. Obstructive pulmonary disease

Mucomyst Nebulized Therapy (Acetylcysteine) (To be assessed by RN only with final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC ,LCD ID L33370

Verify the following information: Name, correct ID number of member, Physician's name signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following diagnoses:

1. Respiratory disease with manifestation, exacerbation or complicated, with persistent thick or tenacious pulmonary secretions.

Tobramycin Nebulized Therapy (TOBI) (To be assessed by RN only with final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC ,LCD ID L33370

Verify the following information: Name, correct ID number of member, Physician's name signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following diagnoses:

Tuberculosis of lung

a. Cystic fibrosis with pulmonary manifestations

b. Bronchiectasis with acute lower respiratory infection
c. Bronchiectasis with (acute) exacerbation
d. Uncomplicated Bronchiectasis

Tyvaso Nebulized Therapy (Treprostinil) (To be assessed by RN only with final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC ,LCD ID L33370

Verify the following information: Name, correct ID number of member, Physician's name signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following diagnoses:

1. The beneficiary has a diagnosis of pulmonary artery hypertension.

2. The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.); and

3. The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, the following criteria (a-d) must be met:

    a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
    b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; and
    c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and
    d. Treatment with oral calcium channel blocking agents has been tried and failed or has been considered and ruled out.

Ventavis Nebulized Therapy (iloprost) (To be assessed by RN only with final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC, LCD ID L33370
Verify the following information: Name, correct ID number of member, Physician's name signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following diagnoses:

1. The beneficiary has a diagnosis of pulmonary artery hypertension.

2. The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc.) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.); and

3. The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, anorexigens or congenital left to right shunts. If these conditions are present, the following criteria (a-d) must be met:

    a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and
    b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; and
    c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and
    d. Treatment with oral calcium channel blocking agents has been tried and failed or has been considered and ruled out.

Nebulized Therapy Process for non-Capitated Codes (To be assessed only by RN)

Medicare Reference: CGS Administrators, LLC, LCD L33370

1. Verify the following information: Name, correct ID number of member, Physician's name signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following diagnoses:

2. Bronchitis, Asthma, Chronic Obstructive Pulmonary Disease (COPD), and Respiratory Conditions due to External Agents.

Will be authorized and not sent to medical review those authorization requests for members with chronic and severe respiratory conditions, included End stage COPD, End stage Pulmonary Fibrosis, Terminal Pulmonary CA with permanent obstruction and Bronchial Spasms ("if the clinical information is inconclusive or insufficient, the requisition will be sent to Medical Review evaluation").

Members with mental or degenerative conditions.

- Advanced Alzheimer's disease
- Parkinson's
- Mental retardation

- Multiple Sclerosis
- Inability to use MDI/DPI should be deemed. Contraindications or therapy failure with the use of MDI/DPI by the member.
- Members with combined respiratory therapy treatment and oxygen dependent.
- Requisitions that come with written medical justification of inability (lack of coordination) to manage inhaler.

For reference these are the Capitated Codes:

1. J7626- Pulmicort /Budesonide
2. Q0513- Dispensing Fee (no preauthorization required)
3. J7614- Xopenex/Levalbuterol
4. J7613- Albuterol (no preauthorization required)
5. E0570- Nebulizer (no preauthorization required)
6. J7620- Duoneb (no preauthorization required)
7. J7644- Ipratropium (no preauthorization required)
8. A7015- Aerosol Mask, used with DME Nebulizer (no preauthorization required)
9. A7003- Administration Fee Set, With Small Volume Non-Filter Mastectomy Bra Nebulizer, Disposable (no preauthorization required)
10. J7605- Brovana (preauthorization required)

Cervical Traction Devices (to be assessed by RN or clinical coordinator):

Medicare Reference: CGS Administrators, LLC LCD ID L33823

Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI, and medical order with valid date (no more than 30 days of expedition).

Indications and Limitations of Coverage and/or Medical Necessity:

Cervical traction devices (E0840-E0855 and E0860) are covered only if both of the following criteria are met:

1. The beneficiary has a musculoskeletal or neurologic impairment requiring traction equipment; and

2. The appropriate use of a home cervical traction device has been demonstrated to the beneficiary and the beneficiary tolerated the selected device.

3. If criteria 1 and 2 are not met, cervical traction will be denied as not reasonable and necessary.

4. Cervical traction devices described by code E0849 or E0855 are covered only when criteria 1 and 2 above and either criterion A, B or C below has been met:

a. The beneficiary has a diagnosis of temporomandibular joint (TMJ) dysfunction; and has received treatment for the TMJ condition; or,
b. The beneficiary has distortion of the lower jaw or neck anatomy (e.g., radical neck dissection) such that a chin halter is unable to be utilized; or,

The treating physician orders and/or documents the medical necessity for greater than 20 pounds of cervical traction in the home setting.

Coaguchek - International Normalized Ratio (INR) Monitoring (To be assessed only by RN)

Medicare Reference: NCD Database ID 190.11

CPT Codes:

G0248	DEMONSTRATION, AT INITIAL USE, OF HOME INR MONITORING FOR PATIENT WITH MECHANICAL HEART VALVE(S) WHO MEETS MEDICARE COVERAGE CRITERIA, UNDER THE DIRECTION OF A PHYSICIAN; INCLUDES: DEMONSTRATING USE AND CARE OF THE INR MONITOR, OBTAINING AT LEAST ONE BLOOD SAMPLE, PROVISION OF INSTRUCTIONS FOR REPORTING HOME INR TEST RESULTS, AND DOCUMENTATION OF PATIENT ABILITY TO PERFORM TESTING.
G0249 (Strips)	PROVISION OF TEST MATERIALS AND EQUIPMENT FOR HOME INR MONITORING TO PATIENT WITH MECHANICAL HEART VALVE(S) WHO MEETS MEDICARE COVERAGE CRITERIA; INCLUDES PROVISION OF MATERIALS FOR USE IN THE HOME AND REPORTING OF TEST RESULTS TO PHYSICIAN; PER 4 TESTS
A9900 (Lancets)	MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE.

Indications & Required Documentation

a. The monitor and the home testing must be prescribed by a physician and the following patient requirements must be met:

b. The beneficiary requires chronic oral anticoagulation with warfarin for a mechanical heart valve, chronic atrial fibrillation, or venous thromboembolism; and

c. Must have been anticoagulated for at least three months prior to use of the home INR device.

d. Must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and

e. Self-testing with the device is limited to a frequency of once per week.

NOTE: Porcine valves are not covered so Medicare will not make payment on home INR monitoring for patients with porcine valves.

CPT code G0248 will be assigned for initial supply and CPT G0249 will be assigned for subsequent orders or refills every 6 months.

Commode (To be assessed by RN and Clinical Coordinator)

Medicare Reference: CGS Administrators, LLC LCD L33736

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, NPI, signature and medical order with valid date (no more than 60 days of expedition), weight and height (optional).

2. Commode is covered when the patient is physically unable to use the sanitary facilities in the home. This would occur under the following conditions: (documenting):

    a. Patient confined to a single room,
    b. Patient confined to one area or level (second floor) from the residence where no toilet facilities exist.
    c. Patient confined to home and there are no toilet facilities.

3. Requests for large or extra-large commode (300 pounds or more) (E0168), evaluated with the same criteria of the regular commode. In addition, the member's weight and height is taken in consideration. Commode with detachable arms is covered when member has the need to be transferred (E0165).

4. Commode with seat elevation mechanism is covered if the member has the medical need for a regular commode and requires the assistance of elevation mechanism (E0170, E0171).

Compression Stockings (Delegated Service to Home Orthopedics Provider)
(To be assessed by RN and Clinical Coordinator)

Medicare Reference: CGS Administrators, LLC LCD ID L33831

1. Purpose: To define the internal policy in which the Delegated entity Home Orthopedics will apply the clinical coverage criteria and or medical necessity, indications, limitations and documentation requirements to be used in the preauthorization process for Gradient Compression Stockings. MMM/PMC/FP

2. Internal Policy: Compression Stocking (Gradients Below Knee, thigh length, full length, waist length 18-20, 20-30, 30-40, 40-50)

3. Summary: Pressure in garments prescribed for lower extremity use typically range from 34 mm Hg to greater than 49 mm Hg; pressure in garments prescribed for upper extremity use typically range from 18 mm Hg to 32 mm Hg. Evidence supports use of compression stockings for improvement in venous disease, after sclerotherapy, and for the prevention of varicose veins, post-thrombolytic syndrome, and venous thromboembolism in non-mobile patients. Stockings tend to wear out at approximately 6 months.

4. Indications and coverage criteria:

   Appropriate condition, as indicated by 1 or more of the following:

   - Venous insufficiency I87.2
   - Venous stasis ulcer I87.319, 187.312, I87.311, I87.313
   - Following invasive procedure on saphenous vein (eg, vein stripping, laser ablation, radiofrequency ablation
   - Embolism and thrombosis of superficial veins of lower extremities I82.81
   - Prevention or treatment of deep venous thrombosis of lower extremity I82.503
   - Prevention of post-thrombotic syndrome I87.002
   - Postural hypotension I95.1
   - Lower and upper extremity lymphedema following node dissection I89.0
   - Degrees of compression 18 – 20 mm Hg and 20-30 mm Hg
   - Asymptomatic varicose veins of unspecified lower extremity I83.90
   - Peripheral vascular disease, unspecified I73.90
   - All diagnoses related to surgical procedures not listed should be considered for coverage criteria.

5. Contraindications for approval (limitations for coverage):

   - Untreated Cellulitis
   - Evidence of arterial Insufficiency
   - Evidence of Severe Heart Failure

   Internal Policy: Amount covered per calendar year for affiliates meeting the above criteria: Two (2) per year

<u>Pneumatic Compression Devices (To be assessed by RN or Clinical Coordinator):</u>

Medicare Reference: CGS Administrators LLC, LCD ID L33829

Primary lymphedema is a disorder of the lymphatic system that occurs on its own. It is inherited and uncommon. Examples (not all-inclusive) are:

- Congenital lymphedema due to lymphatic aplasia or hypoplasia
- Milroy's disease, an autosomal dominant familial form of congenital lymphedema
- Lymphedema praecox

- Lymphedema tarda

Secondary lymphedema:

Secondary lymphedema is a disorder of lymphatic flow that is caused by some other disease or condition. It is more common than primary lymphedema. It is most caused by surgery (especially lymph node dissection, such as for breast cancer), radiation therapy (especially axillary or inguinal), trauma, lymphatic obstruction by tumor, and, in developing countries, lymphatic filariasis. Secondary lymphedema may also result from compression of the lymphatic and venous channels resulting from leakage of fluid into interstitial tissues in patients with chronic venous insufficiency.
Indications:

Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI and medical order with valid date (no more than 30 days of expedition). Medicare will consider a pneumatic compression device for *Lymphedema* diagnosis reasonable and necessary when **all the following** are present:

1. Diagnosis of lymphedema as defined above, and
2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least **one** of the following clinical findings:

    - Marked hyperkeratosis with hyperplasia and hyperpigmentation
    - Papillomatosis cutis lymphostatica,
    - Deformity of elephantiasis,
    - Skin breakdown with persisting lymphorrhea,
    - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and

- Four-week trial of conservative therapy such as regular exercise, elevation of the limb and compression bandage.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device.

Chronic Venous Insufficiency (CVI)

Lymphedema may also be caused by CVI when fluid leaks into the tissues from the venous system. CVI of the lower extremities is a condition caused by abnormalities of the venous wall and valves, leading to obstruction or reflux of blood flow in the veins. Signs of CVI include hyperpigmentation, stasis dermatitis, chronic edema, and venous ulcers. The incidence of lymphedema from CVI is not well established.

Indications:

Medicare will consider a pneumatic compression device for *CVI diagnosis* reasonable and necessary when *all* the following are present:

- Edema in the affected lower extremity
- One or more venous stasis ulcer(s)
- The ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating physician (medication, regular exercise, elevation of the limb, appropriate wound care for the ulcer).
- This service will be determined by honoring the price of the DME Provider who has the equipment available in stock.

CPM – (Continuous Passive Motion) (To be assessed by RN and Clinical Coordinator)

Medicare Reference: CMS - National Coverage Determinations (NCDs)

Active NCDs in Alphabetical Order

Durable Medical Equipment Reference List - 280.1 Version 2 (05/05/2005)

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI and medical order with valid date (no more than 60 days of expedition). Medical order must specify the parameters that the patient will begin traction exercise.

2. Evaluate the request complies with the following indications: osteoarthrosis of leg, tear of cartilage or meniscus of knee, patients in status post arthroscopic knee procedure within the first 10 days.

3. Evaluates whether the patient is receiving physical therapy treatment.

4. Authorized period of rent for 21 consecutive days.

5. It is preferable physician requests should be evaluated 48 hours prior to surgery or in the discharge planning, otherwise submit requisition to medical review.

Therapeutic Shoes, Orthotics Shoes and Inserts for Persons with Diabetes (Delegated Service to Home Orthopedics Provider) (To be assessed by RN and Clinical Coordinator)

Medicare Reference; CGS Administrators LLC, LCD ID L33369, LCD ID L33641

Summary: For both items to be covered by Medicare, the patients must comply with clinical criteria and the requested service must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member and meet all other applicable Medicare statutory and regulatory requirements and health plan requirements based on the medical

necessity of the patient actual condition. All diagnoses codes related to surgical procedures not listed should be considered for coverage criteria.

Therapeutic shoes, inserts and/or modifications to therapeutic shoes are covered if **all of the following** criteria are met:

1. The beneficiary has diabetes mellitus; and

2. The certifying physician has documented in the beneficiary's medical record **one** or more of the following conditions:

    a. Previous amputation of the other foot, or part of either foot, or
    b. History of previous foot ulceration of either foot, or
    c. History of pre-ulcerative calluses of either foot, or
    d. Peripheral neuropathy with evidence of callus formation of either foot, or
    e. Foot deformity of either foot, or
    f. Poor circulation in either foot; and

3. The certifying physician has certified that indications (1) and (2) are met and that he/she is treating the beneficiary under a comprehensive plan of care for his/her diabetes and that the beneficiary needs diabetic shoes.
4. For a coverage criteria of therapeutic shoes a medical order is required specifying the type of service. Separate inserts may be covered and dispensed independently of diabetic shoes if the shoes supplier verifies in documentation that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found in this policy for depth shoes of custom molded shoes.

5. A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement. A new order is required for the replacement of any shoe. A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file. The supplier must obtain a signed statement from the physician who is managing the patient's systemic diabetes condition (i.e., the certifying physician) specifying that the patient has diabetes mellitus and is being treated under a comprehensive plan of care for his/her diabetes and needs diabetic shoes. The certifying physician must be an M.D. or D.O. and may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.

6. The "Statement of Certifying Physician for Therepeutic Shoes form is recommended. Whatever form is used, it must contain all the elements contained as recommended. This statement must be completed, signed, and dated by the certifying physician. A new Certification Statement is required for a shoe, insert of modification provided more than one year from the most recent Certification Statement on file.

7. CMN document is recommended, and the certifying physician **may not** be a podiatrist.

8. A custom molded shoe (A5501) is covered when the beneficiary has a foot deformity that cannot be accommodated by a depth shoe. The nature and severity of the deformity must be well documented in the supplier's records and available upon request. If a custom molded shoe is requested but the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary.

9. Diagnoses for to be consider for the approval of Orthopedics Shoes:

    a. Unequal limb length (acquired), unspecified M21.7
    b. Other acquires deformities of unspecified foot M21.6X9
    c. Non-pressure chronic ulcer of other part of unspecified foot with unspecified severity L97.509
    d. Other specified injuries of unspecified foot S99.829
    e. Unspecified injury of ankle and foot S99.9
    f. Any surgery in the foot area
    g. CPT: L3216, L3221, L3224, L3225, L3230, L3250, L3260

10. Contraindications for approval of both diabetic and orthotic shoes (limitations for coverage): For diabetic shoes, if the patient does not have diagnoses of Diabetes Mellitus and for the orthotics shoes if the patient does not have an integral part of prosthesis with a partial amputation.

11. Prosthetic shoes are covered if they are an integral part of prosthesis for patients with a partial foot amputation.

    - Orthopedics Shoes are also covered if they are an integral part of a covered leg brace described by codes L1900, L1920, L1980-L2030, L2050, L2060, L2080, or L2090. Oxford shoes (L3224, L3225) are covered in these situations.

    - Shoes, inserts, and modifications are covered in limited circumstances. They are covered in selected beneficiaries with diabetes for the prevention or treatment of diabetic foot ulcers.

Amount covered per calendar year for affiliates meeting the above criteria:

- One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (A5512 or A5513); or
- One pair of depth shoes (A5500) and 3 pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes).

External Breast Prostheses (Delegated Service to Home Orthopedics Provider)
(To be assessed by RN and Clinical Coordinator)

Medicare Reference; CGS Administrators LLC, LLC LCD ID L33317, LCA A52478

1. Breast prosthesis is covered for a patient who has had a mastectomy.

   An external breast prosthesis garment, with mastectomy form (L8015) is covered for use in the postoperative period prior to permanent breast prosthesis or as an alternative to mastectomy bra and breast prosthesis.

   Breast prostheses, silicone or equal, with integral adhesive (L8031) have not been demonstrated to have a clinical advantage over those without the integral adhesive. Therefore, if L8031 is billed, it will be denied as not reasonable and necessary.

   The medical necessity for the additional features of a custom fabricated prosthesis (L8035) compared to a prefabricated silicone breast prosthesis has not been established, and therefore, if an L8035 breast prosthesis is request, it will be denied as not reasonable and necessary.

An external breast prosthesis of the same type can be replaced at any time if it is lost or is irreparably damaged (this does not include ordinary wear and tear). External breast prosthesis of a different type can be covered at any time if there is a change in the patient's medical condition necessitating a different type of item.

Amount covered for affiliates meeting the above criteria: One every two (2) years.

Mastectomy Bra (Delegated Service to Home Orthopedics Provider)
(To be assessed by RN and Clinical Coordinator)

Medicare Reference; CGS Administrators LCD, LLC LCD ID L33317

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI, and medical order with valid date (no more than 90 days of expedition).

2. A mastectomy bra (L8000) is covered for a patient who has a covered mastectomy form (L8020) or silicone (or equal) breast prosthesis (L8030) when the pocket of the bra is used to hold the form/prosthesis.

Internal Policy: ***Amount covered for affiliates meeting the above criteria; maximum of 6 per year.***

Prefabricated Knee Orthoses (Delegated Service to Home Orthopedics Provider)
(To be assessed by RN and Clinical Coordinator)

Medicare Reference; CGS Administrators, LLC, LCD ID L33318, LCA ID A52465

A prefabricated knee orthosis will be covered if **one** of the following criteria is met:

1. Beneficiaries who have weakness or deformity of the knee and require stabilization.

2. The beneficiary is ambulatory and has knee instability due to *genu recurvatum* (hyperextended knee).

3. The beneficiaries have temporary loss of range of motion of a joint following injury, surgery, casting, or other immobilization.

Internal Policy: *Amount covered for affiliates meeting the above criteria*; one (1) per year for each affected knee.

Thoracic-Lumbar-Sacral, Orthoses (Delegated Service to Home Orthopedics Provider)
(To be assessed by RN and Clinical Coordinator)

Medicare Reference: CGS Administrators, LLC LCD ID L33790 and LCA A52500

I. Purpose: To define the internal policy in which MMM/PMC/FP will apply the clinical coverage criteria and or medical necessity, indications, limitations and documentation requirement to be used in the preauthorization process for the services of Lumbar Orthosis.

II. Lumbar Orthosis
Includes Thoracic-lumbar-sacral, Lumbar, Lumbar-sacral

III. Summary: Thoracic-lumbar-sacral, Lumbar, Lumbar-sacral Orthosis are used as part of the treatment of preventing pain, reducing pain or provide support by restricting mobility of the trunk of the body.

A thoracic-lumbar-sacral orthosis, Lumbar orthosis or lumbar-sacral orthosis are covered when it is ordered for one of the following indications:

1. To reduce pain by restricting mobility of the trunk; or

2. To facilitate healing following an injury to the spine or related soft tissues; or

3. To facilitate healing following a surgical procedure on the spine or related soft tissue; or
4. To otherwise support weak spinal muscles and/or a deformed spine.
5. Documentation must be sufficiently detailed to include, but is not limited to, a detailed description of the type of device which is requested (plastic, rigid, semi –rigid, custom, etc.)

Limitations:

Flexible spinal support garments that are made primarily of elastic material will be denied as noncovered, no benefit category.

If a spinal orthosis is provided and coverage criteria are not met, the item will be denied as not medically necessary.

Enteral and Parenteral Nutritional Therapy (To be assessed by RN and Clinical Coordinator)

Medicare Reference: CGS Administrators, LLC LCD ID L33783, L33798 and L11553

Indications:

Parenteral Nutrition Therapy

Daily parenteral nutrition is considered reasonable and necessary for a patient with;

1. Severe pathology of the alimentary tract which does not allow absorption of enough nutrients to maintain weight and strength commensurate with the patient's general condition.

    - An example of a condition that typically qualifies for coverage is a massive, small bowel resection resulting in severe nutritional deficiency despite adequate oral intake.
    - **NUTRIENTS:** A total caloric daily intake (parenteral, enteral, and oral) of 20-35 cal/kg/day is considered sufficient to achieve or maintain appropriate body weight. The ordering physician must document in the medical record the medical necessity for a caloric intake outside this range in an individual patient. The ordering physician must document the medical necessity for protein orders outside of the range of 0.8-1.5 gm/kg/day, dextrose concentration less than 10%, or lipid use greater than 500 grams (150 units of service of code B4185) per month.

Enteral Nutrition Therapy

Enteral nutrition is considered reasonable and necessary for a patient with:

1. A functioning gastrointestinal tract who, due to pathology to, or nonfunctional of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition.

    - Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding.

    - If a pump is requested, it must be supported by enough medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome.

Enteral feedings are administered by:

- Via nasogastric tube
- Via gastric tube (PEG)

Enteral food Administration Methods Enteral feedings are administered through machine and/or syringes (gravity):

- Enteral feedings are administered via gastric tube (PEG) with machine, and also via syringe (gravity)

Home Automatic Blood Pressure Monitor – CPT A4670 (RN and Clinical Coordinator when required)

Internal Criteria / Health Plan Benefit Coverage

To be eligible for a home automatic blood pressure monitor, the affiliate must be enrolled with MMM/PMC and must have the over-the-counter benefit for this item. Refer to internal current instructions.

Mobility Assistive Equipment (MAE)

Medicare Reference: Medicare National Coverage Determinations (National Coverage Decisions) (PUB. 100-03) Chapter 1 - Coverage Determinations Section 280.3 Mobility Assistive Equipment (MAE), LLC LCD L33791and L11450 (walkers) L11443 (manual wheelchair), LCD L33788 (custom manual wheelchair), LCD L33789 (custom motorized wheelchairs)

Standard walkers, Safety rollers (standard and bariatric rollators), Manual Wheelchairs, (RN and Clinical Coordinator), Customized manual wheelchair, motorized wheelchairs and scooters; (To be assessed only by RN).

1. Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI, and medical order with valid date (no more than 60 days of expedition), weight and height (optional).

2. Evaluate compliance with the following: members confined to bed or wheelchair that suffer functional mobility limitation and do not have the ability to perform their mobility related activities of daily living (MRADL'S) as: going to the bathroom, feeding, getting dressed, bathing, cleaning, etc.

3. Requests for MAE equipment should comply with one or more of the criteria mentioned above. Nurse or coordinator should make an estimate of the member's physical, cognitive, and emotional limitations and the ability to use MAE equipment for their daily routine within their home. To compliance of bariatric rollator, patient must exceed 300 pounds and meet

the above criteria.

4. Attached sequenced questions that will guide us for the evaluation and determination of requests (MAE). Refer to disclaimer.

5. Patient during a rehabilitation process should be taken into consideration when evaluating MAE equipment.

6. Requests for power wheelchair (PWC) or scooters (POV) should be accompanied by complete evaluation (Face to Face) by primary or treating specialist in all sections that apply. The doctor's answers should be evaluated and will be determined according to the MAE algorithm by CMS (Center for Medicare and Medicaid services). *Assessed only by clinical personnel*

7. If necessary, the request should include accessories needed for the assisted MAE.

8. Options and accessories for wheelchairs are covered if the patient has a wheelchair that meets Medicare coverage criteria and the option/accessory itself are medically necessary. If criteria are not met, the item will be referred to the Medical Director for final case resolution.

Custom Manual Wheelchair (To be assessed by RN only with the final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC LCD ID L33789

A manual custom wheelchair for use inside the home is covered if:

1. The beneficiary has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. A mobility limitation is one that:

    a. Prevents the beneficiary from accomplishing an MRADL entirely, or
    b. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
    c. Prevents the beneficiary from completing an MRADL within a reasonable time frame.

2. The beneficiary's mobility limitation cannot be sufficiently resolved using an appropriately fitted standard wheelchair that incorporates seating modifications or other options or accessories.

3. The beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for use of the manual custom wheelchair that is provided.

4. Use of a manual wheelchair will significantly improve the beneficiary's ability to participate in MRADLs and the beneficiary will use it on a regular basis in the home.

5. The beneficiary has not expressed an unwillingness to use the manual custom wheelchair that is provided in the home.

6. The beneficiary has enough upper extremity function and other physical and mental capabilities needed to safely self-propel the manual custom wheelchair that is provided in the home during a typical day. Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.

7. The beneficiary has a caregiver who is available, willing, and able to provide assistance with the wheelchair.

8. Documentation must include a description of the beneficiary's unique physical and functional characteristics that require a customized manual wheelchair base.

Limitation:

A custom manual wheelchair is not reasonable and necessary if the expected duration of need is less than three (3) months. (E.g., operative recovery)

Custom Motorized Wheelchair (To be assessed by RN only with the final assessment of Medical Director):

Medicare Reference: CGS Administrators, LLC LCD ID L33789

A motorized custom wheelchair for use inside the home is covered if:

1. The beneficiary has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home.

2. A mobility limitation is one that:

    a. Prevents the beneficiary from accomplishing an MRADL entirely, or
    b. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; or
    c. Prevents the beneficiary from completing an MRADL within a reasonable time frame.

3. The beneficiary's mobility limitation cannot be sufficiently and safely resolved using an appropriately fitted cane or walker.
4. The beneficiary *does not* have sufficient upper extremity function to self-propel an optimally configured manual wheelchair in the home to perform MRADLs during a typical day.

a. Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.
b. An optimally configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate no powered accessories.

5. Documentation must include a description of the beneficiary's unique physical and functional characteristics that require a customized manual wheelchair base.

Limitation:

A custom motorized wheelchair is not reasonable and necessary if the expected duration of need is less than three (3) months. (E.g., operative recovery)

Oxygen Therapy/Gas, Liquid stationary or portable/Oxygen during travel
(To be assessed only by RN)

Medicare Reference: CGS Administrators, NCD 240.2

Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI, and medical order with valid date (no more than 60 days of expedition), lighterage, hours used, and duration. Request should indicate if the oxygen is by nasal canula or mask and should indicate if the oxygen is a portable oxygen system.

Oxygen therapy and oxygen equipment is covered in the home for acute or chronic conditions, short- or long- term, when the patient exhibits hypoxemia as defined below:

Group I:

1. An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air; or

2. An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation; or,

3. An arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise [defined as either the functional performance of the patient or a formal

exercise test], for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

Group II:

Coverage is available for patients whose arterial PO2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89%, if there is:

1. Dependent edema suggesting congestive heart failure; or,
2. Pulmonary hypertension or core pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVFL; or,
3. Erythrocythemia with a hematocrit greater than 56%.

Additional information:

- Oxygen services furnished by an airline to a beneficiary are non-covered. Payment for oxygen furnished by an airline is the responsibility of the beneficiary and not the responsibility of the supplier.

- Medicare does not cover items or services provided/used outside the United States and its territories. The supplier is not required to provide or arrange for oxygen use in those situations.

- Every case that does not meet these rules must be reviewed by the Medical Director.

Limitations:

Oxygen therapy and oxygen equipment in the home **will not be covered** in the following circumstances:

1. Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments; or,
2. Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting; or,
3. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO2 improves the oxygenation of tissues with impaired circulation; or,
4. Terminal illnesses unless they affect the ability to breathe.

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (To be assessed only by RN)

Medicare Reference: CGS Administrators, LLC LCD ID L33718

1. Verify the following information: Name, correct member ID number, Physician's name and signature, medical order with valid date (no more than 60 days of expedition), DME parameters (cms H2O), IPA, EPA).

2. Requests for C-PAP (Continuous Positive Airway Pressure) Code E0601 or B-PAP (Bi-level Positive Airway Pressure) code E0470 or E0471 should come accompanied by the diagnoses and titration sleep study (PSG) and measurements below.

3. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:

    a. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for obstructive sleep apnea.
    b. The patient has a Medicare-covered sleep test that meets either of the following criteria (1 or 2):

4. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events: or,

5. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:

    a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
    b. Hypertension, ischemic heart disease, or history of stroke
    c. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.
    d. An E0470 device is covered for those patients with OSA who meet criteria A-C above, in addition to criteria one:
    e. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

6. Verify if the request includes other accessories such as: Hot or cold humidifier, type of mask, if the oxygen is requested in combination with the equipment. If special DME are requested as: C-PAP auto set, C-PAP C-Flex, Respironic Smart Card Remstar. Verify recommendations on polysomnography.

7. Definitions:

    a. Apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea

and hypopnea per hour of sleep without the use of a positive airway pressure device.

b. Respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device.
c. Apnea is defined as the cessation of airflow for at least 10 seconds.
d. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.
e. Complex sleep apnea (CompSA) is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared.

Specification for RAD (To be assessed only by RN)

For an E0470 or an E0471 (RAD) to be covered, the treating physician must fully document in the patient's medical record symptoms characteristics of sleep associated hypoventilation, such as daytime hyper somnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. and the patients present the following clinical disorder groups characterized as: (I) restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities), (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA) or complex sleep apnea (Comp SA), or (IV) hypoventilation syndrome, and who also meet the following criteria A to C:

1. Restrictive thoracic disorders:

    a. (Progressive neuromuscular diseases, for example Amyotrophic Lateral Sclerosis "Lou Gehrig's Disease") or a severe thoracic cage abnormality for example post-thoracoplasty, and
    b. one of the following:
        - An arterial blood gas PaCO2, done while awake and breathing the patient's usual FIO2 is greater than or equal to 45 mm hg, or
        - Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing to compare it against patient's usual FIO2 or
        - For a neuromuscular disease (only), either
            * Maximal inspiratory pressure is less than 60 cm H2O or
            * Forced vital capacity is less than 50% predicted.

    c. Chronic obstructive pulmonary diseases do not contribute significantly to the patient's pulmonary limitation.

2. Severe COPD: An E0470 device is covered if all criteria (i – iii) are met,

    a. an arterial blood gas Pa CO2, done while awake and breathing the patient's usual FIO2, is greater than or equal to 52 mm Hg
    b. sleep oximetry demonstrates oxygen saturation less than or equal to 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the patient's usual FIO2 (whichever is higher)

c. Prior to initiating therapy, OSA and treatment with a continuous C- PAP has been considered and ruled out.

An E0471 device will be covered for a patient with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.

Situation 1 For Group II patients (COPD) who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met.

a. An arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, shows that the beneficiary's PaCO2 worsens ≥7 mm HG compared to the original result from criterion i, (above).
b. A facility-based PSG demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events – i.e., AHI <5.

Situation 2 For Group II patients (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:

a. An arterial blood gas PaCO2 is done while awake and breathing the patient's prescribed FIO2, still remains ≥ 52 mm Hg.
b. Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation ≤ 88% for ≥ 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient's prescribed FIO2 [whichever is higher].
c. Central Sleep apnea or Complex sleep apnea: An E0470 or E0471 device is covered when, prior to initiating therapy, a complete facility-based, attended polysomnogram (PSG) must be performed documenting the following (i and ii):
    i. The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA), and
    ii. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the patient's usual FIO2.
d. Hypoventilation Syndrome:

    An E0470 device is covered if criteria III, IV, and either V or VI are met.

    i. An initial arterial blood gas PaCO2, done while awake and breathing the patient's prescribed FIO2, is ≥45 mm Hg.

    ii. Spirometry shows an FEV1/FVC ≥70% and an FEV1 ≥50% of predicted. (Refer to II. SEVERE COPD (above) for information about device

coverage for patients with FEV1/FVC <70% or FEV1 <50% of predicted).

iii. An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the patient's prescribed FIO2, shows the beneficiary's PaCO2 worsened ≥7 mm HG compared to the original result in criterion 1 (above).

iv. A facility-based PSG demonstrates oxygen saturation ≤88% for ≥5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events – i.e., AHI <5.

Oral Appliances for Obstructive Sleep Apnea (To be assessed by RN only with the final Assessment of the Medical Director)

Medicare Reference: CGS Administrators, LLC, LCD ID L33611, LCA A52512

A custom fabricated mandibular advancement oral appliance (E0486) used to treat obstructive sleep apnea is covered if criteria A - D are met (all the following):

A. The beneficiary has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing that includes:

1. a focused cardiopulmonary and upper airway system evaluation
2. neck circumference and,
3. body mass Index (BMI)
4. Epworth Sleepiness Scale

B. The beneficiary has a Medicare-covered sleep test that meets one of the following criteria (1 - 3):

1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events: or,
2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:

   a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
   b. Hypertension, ischemic heart disease, or history of stroke; or,

3. If the AHI> 30 or the RDI> 30 and meets either of the following (a or b):

   a. The beneficiary is not able to tolerate a positive airway pressure (PAP) device; or,
   b. The treating physician determines that the use of a PAP device is contraindicated.

c. The device is ordered by the treating physician following a review of the report of the sleep test. (The physician who provides the order for the oral appliance could be different from the one who performed the clinical evaluation in criterion A.)
d. The device is provided and billed for by a licensed dentist (DDS or DMD).

Diagnostic Services & Procedures

Cytogenetic Studies (To be assessed by RN with final assessment by Medical Director)

Medicare Reference to LCD as applied for each code.

1. Verify the following information: Name, correct member ID number, Physician's name and signature, medical order with valid date (no more than 30 days of expedition).
2. Diagnosis related to the test.
3. Reason for requesting the test.
4. Current treatment of the beneficiary or treatment plan.
5. Results of studies or related laboratories conducted prior to request of the test.

With all the data collected, refer to the Medical Director for final determination.

Molecular Pathology (MP Specialist) Evaluation Process:

MP consultants are experts who evaluate the different mutations of tumors, biomarkers, and DNA chain, in order to help provide accurate diagnoses that result in a more personalized and individual treatment for each condition. MP only review cases related to Cancer.

Verify the following information: Name, correct member ID number, Physician's name address, license, signature, NPI, and medical order with valid date (no more than 30 days of expedition. The investigation must include:

1. Pathology Report, diagnosis, CPT codes
2. Most recent office notes to include notes from Surgeon/Pathologist
3. Requestor Contact information
4. Requestor NPI

Refer all data by email to MP so they can evaluate and bring recommendations, the final determination will be assessed by our Medical Director.

Oncotype DX

A diagnostic test that quantifies the likelihood of disease recurrence in women with early-stage breast cancer and to assess the likely benefit from certain types of chemotherapy.

Medicare Reference: First Coast Service Options, Inc. LLC LCD IDL33586

a. INDICATIONS: As medically reasonable and necessary, with case-by-case review as needed, when used to assess the need for adjuvant chemotherapy in patients with recently diagnosed breast cancer (six months or less have elapsed) when all the following criteria are met:

   i. Breast cancer is no metastatic (node-negative) (lymph nodes with micro metastases are not considered positive); and
   ii. Estrogen positive breast carcinoma with 1-3 positive nodes; and
   iii. Breast cancer is unilateral and non-fixed (i.e., tumor not adhered to chest wall); and
   iv. Breast tumor is hormone receptor-positive (estrogen receptor (ER)- positive or progesterone receptor (PR)-positive); and
   v. Breast tumor is HER2-receptor negative; and
   vi. Breast tumor size is 06.1 cm with moderate/poor differentiation or unfavorable features (e.g., angiolymphatic invasion, high nuclear grade, or high histologic grade), OR tumor size is >1 cm; and
   vii. Breast tumor is stage 1 or stage II; and
   viii. Breast cancer will be treated with hormonal therapy; and
   ix. Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities); and
   x. Testing is being done specifically to guide the decision as to whether adjuvant chemotherapy will be used and, prior to testing the patient and oncologist have discussed the potential results of the test and agree to use the results to guide therapy (i.e., the patient will forgo adjuvant chemotherapy if Oncotype DX TM score is low).

b. Medical tests are covered only when ordered by a treating oncologist, when necessary for diagnosis or treatment decisions, and when used in patient care (42 CFR 410.32). Failure to meet these criteria, the requisition will be submitted to the Medical Director.

Mamma Print (Unlisted Molecular Procedure)
(To be assessed by RN with final assessment by Medical Director):

Reference**:** Internal Medical Criteria based on LCA ID A53104

Mamma Print studied a group of 70 genes to determine their level of activity, and then calculates a score for relapse expressed in terms of low risk or high risk.

Indications and documentations required:

Mamma Print test will be covered by Medicare when it's reasonable and necessary to analyze breast cancer in early stages in patients with the following characteristics:

- In stage I or stage II invasive breast cancer
- ER negative or ER Positive (ER= Estrogen Receptor)
- Tumor size less than 5.0 cm
- Lymph nodes negative, or with modal micro metastases (less than 2.0 mm) or no more than three positive lymph nodes

BRCA 1 and BRCA 2 (To be assessed by RN with final assessment by Medical Director):

Medicare Reference; CGS Administrators, LLC LCD ID L36499
Medicare covers these tests when they are reasonable and necessary for the diagnosis or treatment of the following conditions:

1. Personal History of Female Breast Cancer and ANY of the following indications:

    - Diagnosed at age 45 or younger.
    - Diagnosed at age 50 or younger with at least one close blood relative* with breast cancer at any age.
    - Diagnosed with two breast primaries (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors) when the first breast cancer diagnosis occurred prior to age 50.
    - Diagnosed at age 60 or younger with a triple negative breast cancer (estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative).
    - Diagnosed at age 50 or younger with a limited family history (e.g., fewer than two first or second-degree female relatives or female relatives surviving beyond 45 years in the relevant maternal and/or paternal lineage).
    - Diagnosed at any age and there are at least two close blood relatives* with breast cancer at any age.
    - Diagnosed at any age with at least one close blood relative* with breast cancer at age 50 or younger.
    - Diagnosed at any age and there are at least two close blood relatives* with pancreatic cancer or prostate cancer with Gleason score >7 at any age.
    - Diagnosed at any age with at least one close blood relative* with epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer.
    - Close male blood relative* with breast cancer.
    - Individual of Ashkenazi Jewish descent begin testing with Ashkenazi Jewish founder specific mutations.

2. Personal History of Other Cancer: BRCA1 and BRCA2 genetic testing for susceptibility to breast or ovarian cancer is covered in adults when there is a personal history of ANY of the following indications:

    - Personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer.
    - Personal history of male breast cancer.
    - Personal history of pancreatic cancer or prostate cancer with Gleason score =7 at any age, =1 close blood relatives* with breast (=50 y), invasive ovarian, pancreatic cancer, or prostate cancer with Gleason score =7 at any age.
    - Personal history of pancreatic cancer at any age with Ashkenazi Jewish ancestry

3. Multigene Panels: BRCA1 and BRCA2 genetic testing for susceptibility to breast or ovarian cancer with Multigene next generation sequencing (NGS) panels is covered when all the following criteria are met:

    - Pretest genetic counseling by a cancer genetics professional independent of the laboratory has been performed and posttest genetic counseling by a cancer genetics professional independent of the laboratory is planned.
    - All genes in the panel are relevant to the personal and family history for the individual being tested (large panels with genes that are not relevant to the individual's personal and family history are not reasonable and necessary);
    - Criteria listed under Section 1, Personal History of Female Breast Cancer and/or Section 2 Personal History of Other Cancer are met.
    - Individual also meets criteria for at least ONE other hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to Li-Fraumeni Syndrome, Cowden Syndrome, or Lynch Syndrome.

Limitations:

BRCA testing is limited to **once-in-a-lifetime**. If a patient has been previously tested for BRCA1 and BRCA2, repeat testing prior to Olaparib therapy is not reasonable and necessary and will not be covered by Medicare.

Non-Covered Indications

BRCA1/BRCA2 genetic testing for susceptibility to breast or ovarian cancer is not covered for any other indication including any of the following because it is considered not medically reasonable and necessary for these indications:

- Genetic screening in the general population. Such testing is considered screening and is excluded by Medicare statute. An ABN must be obtained for BRCA 1 and BRCA 2 testing for individuals without signs and symptoms of breast, ovarian or other hereditary cancer syndromes as indicated in this policy.
- Testing of individuals with no personal history of breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer. Such testing is considered screening and is excluded by Medicare statute. An ABN must be obtained for BRCA 1 and BRCA 2 testing for individuals without signs and symptoms of breast, ovarian or other hereditary cancer syndromes as indicated in this policy.
- Testing of individuals under the age of 18 years.

MRI, MRA, CT scan and other related services
(To be assessed by RN or Clinical Coordinator):

1. Verify the following information: Name, correct member ID number, Physician's name address, license, signature, NPI, and medical order with valid date (no more than 30 days of expedition).

These diagnostic services are evaluated according to Medicare indications and MCG reference criteria for specific anatomic areas.

Therapeutic Services

Ambulatory Physical Therapy Services (To be assessed by RN, Clinical Coordinator, & Therapy Network of Puerto Rico (TNPR)

Apollo Guidelines used by TNPR Delegated Entity

1. Verify the following information: Name, correct member ID number, Physician's name address, license, signature, NPI, and medical order with valid date (no more than 30 days of expedition). Should include physiatrist and /or certified therapist evaluation and treatment plan.

2. Requisitions are being evaluated and processed by Therapy Network of Puerto Rico to assure expertise and quality service in this medicine field.

3. Previous authorizations will be considered by TNPR staff.

4. This part of the plan processes the adverse determinations referred to by TNPR with the clinic investigation and the recommendation of the Medical Director of TNPR, for a possible adverse determination.

5. The final decision will be taken by de Medical Director of MSO.

Surgical Procedures

Blepharoplasty, Blepharoptosis, Surgical Procedures of the brow, Canthoplasty and related eye Surgeries (To be assessed only by RN with a final assessment by the Medical Director)

Medicare Reference: First Coast Service Options, Inc. LCD ID L34028, LCA ID A57025 Version 14

Indications:

Functional blepharoplasty procedures and surgical procedures of the brow will be considered medically reasonable and necessary in the following situations:

1. When the goal of the surgery is to restore function and normalcy to a structure that has been altered by trauma, infection, inflammation, degeneration, neoplasia, or developmental errors or;
2. When there is interference with visual field, near or far visual impairment, or difficulty reading due to **any of the following**:

- Dermatochalasis, pseudoptosis, blepharochalasis, blepharoptosis, brow ptosis causing malposition of the upper eyelid1 and demonstrating a MRD1 (Margin reflex distance) of 2 mm or less.
- Looking through the eyelashes or seeing the upper eyelid skin as commonly seen with ptosis.
- When there is visual impairment secondary to redundant skin weighing down on upper lashes resulting in eye strain, headache and loss of vision.
- When there is chronic, symptomatic dermatitis of pretarsal skin caused by redundant upper lid skin which has not been successfully treated by conservative measures such as education regarding hygiene, antibiotics, etc.; or

3. Visual field testing demonstrating a 12 to 15 degrees superior field loss or 24% to 30% superior visual field impairment; or

4. When there is the presence of prosthesis difficulties in an anophthalmic socket; or

5. When there is laxity of the lower eyelid tissues causing lower eyelid ectropion resulting in eye irritation and inflammation and excessive tearing; or
6. When there is inward rotation of the eyelid margin causing entropion where the eyelashes are contacting the cornea resulting in discomfort, redness, tearing, and foreign body sensation; or
7. Lower eyelid edema, tumor or mass causing signs and symptoms of eyelid ectropion.

Limitations:

Blepharoplasty and surgical procedures of the brow performed for the sole purpose of improving appearances are considered not medically reasonable and necessary.

Documentation Requirements

a. History and Physical which includes, clinical notes, supporting a decrease in peripheral vision and/or upper field vision and complaints and findings secondary to eyelid or brow malposition in example:

   - Interference with vision or visual field, related to activities such as, difficulty reading due to upper eyelid drooping, looking through the eyelashes, seeing the upper eyelid skin, or brow fatigue.
   - Chronic eyelid dermatitis due to redundant eyelid skin.
   - Difficulty wearing prosthesis.

b. Visual Fields-Visual Fields must be recorded using either a Goldman Perimeter (III 4-E test object) or a programmable automated perimeter.

c. Photographs – Preoperative photographs in the form of prints or slides are required to be submitted with the medical record when requested. The photographs must be frontal view, canthus to canthus with the head perpendicular to the plane of the camera (not tilted) to demonstrate a skin rash or position of the true lid margin or the pseudo-lid margin. If redundant skin coexists with true lid ptosis,

additional photos must be taken with the upper lid skin retracted to show the actual position of the true lid margin. Oblique photos are only needed to demonstrate redundant skin on the upper eyelashes when this is the only indication for surgery.

Note: If a blepharoplasty and/or a blepharoptosis repair procedure are requested for both eyes, it must include documentation and photos for each eye and must include the presence of Hering's Law meeting one of the above criteria in bullets 3 or 4. Hering's Law of equal innervation to both upper eyelids may be considered in the documentation to perform bilateral ptosis repair in which the position of one upper eyelid has marginal criteria and the other eyelid had good supportive documentation for ptosis surgery.

d. Margin reflex distance (MRD1) of 2 mm or less.

Cochlear Implant Devices (To be assessed by RN only with the final assessment of Medical Director):

Medicare Reference: NCD Database 50.4

Medicare will cover a cochlear implantation for those patients who meet **all the following** criteria:

1. Benefit from amplification is defined by test scores of less than or equal to 40% correct in the best-aided listening condition on tape-recorded tests of open-set sentence cognition (audiometry)

2. Diagnosis of *bilateral* moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids.

3. Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation.

4. Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system.

5. No contraindications to surgery; and

6. The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

Laser Capsulotomy Surgery (To be assessed by RN)

Medicare Reference: Based on CGS Administrators, LLC. - LCD ID L33946

Laser capsulotomy surgery reduces glare and improves vision. Allows light to pass through the cloudy areas of the lens capsule that can form after cataract surgery, the patient must comply with all of the following:

Indications and coverage criteria:

1. Posterior darkening (opacification) of the eye capsule after cataract surgery that decreased the ability to carry out activities of daily living including (but not limited to) reading, watching television, driving, or meeting occupational or a vocational expectation; and
2. The patient has a best-corrected visual acuity of 20/50 or worse at distance or near; or additional testing shows one of the following:
   a. Consensual light testing decreases visual acuity by two lines, or
   b. Glare (test that measures the glare that reduces visual quality caused by increased light on the retina) testing decreases visual acuity by two lines; and
3. The patient has determined that he/she is no longer able to function adequately with the current level of visual function; and
4. Other eye diseases have been ruled out as the primary cause of visual functional disability including but not limited to macular degeneration or diabetic retinopathy, except for the instance in which significant visual debility, in the judgement of the treating physician, is deemed secondary to ACO or PCO and laser treatment would provide the patient with improved functionality; and
5. The documentation from the treating physician indicates that improvement in visual function will be expected after laser capsulotomy and that the patient has been educated on the risks, benefits, and alternatives to surgery (e.g., the avoidance of glare, use of optimal eyeglasses prescription, etc.) during the preoperative ophthalmologic evaluation.
6. For patients with a best-corrected visual acuity of 20/40 or better, anterior and/or posterior capsulotomy will be considered if all other criteria have been met and documented to support the medical necessity of the procedure for that patient.

Lipectomy / Panniculectomy other areas except abdomen and Assisted Suction Lipectomy (To be assessed only by RN with a final assessment by the Medical Director):

Medicare reference: Noridian Healthcare Solutions, LLC. / Internal Criteria based on L33482
Indications and coverage criteria:

1. Verify the following information: Name, correct member ID number, Physician's name and signature, medical order with valid date (no more than 30 days of expedition).
2. Diagnosis related to the procedure.
3. Reason for requesting the surgery.
4. Current treatment of the beneficiary or treatment plan.
5. Symptoms

Suction-Assisted-Lipectomy
Suction-assisted lipectomy is a surgical procedure employing high vacuum pressure to suction away localized collections of unwanted fat. When the procedure is utilized to remove a lipoma, it is considered reconstructive surgery. The clinical record must clearly demonstrate medical necessity for the lipoma removal as most such tumors are benign and do not require removal. All other uses are currently considered cosmetic in nature and non-covered.

After obtaining all the information, submit the requisition for final determination by the Medical Director.

Sterilization (To be assessed by RN):

Medicare References: NCD Database ID 230.3, Version 1
Indications & Required Documentation:

1. Platinum Coverage (for elective surgery) or;
2. Evidence of one or more of the following conditions:
a. Diagnosis of tumor.
b. Cancer or organ damages of the reproductive system.

c. Mental retardation and that the procedure is part of a treatment for complications of a disease or reproductive harm.
3. Preoperative signed consent

Limitations:

Elective hysterectomy, tubal ligation, vasectomy, and if the primary indication for these procedures is sterilization; is not covered for other covered than Platinum.

Cyber knife Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (To be assessed by RN with final assessment by Medical Director)

Medicare Reference: First Coast Service Options, Inc. LCD ID L33410

Indications

1. SRS/SBRT: cranial lesions will be considered medically reasonable and necessary for the following indications:

    - Primary central nervous system malignancies, generally under 5 cm and as a boost treatment for larger cranial, base of skull, or spinal lesions that have been treated initially with external beam radiation therapy or surgery (i.e., grade III and IV gliomas, oligodendrogliomas, sarcomas, chondrosarcomas, chordomas, and nasopharyngeal or paranasal sinus malignancies).

- Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent boney structures.

- Benign brain tumors and spinal tumors such as cranial meningioma's, acoustic neuromas, other schwanomas, pituitary adenomas, pineal cytomas, craniopharyngiomas, glomus tumors, and hemangiolastomas.

- Cranial arteriovenous malformations and hemangiomas.

- Trigeminal neuralgia not responsive to medical management.
- Metastatic brain lesions, generally limited in number, with stable systemic disease, Karnofsky Performance Status 40 or greater (or expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations or an Eastern Cooperative Oncology Group (ECOG): Performance Status of 3 or less (or expected to return to 2 or less with treatment).

- Relapse in a previously irradiated cranial or spinal field where additional stereotactic precision is required to avoid unacceptable vital tissue radiation.

- Other cranial non-neoplastic conditions for which it has been proven effective, e.g., movement disorders such as Parkinson's disease, essential tremor and other disabling tremor that are refractory to conventional therapy, such as severe, sustained trigeminal neuralgia not responsive to other modalities.

- Stereotactic Body Radiation Therapy (SBRT) is an emerging treatment method that utilizes externally generated high dose ionizing radiation in certain cases to inactivate or eradicate (a) defined target (s) within the body.

Indications

SBRT will be considered medically reasonable and necessary for certain conditions if the following criteria are met:

- Either #1, #2, or #3 must be present and

- Either #4 or #5 must be present and

- #6 must always be present.

1. When dose constraints to normal tissues limit the total dose of radiation safely deliverable to the tumor with other indicated methods.

2. When there is a reason to believe that doses generally thought to be above the level otherwise attainable with other methods might improve control rates.

3. In circumstances when the higher levels of precision associated with SBRT as compared to other radiation methods are necessary, i.e., clinically relevant.

4. For the treatment of primary lesions, the intent of treatment must be curative except for lesions within the pancreas or liver.

5. For the treatment of metastatic lesions, there must be:

   - The expectation of a long-term benefit (> 6 months) that could not have been attained with conventional therapy.

   - The expectation of a complete eradication of the metastatic lesion that could not have been safely accomplished with conventional therapy, as evidenced by a dosimetric advantage for SBRT over other forms of radiation therapy.

6. The patient's record demonstrates why SBRT is considered the treatment of choice for the individual patient. Specifically, the record must address the lower risk to normal tissue, the lower risk of disease recurrence, and the advantages of the treatment over conventional radiation therapy, IMRT or 3-dimensional conformal radiation. Dosimetric evidence of reduced normal tissue toxicity and/or improved tumor control must be maintained.

SBRT will be considered medically reasonable and necessary if only the above criteria are met as specified for the following conditions:

Spinal Lesions

- Previously untreated spinal metastases or spinal metastases that have recurred after conventional radiotherapy and clinical reasons preclude a surgical approach.

Lung Cancer

- Early-stage Bronchogenic Carcinoma -treatment of early-stage bronchogenic carcinomas in medically unresectable patients
- Pulmonary Metastatic Disease -patient has limited pulmonary metastatic disease and no active disease elsewhere in the body,
- Patients that might otherwise be candidates for resection but precluded by co- existing medical condition(s) or technically difficult lesion location.
- Recurrent Disease- Very selected cases for long-term palliative use

Liver Cancer

- Primary hepatocellular carcinoma- Patients who are not surgical candidates.
- Secondary metastases to the liver, not amenable to surgical resection. It is generally limited

to less than four simultaneous lesions.

Pancreatic Cancer

- Palliative intent and selected cases for curative intent or unresectable.
- Kidney and Adrenal Gland
- Primary and metastatic tumors

Limitations:

1. Treatment for anything other than a severe symptom or serious threat to life or critical functions, not responsive or reasonably amenable to another therapy.

2. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.

3. In general, stereotactic radiosurgery is not indicated for cancers that are widespread with cerebral or extra-cranial metastases. The intent of treatment should be curative, except in cases where radiosurgery will provide the best palliation, resulting in significant quality of life.

4. Patients with poor performance status (Karnofsky Performance Status < 40), - see Karnofsky performance status below* or eastern cooperative oncology group (ecog) performance status >

*Karnofsky Performance Scale (Pérez and Brady, p 225)

100	Normal; no complaints, no evidence of disease
90	Able to carry on normal activity; minor signs or symptoms of disease
80	Normal activity with effort; some signs or symptoms of disease
70	Cares for self; unable to carry on normal activity or to do active work
60	Requires occasional assistance but is able to care for most needs
50	Requires considerable assistance and frequent medical care
40	Disabled; requires special care and assistance
30	Severely disabled; hospitalization is indicated although death not imminent
20	Very sick; hospitalization necessary; active supportive treatment is necessary
10	Moribund, fatal processes progressing rapidly
0	Dead

Eastern Cooperative Oncology Group: Performance Scale and corresponding Karnofsky Rating (Cancer Medicine 5th ed)

0	Fully active, able to carry on all pre disease activities without restriction Karnofsky 100).
1	Restricted in physically strenuous activity, but ambulatory and able to carry out work of a light or sedentary nature, for example, light housework/office work (Karnofsky 80-90)

2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours (Karnofsky-70)
3	Capable of limited self-care, confined to bed or chair 50% or more of waking hours (Karnofsky 40-50)
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair (Karnofsky 30 or less)
5	Dead

5. A claim for stereotactic cingulotomy as a means of psychotherapy, considered investigational, per Medicare National Coverage Determinations (NCD) Manual, Publication 100-03, Chapter 1, Part 2, Section 160.4.

6. Lesions of bone, breast, uterus, ovary and other internal organs not listed above are not covered for primary definitive SBRT as literature does not support an outcome advantage over other conventional radiation modalities.

Hyperbaric Oxygen Therapy (HBOT) not related wound care services (To be assessed only by RN)

Medicare Reference: First Coast Service Options, Inc. LCD ID L28909

Indications and coverage criteria: The Hyperbaric Oxygen Therapy not related to wound care services, if medically necessary will be covered for the following conditions:

1. Acute carbon monoxide intoxication.
2. Decompression illness.
3. Gas embolism.
4. Osteoradionecrosis as an adjunct to conventional treatment.
5. Soft tissue radio necrosis as an adjunct to conventional treatment.
6. Cyanide poisoning.

Documentation Requirements:

There must be medical documentation to support the condition for which HBO therapy is being given. Documentation for all services should be maintained on file and be available for the prior authorization process (e.g., progress notes and treatment record) to substantiate medical necessity for HBOT.

This medical documentation must include:

1. An initial assessment which will include a medical history detailing the condition requiring HBOT. Medical history should list prior treatments and their results including antibiotic therapy and surgical interventions. This assessment should also contain information about adjunctive treatment currently being rendered.

2. Physician progress notes.

3. Any communication between physicians detailing past or future (proposed) treatments.

4. HBO treatment records describing the physical findings, the treatment rendered and the effect of the treatment upon the established goals for therapy.

5. For conditions where HBO is covered as an adjunctive treatment, the documentation should include information concerning all treatment modalities utilized.

6. For patients treated for Osteoradionecrosis, history of radiation therapy (including date and anatomical site of radiation therapy), with evidence of necrotic bone tissue breakdown, and radiographic studies, if available, to confirm the diagnosis.

7. For patients treated for soft tissue radio necrosis, history of radiation therapy and clinical photographs of the necrotic site will help support the medical necessity of HBO services. (Please refer to detail prior authorization documentation requirements for Post- Radiation Cystitis below).

Pre-Authorization documentation requirements for HBOT in Post-Radiation Cystitis:

1. History and physical exam

2. Minimum recent laboratories results
    a. CBC, differential and platelets
    b. Complete urinalysis
    c. PT, PTT, INR

3. Copy of cystoscopy report and photos

4. Certification by radiation therapist about treatment received (date).

5. Evidence documentation of prior failure to conventional treatment (progress note, procedure reports, etc., biopsy report (if not done, why?).

Limitations:

HBO therapy should not be a replacement for other standard successful therapeutic measures; however, it is the treatment of choice and standard of care for decompression sickness and arterial gas embolism. Traumatic or spontaneous pneumothorax constitutes contraindications to adjunctive HBO therapy only if untreated. Pregnancy is considered a contraindication to HBO therapy except in the case of carbon monoxide poisoning where it is specifically indicated.

Coding Information

CPT/HCPCS Codes: 99183 (Physician Attendance and supervision of Hyperbaric Oxygen therapy, per session) C1300 (Hyperbaric Oxygen under pressure, full body Chamber, per30 minute interval)

Transcatheter Aortic Valve Implant/Replacement TAVI/TAVR
(To be assessed only by RN with a final assessment by the Medical Director):

Medicare Reference: Medicare National Coverage Determinations Manual Chapter 1, Part 1, Section 20.32

Indications:

1. Evaluation from one cardio thoracic surgeon who recommend the surgery
2. Severe Aortic Stenosis
3. Symptoms (eg; syncope, difficulty breathing, chest pain)
4. High surgical risk or "inoperable patient" due to:
   a. Renal, lung or liver disease
   b. Ventricular dysfunction,
   c. Pulmonary hypertension
   d. Thoracic radiation
   e. Porcelain aorta
   f. Fragility

Limitations:

1. Active endocarditis
2. Active sepsis
3. Contraindications for use of aspirin and / or anticoagulant
4. Previously implanted mechanical aortic valve.

Percutaneous Left Atrial Appendage Closure (LAAC) with Watchman device to be assessed by RN only with final assessment of Medical Director:

Medicare Reference: NCD ID 20.34

Verify the following information: Name, correct ID number of member, Physician's name signature, license, NPI and medical order with valid date (no more than 6 months of expedition), dose information, frequency, and duration of complete treatment. Verify if the request is in compliance with the following:

1. The procedure must be performed *by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon* (s) that meets the following criteria:

a. Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,
b. Has performed ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and,
c. Continues to perform ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period.

2. The patient is enrolled in, and the MDT and hospital must participate in, a prospective, national, audited registry that:

   a. consecutively enrolls LAAC patients, and,
   b. tracks the following annual outcomes for each patient for a period of at least 4 years from the time of the LAAC:

      - Operator-specific complications
      - Device-specific complications including device thrombosis
      - Stroke, adjudicated, by type
      - Transient Ischemic Attack (TIA)
      - Systemic embolism
      - Death
      - Major bleeding, by site and severity

3. Diagnosis of valvular atrial fibrillation

4. Greater than 75 y / o and results of CHADS2 greater than or equal to 2 or;

5. Greater than 65 y / o and results of CHA2D2-VASC greater than 3

6. Therapeutic failure of anticoagulants

Limitations:

LAAC is non-covered for the treatment of *Nonvalvular atrial fibrillation* (NVAF) when not furnished under Coverage with Evidence Development according to the above-noted criteria.

Penile Implant Prostheses (To be assessed only by RN with final assessment by the Medical Director)

Medicare Reference: Medicare National Coverage Determinations (National Coverage Decisions) (PUB. 100-03) Chapter 1 - Coverage Determinations - Renal and Genitourinary System - ESRD Services (Updated through Rev. 159, Effective: 10/01/14; Issued: 11/30/12)

IMPOTENCE OF ORGANIC ORIGIN

Indications & Required Documentation

The following clinical evidence must be received in order to assess Medical Necessity
(Final determination will always be made by Medical Director):

1. Patient's statement consent written by him, or his doctor signed by both parties expressing that his libido is intact and there are social and psychological benefits for the treatment to be provided, and that he was properly oriented about alternate treatment methods for impotence.

2. Complete medical history about previous alternate treatment failure for erectile dysfunction.

3. Clinical evidence establishing primary erectile dysfunction causes of origin (NOT psychological); not limited to one or more of the following:

    a. History of previous surgical intervention(s) to the genitourinary system (e.g., prostate surgery, genitourinary system tumor removal, etc.)

    b. History of continuous use of medications that can cause erectile dysfunction including antipsychotics, antidepressants, antihypertensive agents, and anticholinergics.

    c. Clinical evidence of injury to the genitourinary system.

    d. Complementary laboratory tests to sustain the diagnosis suggested by the history and/or physical examination including, but not exclusive of, other laboratory tests urinalysis, FBS, Serum testosterone, and prolactin, if testosterone levels are decreased, if necessary.

Reduction Mammoplasty (To be assessed by RN only when cancer diagnosis is present, if not, with the final assessment of Medical Director)

Medicare Reference: First Coast Service Options, Inc. LCD ID L33939

Macromastia (female breast hypertrophy) is the development of abnormally large breasts in the female. Gynecomastia is the excessive growth of the male mammary glands. These conditions can cause significant clinical manifestations when the excessive breast weight adversely affects the supporting structures of the shoulders, neck and trunk.
Indications:
Medicare will consider reduction mammoplasty reasonable and necessary when performed in the presence of significantly enlarged breasts and the presence of at least one of the following:

- Documentation that suggests a history of back and/or shoulder pain which adversely affects activities of daily living (ADLs) unrelieved by conservative analgesia (e.g., such as NSAID, compresses, massage, etc.), supportive measures (e.g., such as garments, back brace, etc.), physical therapy, and/or correction of obesity.

- Documentation that suggests a history of significant arthritic changes in the cervical or upper thoracic spine, optimally managed with persistent symptoms and/or significant restriction of activity.

- Signs and symptoms of ulnar paresthesia (e.g., evidenced by nerve conduction studies), cervicalgia, torticollis, and acquired kyphosis.

    - Signs and symptoms of intertrigo maceration or infection of the inframammary (e.g., hyperpigmentation, bleeding, chronic moisture, and evidence of skin breakdown), skin refractory to dermatologic measures.
    - Signs and symptoms of shoulder grooving with skin irritation (e.g., areas of excoriation and breakdown) by supporting garment.

    - Medicare will consider reduction mammoplasty reasonable and necessary when performed to achieve symmetry following removal and/or reconstruction of a breast due to malignancy, and will not need the final assessment of the Medical Director, unless the Servicing Physician is a Non-Participant Provider

    - Failure to meet this criteria, patient or MD interview must be performed then submit all gathered information (including patient related Hx.) for final medical review and determination.
    -

Breast Reconstruction (To be assessed by RN only with the final assessment of Medical Director)

Reference: Internal Criteria based on Wisconsin Physicians Service Insurance Corporation LCD ID L34698

Breast reconstruction surgery (for cancer diagnosis) of the affected and the contralateral unaffected breast will be covered for those beneficiaries who met **one** or more of the following:

1. Following a medically necessary mastectomy.

2. Removal or revision of a breast implant is considered medically necessary when it is removed for one of the following reasons:

    - Mechanical complication of breast prosthesis; including rupture or failed implant, and/or implant extrusion
    - Infection or inflammatory reaction due to breast prosthesis; including infected breast implant, or rejection of breast implants.

    - Other complications of internal breast implant; including silicone, granuloma, interference with diagnosis of breast cancer, and/or painful capsular contracture with disfigurement.

Sclerotherapy – Treatment of varicose veins of the lower extremity (To be assessed by RN)

Medicare Reference: First Coast Service Options, Inc. LCD ID L33762

Indications & Required Documentation

Varicose veins are caused by venous insufficiency as a result of valve reflux (incompetence). The venous insufficiency results in dilated, tortuous, superficial vessels that protrude from the skin of the lower extremities. Spider veins (telangiectasia) are dilated capillary veins that are most often treated for cosmetic purposes and are not covered by Medicare.

Sclerotherapy (liquid or foam) is performed for signs and symptoms of diseased vessels and can be used as an adjunct to surgical or ablative therapy (radiofrequency or laser). Sclerotherapy for cosmetic purposes is not considered medically reasonable and necessary. The size of the vessels being treated with sclerotherapy (liquid or foam) must be such that a long-lasting effect can be expected and that an acceptable risk/benefit outcome is favorable to the patient. With this, literature supports that the goal of treatment is to eliminate the primary and secondary sources of reflux, to reduce the reoccurrence of varicosities.

Ligation and stripping of varicose veins is a treatment option that aims to eliminate reflux at the saphenofemoral or saphenopopliteal junction.

Medicare will consider sclerotherapy (standard or foam) and/or ligation with or without stripping medically necessary when the following indications are met:

1. A 3-month trial period of conservative therapy that includes but is not limited to any of the following:

    - Weight reduction
    - Daily exercise plan
    - Leg elevation
    - Use of graduated compression stockings

2. If, despite conservative therapy, the patient is symptomatic and presents with any of the following:
    - Signs and symptoms of significantly diseased vessels of the lower extremities such as stasis ulcer of the lower leg, significant pain and significant edema that interferes with activities of daily living.
    - Bleeding

Limitations:

- Pregnant women
- Patients on anti-coagulant therapy*

- The inability to tolerate compressive bandages or stockings
- Severe distal arterial occlusive disease
- Obliteration of deep venous system
- Allergy to the sclerosant
- Hypercoagulable state

* Note for patients receiving anticoagulant therapy: if the decision is made to proceed with the service, the medical record should clearly support that the benefit outweighs the risk and the justification to proceed with the service should be given.

Telangiectasia and their feeding reticular veins are considered medically reasonable and necessary for patients with spontaneous and/or traumatic venous hemorrhage.

Home Care Services (To be assessed by RN and Clinical Coordinator)

Medicare Reference: Medicare Benefit Policy Manual Chapter 7 - Home Health Services for adults

1. 1. Verify the following information: Name, correct member ID number, Physician's name address, license, signature, NPI, and medical order with valid date (no more than 30 days of expedition).
2. 2. The clinical and/or clinical representative must review medical orders and documentation received to validate which service is requested to handle the request according to the requested document, priority, and clinical need.
3. 3. Home health services requirements of home health services must be all the following:
   • Ordered by and remains under the direction of the treating physician.
   • Consistent with the approved written individualized care plan.

4. Every medical order must include at least: Member acute or chronic medical condition or diagnosis causing the need for home health care. Documentation of the medical necessity of the service(s) to be provided in the home progress notes, specialist and subspecialist notes (neurology, pulmonology, cardiology, etc.); available studies and all available documents that support and validate the clinical condition of the member.
5. Receive services in the home homebound patients, who are under the care of a treating physician and who meet all the following requirements:
• Need services due to a medical condition, illness, or injury, which must be provided at the place of residence.
• That prevents you from leaving the home, as it is medically contraindicated and would increase the medical risk of exacerbation or deterioration of the condition.
• The beneficiary cannot leave the home without the help of another person.
• Services are medically necessary and reasonable for the treatment of the illness, injury, or condition and are documented.
• Require services that can be provided safely, effectively, and efficiently in the home.
• Live in a residence that is not a hospital, nursing facility, or intermediate care facility for people with intellectual disabilities.

Note: Services cannot be provided solely because of the recipient's age, environment, comfort, or lack of transportation.

6. Requests for continuity of services, a new medical order will be required explaining the need of the extension of the services requested and a new treatment plan (based on actual patient condition) also must be included for the extension of the required services.
7. The home health agency must provide the treating physician with a summary of the beneficiary's condition (plan of care) at least every 60 days. The summary must include all information necessary to support the justification for termination or continuation of home health services.

Comprehensive Outpatient Rehabilitation Facility (CORF) (To be assessed by RN only)

Medicare reference: Medicare Benefit Policy Manual Chapter 12 (CORF) Coverage

1. Verify the following information: Name, correct member ID number, Physician's name address, license, signature, NPI, and medical order with valid date (no more than 60 days of expedition), weight and height (optional).

2. Damage, disability, illness, or the need to improve the function of a body part that has malformed or has been amputated and for these reasons a level of service is required by the CORF.

Documentation requirements:

1. Includes medical history of the condition, current diagnosis, clinical findings, and contraindications for treatment and / or rehabilitation goals expected and are directly related to the injury or disability.

2. Medical order must apply all disciplines, PT, ST, OT and orthotics, on an outpatient basis.

Non-Participant Providers Process ("office visits")(RN and Clinical Coordinator)
Non-Participant Provider to a Participant Provider

Requests received from aContracted Physician for a Non-Contracted Physician or Facility:

1. Evidence of treatment/evaluation is validated with the non-contracted provider who will offer the service.

2. It is validated in our system if the member has a past or existing relationship with the non-contracted provider who will offer the service. If it cannot be validated, a call is made to the medical office to verify the information.

3. A call is made to the member, and we will offer alternatives of Physicians or Facilities within the Network, if affiliate accepts; we will proceed with the coordination of the service. In this scenario, cancellation of the request is documented, documenting all the steps taken.

4. If the member does not accept the alternatives, we will document the steps taken, clinical history and justification and will refer to the Medical Reviewer for final determination by clinical criteria.

5. In the event that the non-participant provider that will provide the service (Servicing) is a Physician and we observe in history that there is a doctor-patient relationship, and meets clinical criteria, it will be authorized without needing to refer to the Medical Reviewer.

6. If, when evaluating the service request, it meets the established clinical criteria, and there is a doctor-patient relationship, it will be authorized without needing to refer to the Medical Reviewer.

Important:

For Pre-authorization process purposes, it does Not Apply to refer to the Medical Reviewer for possible denial a case <u>where the requesting Service Provider (Requesting) is Non-Participant</u>.

<u>Brain Pet Scan CPT 78608 (To be assessed by RN only)</u>

Medicare Reference: National Coverage Determinations Manual, Chapter 1; Part 4; Section 220.6.13

Verify the following information: Name, correct member ID number, Physician's name, address, license, signature, NPI, and medical order with valid date (no more than 30 days of expedition).

These diagnostic services are evaluated according to Medicare LCD/NCD indications and MCG reference criteria for specific anatomic areas, or when LCD/NCD is not specific for particular situations.

Positron Emission Tomography (PET) scans for either the differential diagnosis of fronto-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements:

1. A recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD.
2. Patient have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.
3. Documented symptoms such as:

    a. social disinhibition
    b. awkwardness
    c. difficulties with language
    d. loss of executive function

4. The patient has had a comprehensive clinical evaluation including assessment of:
   a. activities of daily living
   b. physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales, or
5. The evaluation of the patient has been conducted by a neurologist.
6. The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through PET is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment.
7. Date of onset of symptoms; date of diagnosis of clinical syndrome
8. Mini-mental study results
9. Neuropsychological studies results
10. Brain MRI or Brain CT Scan results
11. Vitamin B12 or thyroid hormone laboratory results
12. Evidence of drug treatment.

Limitations:

A brain single photon emission computed tomography (SPECT) or Brain PET scan has not been obtained for the same indication. The results of a prior SPECT or PET scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, a Brain PET scan may be covered after 1 year has passed from the time the first SPECT or Brain PET scan was performed.

Failure to meet these criteria, the requisition will be submitted to Medical Director for final determination.

Signature on File

Chief Medical Officer Date

Disclaimer:
The following evaluation process should be applied to each requisition. These steps were created to improve assertiveness on decision making (Case determination). All staff (clinical and non-clinical personnel) must follow these steps in order to assess medical necessity. Algorithms (guideline questions) were created to facilitate decision making for non-clinical personnel.

Evaluation Process: (For clinical and Non-Clinical Personnel)

1. Make sure the requisition received meets administrative criteria prior evaluation (Platinum Coverage requirements (if applies), issuance date (no more than 30 days, or 60 days for DME), MD signature, etc.)

2. Identify any note made by MD regarding patient condition vs. requested service.

3. If there's no additional information (progress notes, or previous studies) to justify service, then follow these steps:

    a. Before trying to contact patient or MD office, verify patient's clinical history on systems' applications. Pay close attention to system notes, made on previous cases. Usually, the information required is already registered due to previous interviews, and interventions to patient, MD, or related parties.

    b. If system allows it, verify attached progress notes or documentation on previous cases (this is a good source of information, establishing patient's prior conditions), even information on cases that have been denied could be beneficial. Remember, it is only to find information for service justification.

    c. If steps a or b didn't work, then proceed to contact patient or MD office, and ask questions specifically related to service requisition. If there's no contact, use the Waiting Information process, and always keep in mind the Turn Around Time.

        * Finally, compare gathered information vs. criteria to process authorization, if clinical guidelines criteria are not met, then proceed to submit requisition for Medical Review Determination. *