DURABLE MEDICAL EQUIPMENT

AND

MEDICAL SUPPLY FORMULARY

Utilization Management

DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLY FORMULARY

NOTES: Items in bold require Utilization Management approval (refer to the Durable Medical Equipment Procedure flow chart on the next page).
Items marked with an asterisk (*) are supplies.

Dermatology
Burn Garment
Negative Pressure Wound Therapy/Vacuum Assisted Closure
Pressure Reducing Support Services - Groups 1, 2 & 3 (Mattresses)
*Wound Care Dressings

Endocrinology
*Diabetic Supplies/Monitors
Insulin Pump

Gastroenterology
*Ostomy Supplies
Sitz Bath
Truss Hernia Support

Hearing Assistive Devices
Hearing Impaired Disability Vest
Hearing Aid

Neurology
Helmet

Obstetrics/Gynecology
Breast Pump

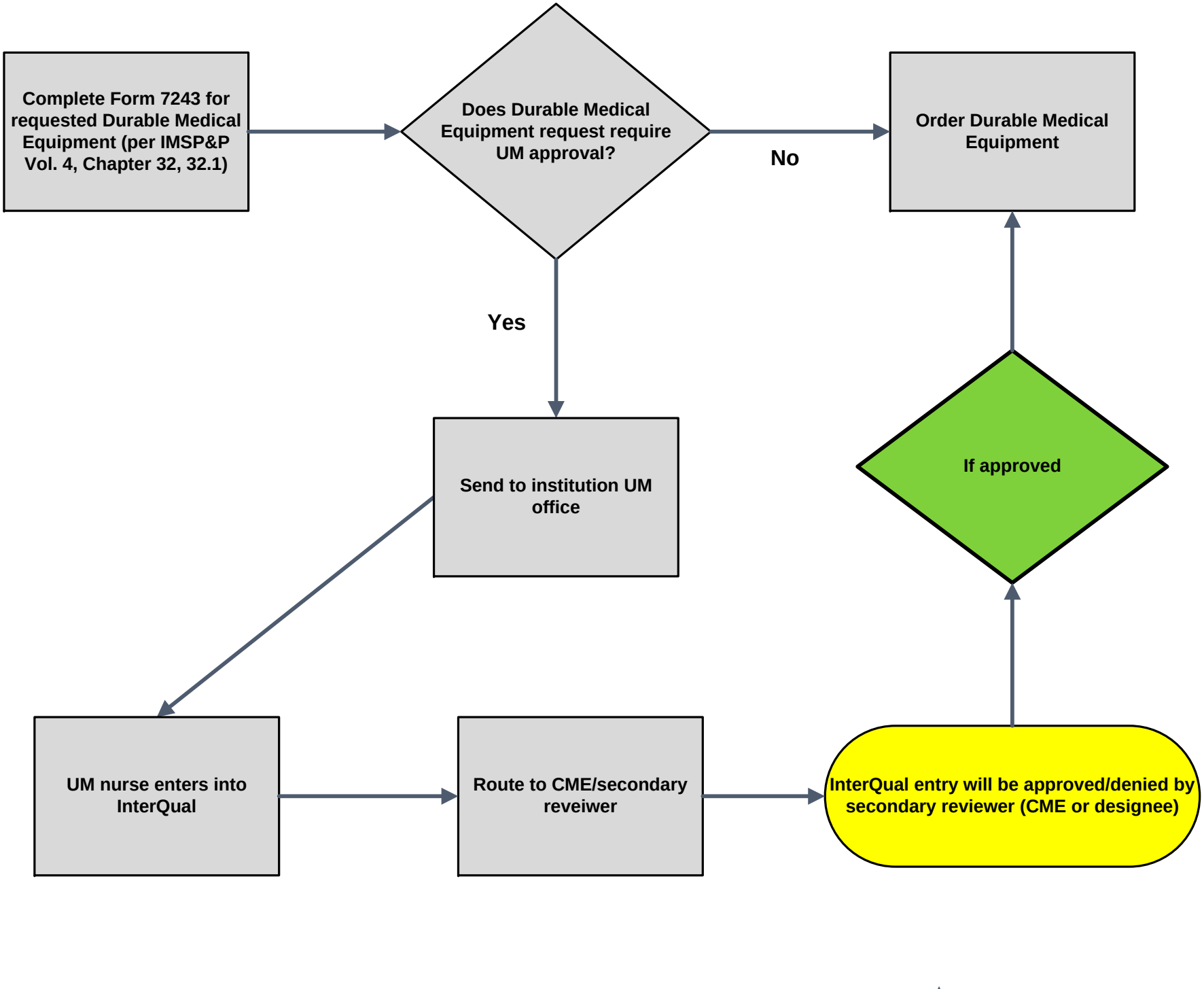
Ophthalmology and Optometry
Eyeglass Frames
Eyeglasses for Aphakia
Ocular Conformers
Scleral Shell Contact Lenses
Therapeutic Contact Lenses
Vision Impaired Disability Vest

Orthopedics
Bone Growth Stimulators, Electrical (Non-Invasive)
Back Braces
Ankle Foot Orthoses/Knee Ankle Foot Orthoses (AFO/KAFO)
Foot Orthoses
Knee Braces
Spinal Orthoses
Wrist Support Brace
Canes
Commode Chair
Compression Stocking
Continuous Passive Motion Device, Lower Extremity (see IQ)
Continuous Passive Motion Device, Upper Extremity (see IQ)
Crutches
Mobility Impaired Disability Vest
Prosthetic Limbs - Lower Extremity
Prosthetic Limbs - Upper Extremity
Standing Frames
Therapeutic Shoes/Orthotics
Toilet Seat Lift (Erector)
Walkers
Wheelchair

Pulmonology
Non-invasive Airway Assistive Devices (CPAP/BiPAP)
Oxygen Concentrators
*Tracheostomy Care Supplies
Voice Prostheses/Augmentative Communication/Speech Generating Device

Urology
*Incontinence Supplies
*Urologic Supplies

DURABLE MEDICAL EQUIPMENT PROCEDURE



DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLY FORMULARY

The following items constitute the Durable Medical Equipment and Medical Supply Formulary:

NOTES: Items in bold require Utilization Management approval.
Items marked with an asterisk (*) are supplies.

Burn Garment				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: A6501 Compression burn garment, bodysuit (head to foot), custom fabricated	Example: Gottfried medical, Inc. Example: Jobst	$$
$	$0 - 50	Example: A6502 Compression burn garment, chin strap, custom fabricated		$$
$$	$51 - 500	Example: A6503 Compression burn garment, facial hood, custom fabricated		$$
$$$	$501 - 1000	Example: A6504 Compression burn garment, glove to wrist, custom fabricated		$$
$$$$	$1000+	Example: A6505 Compression burn garment, glove to elbow, custom fabricated		$$
		Example: A6506 Compression burn garment, glove to axilla, custom fabricated		$$
		Example: A6507 Compression burn garment, foot to knee length, custom fabricated		$$
		Example: A6508 Compression burn garment, foot to thigh length, custom fabricated		$$
		Example: A6509 Compression burn garment, upper trunk to waist including arm openings (vest), custom fabricated		$$

		Example: A6510 Compression burn garment, trunk, including arms down to leg openings (leotard), custom fabricated		$$
		Example: A6511 Compression burn garment, not otherwise classified		$$
		Example: A6513 Compression burn mask, face, and/or neck, plastic or equal, custom fabricated		$$

Variations	**Associated Supplies**

Indications	**Contraindications**
Burn injury	

Establishment of Medical Necessity:	Burn garments (Jobst) are elastic garments (e.g., arm sleeve or stocking) used to provide support and protection from contamination due to a burn injury. These are often inflatable, compression garments. The patient is at risk for a post-burn contracture in the affected area where the garment will be applied, and the patient is receiving physical or occupational therapy. One garment is expected to be usable for 3 to 4 months.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	All of the above	**3-4 months**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
	3 cases/year = $150 - $1500	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Requires Utilization Management Approval.
Contact UM prior to ordering.

Negative Pressure Wound Therapy/Vacuum Assisted Closure
(See InterQual/Durable Medical Equipment/Negative Pressure Wound Therapy (NPWT) Pump)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Prospera Pro-III (pump)	Prospera	$$$$
$	$0 - 50	Example: LipoGel Advanced Wound Dressing	Progressive Wound Care Technologies	$$
$$	$51 - 500	Example: GenTex NPWT Black Foam Dressing Kits	Progressive Wound Care Technologies	$$
$$$	$501 - 1000	Example: GenTex NPWT White Foam	Progressive Wound Care Technologies	$$
$$$$	$1000+			

Variations	**Associated Supplies**
Prospera Pro-II	*Canister (MR-61048
Prospera Pro-III	*Canister vacuum protection filter and solidifier (MR3000CS)
	*Y-Connector with tubing (MR3001)
	*Battery pack (MR50-12103)
	*AC power cord adaptor/charger (MR50-51305)

Indications	**Contraindications**

Establishment of Medical Necessity:	Negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) for non-healing wounds is medically necessary when any **ONE** of the following conditions exists: 1. There are complications of a surgically created wound (e.g., dehiscence, post sternotomy disunion with exposed sternal bone, post sternotomy mediastinitis, or postoperative disunion of the abdominal wall). 2. There is a traumatic wound (e.g., preoperative flap or graft, exposed bones, tendons, or vessels) and a need for accelerated formation of granulation tissue not achievable by other topical wound treatments (e.g., the individual has comorbidities that will not allow for healing times usually achievable with other available topical wound treatments).

	3. There is a chronic, non-healing ulcer with lack of improvement for at least the previous 30 days despite standard wound therapy, including the application of moist topical dressings, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, and weekly evaluations with documentation of wound measurements (i.e., length, width, and depth) in **ONE** of the following clinical situations: a. <u>Chronic Stage III or Stage IV pressure ulcer</u> • The patient has been on an appropriate turning and repositioning regimen. • The patient has used an appropriate pressure relief device (e.g., low air loss bed, alternating pressure mattress) for pressure ulcers on the posterior trunk or pelvis. • The patient's moisture and incontinence have been appropriately addressed. b. <u>Chronic diabetic neuropathic ulcer</u> • The patient has been on a comprehensive diabetic management program. • The patient has had appropriate foot care. • The patient has been non-weightbearing if appropriate. c. <u>Chronic venous ulcer</u> • Compression garments/dressings have been consistently applied. • Leg elevation and ambulation have been encouraged. **The use of NPWT beyond four months may be allowed only when medical necessity continues to be met as previously outlined and there is evidence of clear benefit from the NPWT treatment already received.**

Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☐ **Prescription Requirement**	☒ **Authorization (See InterQual/Durable Medical Equipment /General/Negative Pressure Wound Therapy (NPWT) Pump**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☒ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Prospera Pro-III (pump)	**24-30 months**

	Accessories	Lifespan/Replacement Schedule
	*Canister (MR-61048)	**Single patient use**
	*canister vacuum protection filter and solidifier (MR3000CS)	**Single patient use**
	*Y-Connector with tubing (MR3001)	**Single patient use**
	*Battery Pack (MR50-12103)	**12 months**
	*AC power cord adaptor/charger (MR50-51305)	**N/A**
	*Example: LipoGel Advanced Wound Dressing	**Single use**
	*Example: GenTex NPWT Black Foam Dressing Kits	**Single use**
	*Example: GenTex NPWT White Foam	**Single use**
Clinical References	**InterQual/Durable Medical Equipment/Negative Pressure Wound Therapy (NPWT) Pump**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)	**May be purchased or rented**	
Special Procurement	**(Anticipated annual usage/cost) 15 treatment courses per year average statewide.**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Requires Utilization Management approval.
Contact UM prior to ordering.

Pressure Reducing Support Surfaces - Groups 1, 2 & 3 (Mattresses) (See Also InterQual/Durable Medical Equipment/General/Pressure Reducing Support Surfaces)				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Invacare Care Guard 101 Foam Mattress (Group 1)	Invacare	
$	$0 - 50	Example: Invacare Gel Foam Mattress Overlay (Group 1)		
$$	$51 - 500	Example: Invacare CareGuard APP Alternating Pressure Pad System (Group1)		
$$$	$501 - 1000	Example: Invacare Alternating Pressure Mattress System (Group 2)		
$$$$	$1000+	Example: Invacare Low Air Mattress (Group 2)		
		Example: Invacare microAIR 3500S Low Air Loss System (Group 2)		
		Example: Invacare Low Air Loss with Alternating Pressure Mattress (Group 2)		
		Example: Invacare Lateral Turning Mattress (Group 2)		
		Example: Invacare microAIR Turn-Q Plus Low Air Loss with Rotation System (Group 2)		
		Example: Clinitron Rite Hite Air Fluidized Therapy Bed (Group 3)		

Variations	Associated Supplies
Indications	**Contraindications**
See InterQual/Durable Medical Equipment /General/Pressure Reducing Surfaces	

Establishment of Medical Necessity:	Group 1 pressure reducing support surface includes pressure pads for mattresses, non-powered pressure reducing mattresses and powered pressure reducing mattress overlay systems. A Group 1 mattress overlay or mattress is considered **medically necessary** if the patient meets: • Criterion 1, or • Criterion 2 or 3 and at least one of criteria 4-7 1. Completely immobile - i.e., individual cannot make changes in body position without assistance 2. Limited mobility - i.e., individual cannot independently make changes in body position significant enough to alleviate pressure 3. Any stage pressure ulcer on the trunk or pelvis 4. Impaired nutritional status 5. Fecal or urinary incontinence 6. Altered sensory perception 7. Compromised circulatory status Group 2 pressure reducing support surface includes powered pressure reducing mattresses, semi-electric hospital beds with powered pressure reducing mattresses, powered pressure reducing mattress overlays, advanced non-powered pressure reducing mattresses and advanced non-powered pressure reducing mattress overlays. A Group 2 support surface is considered **medically necessary** if the patient meets: • Criteria 1and 2 and 3, or • Criterion 4, or • Criteria 5 and 6 1. Multiple stage II pressure ulcers located on the trunk or pelvis 2. Individual has been on a comprehensive ulcer treatment program for at least the past 30 days that has included the use of an appropriate Group 1 support surface

3. The ulcers have worsened or remained the same over the past month
4. Large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis
5. Recent myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis (surgery within the past 60 days)
6. The individual has been on a Group 2 or 3 support surface immediately prior to a recent discharge from a hospital or nursing facility (discharge within the past 30 days)

Continued use of a Group 2 support surface is considered **medically necessary** until the ulcer is healed or, if healing does not continue, there is documentation in the health record to show that:

1. Other aspects of the care plan are being modified to promote healing, **or**
2. The use of the Group 2 support surface is medically necessary for wound management

When a Group 2 pressure reducing support surface is prescribed following a myocutaneous flap or skin graft, continued use is considered **medically necessary** for up to 60 days from the date of surgery.

Group 3 pressure reducing support surface (e.g., air-fluidized bed) is a device employing the circulation of warm filtered air through small, silicone coated ceramic beads creating the characteristics of fluid. When the individual is placed in the bed, his or her body weight is evenly distributed over a large surface area, which creates the sensation of "floating."

A Group 3 support surface (air-fluidized bed) is considered **medically necessary** if the patient meets **ALL** of the following:

1. The patient has a stage III (full thickness tissue loss) or stage IV (deep tissue destruction) pressure sore or is status post muscle/skin flap repair of a stage III or IV pressure sore. An air-fluidized bed is typically needed only 6-12 weeks status-post surgery; and
2. The patient is bedridden or chair bound as a result of severely limited mobility; and
3. In the absence of an air-fluidized bed, the patient would require institutionalization; and
4. The air-fluidized bed is ordered, in writing, by the patient's attending physician based upon a comprehensive assessment and evaluation of the patient after completion of a course of conservative treatment designed to optimize conditions that promote wound healing; and

	5. The course of conservative treatment must have been at least one month in duration without progression toward wound healing. This month of prerequisite conservative treatment may include some period in an institution as long as there is documentation available to verify that the necessary conservative treatment was rendered; and Staff is available to assist the patient with activities of daily living, fluid balance, dry skin care, repositioning, recognition and management of altered mental status, dietary needs, prescribed treatments, and management and support of the air-fluidized bed system and its problems such as leakage; and 6. A physician directs the home treatment regimen and re-evaluates and re-certifies the need for the air-fluidized bed every three months; and 7. All other alternative equipment has been considered and ruled out. Continued use of an air-fluidized bed is considered **medically necessary** until the ulcer is healed or, if healing does not continue, there is documentation in the health record to show that: 1. Other aspects of the care plan are being modified to promote healing; **or** 2. The use of the air-fluidized bed is medically necessary for wound management.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☐ **Prescription Requirement**	☒ **UM Authorization Required**	
☒ **Reusable**		☐ **Single Patient Only**	
☒ **Able to Loan**		☐ **Must be purchased by patient**	
☒ **Manufactures User Manual**		☐ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**InterQual/Durable Medical Equipment/General/Pressure Reducing Support Surfaces**	

Quantity:	**1**
Par Levels: (if any, at warehouse, clinic, medical supply area)	**Rent on demand**
Special Procurement	**(anticipated annual usage/cost)**
	Air-Fluidized $90.00 /day (rent)
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

*Wound Care Dressings				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
	*Alginate wound cover
	*Alginate wound filler
	*Composite dressing
	*Contact layer
	*Foam dressing
	*Foam wound filler
	*Gauze
	*Hydrocolloid cover and fill
	*Hydrogel wound cover
	*Hydrogel wound filler
	*Specialty absorptive dressing
	*Transparent film
	*Wound filler not classified
	*Wound pouch
	*Tape
	*Elastic bandage
	*Gauze, elastic
	*Gauze, non-elastic

Indications	**Contraindications**
1. Dressings over a percutaneous catheter or tube (e.g., intravascular, epidural, nephrostomy, etc.) when the catheter or tube remains in place and after removal until the wound heals. 2. For treatment of a wound caused by, or treated by, a surgical procedure.	

Establishment of Medical Necessity:	1. When a wound cover with an adhesive border is being used, no other dressing is needed on top of it and additional tape is usually not required. Reasons for use of additional tape must be well documented. An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes.

	2. Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely medically necessary and the reasons must be well documented. An exception is an alginate or other fiber gelling dressing wound cover or a saline, water, or hydrogel impregnated gauze dressing which might need an additional wound cover. 3. It may not be appropriate to use some combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing (e.g., hydrogel and alginate). 4. Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressings, are meant to be changed at frequencies less than daily, appropriate clinical judgment should be used to avoid their use with primary dressings which require more frequent dressing changes. While a highly exudative wound might require such a combination initially, with continued proper management the wound usually progresses to a point where the appropriate selection of these products results in the less frequent dressing changes which they are designed to allow. An example of an inappropriate combination is the use of a specialty absorptive dressing on top of non-impregnated gauze being used as a primary dressing. 5. Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 5 cm x 5 cm (2 in. x 2 in.) wound requires a 4 in. x 4 in. pad size. 6. Dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds. **Dressing change frequency:** *Alginate wound cover - dressing change once daily *Alginate wound filler- dressing change once daily, up to 2 six inch strips per dressing change *Composite dressing - 3 times per week, 1 dressing per dressing change *Contact layer - once per week *Foam dressing - up to 3 times per week *Foam wound filler - once daily *Gauze - 3 times per day, no more than 2 pads on a wound (non-impregnated) *Gauze - once daily (impregnated - other than water or saline) *Gauze - Non-covered, reduced to regular non-impregnated gauze level (impregnated with water or saline) *Hydrocolloid cover and filler - 3 times per week *Hydrogel wound cover - once daily (or 3 times per week if using adhesive border) *Hydrogel wound filler - once daily, no more than 3 ounces per wound in a 30 day period *Specialty absorptive dressing - once per day (or every other day if using adhesive border)

	*Transparent film - up to 3 times per week *Wound filler not classified - once per day *Wound pouch - up to 3 times per week *Tape - determined by frequency of dressing change *Elastic bandage - 1 per week *Gauze, elastic - determined by the frequency of dressing change of the primary dressing *Gauze, non-elastic **-** determined by the frequency of dressing change of the primary dressing		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Surgical Dressings	**Replace supply once used.**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**The quantity and type of dressings dispensed at any one time must take into account the current status of the wound(s), the likelihood of change, and the recent use of dressings.**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

<table>
<tr><td colspan="5">*Diabetic Supplies/Monitors</td></tr>
<tr><td colspan="2">Reference Brands, Sources, and Relative Prices:</td><td>Reference Brands</td><td>Sources</td><td>Relative Prices</td></tr>
<tr><td>Symbol</td><td>Cost</td><td></td><td></td><td></td></tr>
<tr><td>$</td><td>$0 - 50</td><td>Example: Accu-Chek Aviva Plus</td><td></td><td></td></tr>
<tr><td>$$</td><td>$51 - 500</td><td></td><td></td><td></td></tr>
<tr><td>$$$</td><td>$501 - 1000</td><td></td><td></td><td></td></tr>
<tr><td>$$$$</td><td>$1000+</td><td></td><td></td><td></td></tr>
<tr><td colspan="3">Variations</td><td colspan="2">Associated Supplies</td></tr>
<tr><td colspan="3"></td><td colspan="2">*Alcohol wipes</td></tr>
<tr><td colspan="3"></td><td colspan="2">*Glucose meter strips</td></tr>
<tr><td colspan="3"></td><td colspan="2">*Standard lancet device</td></tr>
<tr><td colspan="3"></td><td colspan="2">*Lancet cartridge</td></tr>
<tr><td colspan="3"></td><td colspan="2">*Standard blood glucose monitors</td></tr>
<tr><td colspan="3">Indications</td><td colspan="2">Contraindications</td></tr>
<tr><td colspan="3">Diabetes</td><td colspan="2"></td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td>Establishment of Medical Necessity:</td><td colspan="4">1. Long-term use in a type 1 diabetic age 25 years or older
2. Long-term use in a type 1 diabetic age 24 years or younger with recurrent, severe hypoglycemic events (i.e., blood glucose < 50 mg/dL) despite appropriate modifications in insulin therapy and compliance with frequent self monitoring of blood glucose (i.e., at least four times daily)
3. Long-term use in a type 2 diabetic with recurrent, severe hypoglycemic events (i.e., blood glucose < 50mg/dL) despite appropriate modifications in insulin therapy, and compliance with frequent self monitoring of blood glucose (i.e., at least four times daily) and EITHER of the following:
a. Fasting C-peptide level ≤ 110% of the lower limit of normal of the laboratory's measurement method AND a concurrently obtained fasting glucose ≤ 225 mg/dL
b. Renal insufficiency with a creatinine clearance (actual or calculated from age, gender, weight and serum creatinine) ≤ 50 ml/minute AND a fasting C-peptide level ≤ 200% of the lower limit of normal of the laboratory's measurement method</td></tr>
<tr><td>Trial Period:</td><td colspan="2">☐ Yes ☒ No</td><td>Time Frame ≥:</td><td></td></tr>
<tr><td>Prescription vs. Authorization</td><td colspan="2">☒ Prescription Requirement</td><td colspan="2">☐ Authorization</td></tr>
</table>

<table>
<tr><td colspan="2">☐ Reusable</td><td colspan="2">☒ Single Patient Only</td></tr>
<tr><td colspan="2">☐ Able to Loan</td><td colspan="2">☐ Must be purchased by patient</td></tr>
<tr><td colspan="2">☐ Manufactures User Manual</td><td colspan="2">☐ Patient Education Handout</td></tr>
<tr><td rowspan="8">Expected Refresh Period:</td><td>Item Name</td><td>Lifespan/Replacement Schedule</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Accessories</td><td>Lifespan/Replacement Schedule</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Clinical References</td><td colspan="2">CMS National Coverage Determination (NCD)</td></tr>
<tr><td>Quantity:</td><td colspan="2"></td></tr>
<tr><td>Par Levels: (if any, at warehouse, clinic, medical supply area)</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Special Procurement</td><td colspan="2">(anticipated annual usage/cost)</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="2">Maintenance</td><td colspan="2">(Service contracts, inspections for clinical performance, safety and compliance)</td></tr>
<tr><td colspan="2"></td></tr>
</table>

Requires Utilization Management approval.
Contact UM prior to ordering.

Insulin Pump
(See InterQual/Durable Medical Equipment/General/Insulin Pump, Ambulatory)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Animas Ping		$$$$
$	$0 - 50	Example: Accu-Chek Spirit		$$$$
$$	$51 - 500	Example: Tandem Diabetes t:slim		$$$$
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
	*Battery
	*Pump cartridge
	*Infusion system with cannula and tubing
	*I.V. prep antiseptic wipe
	*Skin adhesive
	*Dressing

Indications	**Contraindications**

Establishment of Medical Necessity:

See InterQual/Durable Medical Equipment/General/Insulin Pump, Ambulatory

<u>External Insulin Infusion Pumps for Diabetes</u>

CCHCS considers external insulin infusion pumps medically necessary Durable Medical Equipment for the persons with diabetes who meet the criteria in Section 1 or in Section 2 below:

1. Members must meet **ALL** of the following criteria:
   a. The member has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump; and
   b. The member has completed a comprehensive diabetes education program; and
   c. The member has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump; and

<table>
<tr><td></td><td colspan="4">d. The member meets at least one of the following criteria while on multiple daily injections (more than 3 injections per day) of insulin:
1) Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
2) Elevated glycosylated hemoglobin level (HbA1c greater than 7.0%, where upper range of normal is less than 6.0%; for other HbA1c assays, 1% over upper range of normal); or
3) History of recurring hypoglycemia (less than 60 mg/dL); or
4) History of severe glycemic excursions; or
5) Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL)
OR
2. The member has been on a pump prior to enrollment in CCHCS, and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to CCHCS enrollment.

CCHCS considers external infusion pumps for diabetes experimental and investigational where the above-listed criteria are not met.</td></tr>
<tr><td>Trial Period:</td><td colspan="2">☒ Yes ☐ No</td><td>Time Frame ≥:</td><td></td></tr>
<tr><td>Prescription vs. Authorization</td><td colspan="2">☐ Prescription Requirement</td><td colspan="2">☒ UM Authorization Required</td></tr>
<tr><td colspan="2">☐ Reusable</td><td colspan="3">☒ Single Patient Only</td></tr>
<tr><td colspan="2">☐ Able to Loan</td><td colspan="3">☐ Must be purchased by patient</td></tr>
<tr><td colspan="2">☒ Manufactures User Manual</td><td colspan="3">☒ Patient Education Handout</td></tr>
<tr><td rowspan="8">Expected Refresh Period:</td><td colspan="2">Item Name</td><td colspan="2">Lifespan/Replacement Schedule</td></tr>
<tr><td colspan="2">Animas</td><td colspan="2">4 years</td></tr>
<tr><td colspan="2">Accu-Chek</td><td colspan="2">4 years</td></tr>
<tr><td colspan="2">Tandem Diabetes</td><td colspan="2">4 years</td></tr>
<tr><td colspan="2">Accessories</td><td colspan="2">Lifespan/Replacement Schedule</td></tr>
<tr><td colspan="2">Luer lock Infusion system 23”-43” tubing</td><td colspan="2">Head set 72 hour max.
Tube-set 6 days max.</td></tr>
<tr><td colspan="2">Insulin pump cartridge</td><td colspan="2">User dependant</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>Clinical References</td><td colspan="4">InterQual/Durable Medical Equipment/General/Insulin Pump, Ambulatory</td></tr>
<tr><td>Quantity:</td><td colspan="4">1</td></tr>
</table>

Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
	$2,000.00 - $2,500.00 non-contracted rates
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**
	Every 6 months or more often if requested by a physician.

*Ostomy Supplies				
Reference Brands, Sources, and Relative Prices:		Reference Brands	Sources	Relative Prices
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	Associated Supplies
	*Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube
	*Ostomy faceplate
	*Ostomy adhesive remover wipes
	*Ostomy belt
	*Ostomy filter
	*Irrigation supply, sleeve
	*Irrigation supply, bag
	*Irrigation supply, catheter/cone, including brush
	*Ostomy irrigation set
	*Lubricant
	*Ostomy ring
	*Adhesive remover or solvent (for tape, cement or other adhesive)
	*Closed pouch with barrier attached
	*Closed pouch without barrier attached
	*Closed pouch for use on faceplate
	*Closed pouch for barrier with flange
	*Stoma cap
	*Pouch, drainable; with barrier
	*Pouch, drainable: without barrier
	*Drainable pouch for barrier w/flange (2 pc)
	*Urinary pouch with barrier attached (1 pc)
	*Urinary pouch without barrier attached (1 pc)
	*Urinary pouch for barrier w/flange (2 pc)
	*Continent device: plug for continent stoma

	*Continent device: catheter for continent stoma
	*Ostomy accessory: convex insert
	*Bedside drainage bottle w/ or w/out tubing, rigid or expandable
	*Skin barrier, wipes
	*Skin barrier: liquid, (spray, brush, etc.) powder or paste
	*Skin barrier, solid
	*Skin barrier with flange (solid, flexible, or accordion)
	*Adhesive, disc or foam pad
	*Appliance cleaner, incontinence and ostomy appliances
	*Gauze, non-impregnated, non-sterile, pad size 16 sq inches or less, w/out adhesive border
	*Tape
	*Skin barrier: solid 4x4 r equivalent, standard wear with built in convexity
	*Skin barrier: with flange (solid, flexible or accordion), standard wear with built in convexity
	*Skin barrier: with flange (solid, flexible or accordion), extended wear with built in convexity
	*Pouch, drainable, for use on faceplate, plastic
	*Pouch, urinary, for use on faceplate, plastic
Indications	**Contraindications**
For use with a surgically created opening (stoma) to divert urine, feces, ileal contents or other fluids from inside to outside of the body.	

Establishment of Medical Necessity:	1. When liquid barrier is necessary, either a liquid or spray or individual wipes is appropriate. Use of both is not medically necessary. 2. Patients with continent stomas may use the following to manage/prevent drainage: *stoma cap, *stoma plug, or *gauze pads. No more than one type of supply would be medically necessary on a given day. 3. Patients with urinary ostomies may use a bag or bottle for drainage at night. It is not medically necessary to have both.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ Reusable		☒ Single Patient Only
☐ Able to Loan		☐ Must be purchased by patient
☐ Manufactures User Manual		☐ Patient Education Handout
Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	*Ostomy Supplies	Replace once used
	Accessories	**Lifespan/Replacement Schedule**
	See list on pages 20, 21	Used once
Clinical References	CMS National Coverage Determination (NCD)	
Quantity:	The quantity of ostomy supplies needed by a patient is determined to a great extent by the type of ostomy, location, construction and condition of the skin surrounding the stoma. *Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube – 1/months *Ostomy faceplate – 3/6 month *Skin barrier: solid, 4x4 or equivalent, each – 10/month *Ostomy adhesive remover wipes, 50/box – 4/month *Ostomy belt, each – 2/6 month *Ostomy filter, any type, each – #recommended by ostomy therapist – varies *Irrigation supply, sleeve, each – 1/month *Irrigation supply, bag, each – 2/6 month *Irrigation supply, catheter/cone, including brush – 2/6 month *Ostomy irrigation set - #recommended by ostomy therapist – varies *Lubricant per ounce – 4/month *Ostomy ring, each – 10/month *Adhesive remover or solvent (for tape, cement or other adhesive), per ounce – 16/6 month *Closed pouch with barrier attached (1 piece) – 31/month *Closed pouch without barrier attached (1 piece) – 31/month *Closed pouch for use on faceplate – 31/month *Closed pouch for barrier with flange (2 piece) 31/month *Stoma cap – 31/month *Pouch, drainable; with barrier attached (1 piece) – 10/month *Pouch, drainable: without barrier attached (1 piece) – 10/month	

	***Drainable pouch for barrier w/ flange (2 pc system) – 10/month** ***Urinary pouch with barrier attached (1 pc) – 10/month** ***Urinary pouch without barrier attached (1 pc) – 10/month** ***Urinary pouch for barrier w/ flange (2 pc system) – 10/month** ***Continent device: plug for continent stoma – 31/month** ***Continent device: catheter for continent stoma – 1/month** ***Ostomy accessory: convex insert – 10/month** ***Bedside drainage bottle w/ or w/out tubing, rigid or expandable, each– 2/6 months** ***Skin barrier, wipes, per box of 50 – 3/6 months** ***Skin barrier, solid 6x6 or equivalent, each – 10/month** ***Skin barrier, solid 8x8 or equivalent, each – 6/month** ***Skin barrier with flange (solid, flexible, or accordion), any size, each – 10/month** ***Adhesive, disc or foam pad – 10/month** ***Appliance cleaner, incontinence and ostomy appliances, per 16 oz – 1/month** ***Gauze, non impregnated, non sterile, pad size 16 sq inches or less, w/out adhesive border, each dressing – 60/month** ***Tape, all types per 18 square inch – 20/month** ***Skin barrier: liquid (spray, brush, etc) per oz – 2/month** ***Skin barrier: paste, per oz – 4/month** ***Skin barrier: powder, per oz – 10/6 months** ***Skin barrier: solid 4x4 or equivalent, standard wear with built in convexity, each – varies** ***Skin barrier: with flange (solid, flexible or accordion), standard wear with built in convexity, any size, each - varies** ***Skin barrier: with flange (solid, flexible or accordion), extended wear with built in convexity, any size, each - varies** ***Pouch, drainable, for use on faceplate, plastic, each – 10/month** ***Pouch, urinary, for use on faceplate, plastic, each – 10/month**
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Sitz Bath				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
	*Epsom Salt
Indications	**Contraindications**
Perineal injury or infection; relieve pain and speed healing after hemorrhoid surgery or an episiotomy.	

Establishment of Medical Necessity:	The patient has a perineal injury or infection and part of a medically necessary prescribed treatment regimen.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufacturer's User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Sitz Bath	**When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**1**	

Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Truss Hernia Support				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Loin Truss	
Corset Belt	
Abdominal Truss	
Indications	**Contraindications**
Reducible hernia	

Establishment of Medical Necessity:	Used for the purpose of supporting a weak or deformed body part, or restricting or eliminating motion.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufacturer's User Manual**	☐ **Patient Education Handout**

	Item Name	**Lifespan/Replacement Schedule**
Expected Refresh Period:	**Corset or Truss**	**When anatomical change or reasonable wear and tear renders the Truss nonfunctioning.**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD) for Corset Used as Hernia Support (280.11) Publication Number 100-3**	

Quantity:	**1**
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Hearing Impaired Disability Vest				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Indications	**Contraindications**

Establishment of Medical Necessity:	Hearing Impaired: 1. Individual is deaf or severely hearing impaired and requires written notes, sign language, or lip reading accommodation to achieve effective communication. 2. Individual has a hearing impairment in both ears and uses an assistive hearing device to achieve effective communication.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References		

Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Hearing Aid
(See InterQual/Durable Medical Equipment/General/Hearing Aid)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Phonak		
$	$0 - 50	Example: Microtech		
$$	$51 - 500	Example: Resound		
$$$	$501 - 1000	Example: Siemens		
$$$$	$1000+			Per ear

Variations	**Associated Supplies**
	*Batteries

Indications	**Contraindications**
Hearing loss	

Establishment of Medical Necessity:	See InterQual/Durable Medical Equipment/General/Hearing Aid		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**InterQual/Durable Medical Equipment/General/Hearing Aids Clinical Guidelines**	

Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
	$3000 per ear
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**
	1-2 year warranty

Helmet				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Skillbuilders® Head protector	http://www.dmesupplygroup.com/	
$	$0 - 50	Example: Norco protective helmets	http://www.rehabmart.com/category/Protective_Helmets.htm	$48.38
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**
Seizure disorder, behavior disorders that are at risk for injury to the head and face.	

Establishment of Medical Necessity:	Appropriate when ordered by a physician as medically necessary for individuals with seizure or behavior disorders who are at risk for injury to the head and face.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	https://www.cms.gov
Quantity:	**1**
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Breast Pump				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**

Establishment of Medical Necessity:			
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References		

Quantity:	**1**
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Eyeglass Frames				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50		P.I.A. Optical	$
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
UN23	
UN332	
Apollo	

Indications	**Contraindications**

Establishment of Medical Necessity:			
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		Replace yearly or if broken and not able to repair.
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	
Quantity:	**1**
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
	Order from P.I.A. Optical only
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Eyeglasses for Aphakia				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**
Post Cataract Surgery	

Establishment of Medical Necessity:	The following lenses or combinations of lenses are medically necessary following cataract surgery to essentially restore the vision provided by the crystalline lens of the eye. These include: 1. Bifocal spectacles 2. Spectacles for far vision or for near vision		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		Requests for replacement of lost or broken glasses or lenses will be reviewed on an individual basis.
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	**CMS Ruling 05-01 issued May 3, 2005**
Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Ocular Conformers				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Kolberg Plastic conformer	Kolberg Ocular supplies	$
$	$0 – 50	Example: Non- Sterile Silicone Conformer (various sizes)	Wilson Ophthalmic	$
$$	$51 - 500	Example: L48A0 Conformer	Bausch&Lomb	$$
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Vented	
Non-vented	

Indications	**Contraindications**
Conformers are used as post-operative enucleation stints to provide a smooth surface for the lids to blink over while protecting the surgical closure beneath it.	

Establishment of Medical Necessity:	An ophthalmic conformer is a device usually made of molded plastic intended to be inserted temporarily between the eyeball and eyelid to maintain space in the orbital cavity and prevent closure or adhesions during the healing process following surgery.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		Varies by Manufacturer 3 months - 5 years

	Accessories	Lifespan/Replacement Schedule
Clinical References	**CMS National Coverage Determination (NCD), InterQual**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Scleral Shell Contact Lenses				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Erickson Labs northwest		
$	$0 - 50	Example: Danz and associates		
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			$2500-3000

Variations	**Associated Supplies**
	*Lubricants
	*Drops
	*Eye patches
	*Suction cups
	*Lid scrubs

Indications	**Contraindications**

Establishment of Medical Necessity:	Scleral shell contact lenses are medically necessary for the following indications: 1. For the treatment of keratoconjunctivitis sicca or “dry eye"; or 2. When prescribed to support orbital tissue (such as where an eye has been rendered sightless and shrunken by inflammatory disease). Replacement lenses are considered medically necessary if required because of a change in the patient's physical condition (not including refractive changes).		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		5-7 days

	Accessories	Lifespan/Replacement Schedule
	*Lubricants,	
	*Drops	
	*Eye patches	
	*Suction cups	
	*Lid scrubs	
Clinical References	**CMS National Coverage Determination (NCD) for Scleral Shell (80.5); Publication #100-3**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Therapeutic Contact Lenses				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50	Example: Acuvue Oasys	Lensaver.com	$52-71 /24 lenses
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
	*Contact lens solution
	*Rewetting drops
	*Lens case

Indications	**Contraindications**
Keratectomy, corneal erosion, bullous keratopathy, keratoconus	Dry eyes, acute inflammation, corneal hypoesthesia, allergic reaction

Establishment of Medical Necessity:

Therapeutic soft (hydrophilic) contact lenses or gas-permeable fluid ventilated scleral lenses (e.g., Boston Scleral Lens) are medically necessary prosthetics when used as moist corneal bandages for the treatment of severe ocular surface diseases, including:

1. Corneal stem cell deficiency (Stevens-Johnson syndrome/TEN, chemical and thermal injuries to the eye including surgical procedures, aniridia, idiopathic corneal stem cell deficiency and ocular pemphigoid); or
2. Neurotrophic (anesthetic) corneas, such as may result from:
   a. Acquired etiologies, such as may result from acoustic neuroma surgery, trigeminal ganglionectomy, trigeminal rhizotomy, herpes simplex/zoster of the cornea, diabetes; or
   b. Congenital etiologies, such as congenital corneal anesthesia (familial dysautonomia), Seckel's syndrome; or
3. Severe dry eyes (keratoconjunctivitis sicca) (such as from Sjogren's syndrome, chronic graft versus host disease, radiation, surgery, meibomian gland deficiency); or
4. Corneal disorders associated with systemic autoimmune diseases (rheumatoid arthritis, dermatological disorders such as atopic, epidermolysis bullosa, epidermal dysplasia); or
   a. Epidermal ocular disorders (atopy, ectodermal dysplasia, epidermolysis bullosa); or
   b. Corneal exposure (e.g., anatomic, paralytic).

Replacement lenses are considered medically necessary if required because of a change in the patient's physical condition (not including refractive changes).

Trial Period:	☒ **Yes** ☐ **No**	Time Frame ≥:	2 weeks
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	
☐ **Reusable**		☒ **Single Patient Only**	
☐ **Able to Loan**		☐ **Must be purchased by patient**	
☐ **Manufactures User Manual**		☒ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Acuvue Oasys	**Six days for continuous wear Two weeks for daily wear**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD) for Hydrophilic Contact Lens for CORNEAL Bandage (80.1); Publication #100-3**	
Quantity:	**24 per pack X 2**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
	$104-200	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Vision Impaired Disability Vest				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**

Establishment of Medical Necessity:	Vision Impaired: Individual has severe vision impairment which is not correctable to better than 20/200 with corrective lenses in at least one eye.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	
Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Requires Utilization Management approval.
Contact UM prior to ordering.

Bone Growth Stimulators, Electrical (Non-invasive)
(See InterQual/Durable Medical Equipment/Bone Growth Stimulators [Non-invasive])

Reference Brands, Sources, and Relative Prices:		Reference Brands	Sources	Relative Prices
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Osteogenesis Stimulator, Electrical, Non-invasive, Not Spinal Application	Electrical power source
Osteogenesis Stimulator, Electrical, Non-invasive, Spinal Application	

Indications	**Contraindications**
1. Non-union of long bones 2. Failed fusion, where a minimum of 9 months has elapsed since last surgery 3. Congenital pseudoarthrosis 4. As an adjunct to spinal fusion surgery for patients at risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion (3 or more vertebrae) Note: Non-union of long bone fracture is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.	1. Synovial or metaphyseal pseudoarthrosis 2. Fracture gaps >1 cm or necrotic ends 3. Significant motion at the site that is difficult to control 4. Patients with cancer 5. Pregnant patients 6. Patients with permanent pacemakers 7. Infection at the site 8. Disorders of bone metabolism 9. Severe osteoporoses 10. Avascularity at the site 11. Patients with rheumatoid arthritis 12. Patients with nutritional defects 13. Patients on steroids 14. Non compliant patients

Establishment of Medical Necessity:	See InterQual/Durable Medical Equipment/Bone Growth Stimulators (Non-invasive) Consider discontinuing treatment if no signs of healing after 8 weeks of treatment.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☐ **Prescription Requirement**	☒ **UM Authorization Required**	
☒ **Reusable**		☐ **Single Patient Only**	
☐ **Able to Loan**		☐ **Must be purchased by patient**	
☒ **Manufactures User Manual**		☐ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Bone Growth Stimulators, Electrical (Non-invasive)	**When reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD)** **InterQual/Durable Medical Equipment/Bone Growth Stimulators (Non-invasive)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Back Braces				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Cybertech 636 flex	http://www.dme-direct.com	$169
$	$0 - 50	Example: Aspen Summit 631		$243
$$	$51 - 500			
$$$	$501 - 1000	Example: Aspen Evergreen LSO 637		$235
$$$$	$1000+			

Variations	**Associated Supplies**
Thoracic Lumbar Sacral Orthotic (TLSO)	
Lumbar Sacral Orthotic (LSO)	
Lumbar Orthotic (LO)	

Indications	**Contraindications**
To alleviate pain by restricting mobility, post operatively and post-injury to facilitate healing of the spine and/or related tissues to support weak spinal muscles or a deformed spine that significantly impacts the patient's ADLs.	1. Preventative or prophylactic treatment 2. Identical or spare orthosis

Establishment of Medical Necessity:	1. Status post spine or related soft issue injury. 2. Status post spine or related soft tissue surgical procedure. 3. Pain requiring restricted trunk mobility. 4. Weak spinal muscles or deformed spine requiring support.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**Interqual**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Ankle Foot Orthoses/Knee Ankle Foot Orthoses (AFO/KAFO)
(See also I**nterQual/**Durable Medical Equipment**/**General**/**Orthoses, Lower Extremity, Ankle-Foot)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50	Example: Ankle foot Orthotic		$
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Ankle foot orthosis	For ankle contracture, a replacement interface is medically necessary Durable Medical Equipment as long as the patient continues to meet medical necessity criteria for the splint.
AFO foot orthosis	
AFO –Ankle Foot orthotic	

Indications	**Contraindications**
See Medical Necessity section	1. An ankle contracture splint and replacement interface is not medically necessary for patients with fixed contractures and patients with foot drop but without an ankle flexion contracture. 2. Ankle contracture splint and replacement interface is not considered medically necessary when it is used solely for the prevention or treatment of a heel pressure ulcer in nonambulatory patients. 3. AFOs/KAFOs and any related addition are NOT medically necessary when used solely for the treatment of edema and/or for the prevention or treatment of a heel pressure ulcer in ambulatory patients.

Establishment of Medical Necessity	**For nonambulatory patients:** 1. <u>Ankle contracture splints</u> - medically necessary if **ALL** of the following criteria are met: a. The ankle contracture splint is used as a component of a therapy program that includes active stretching of the involved muscles and/or tendons, and b. The contracture is interfering or expected to interfere significantly with the patient's functional abilities, and c. There is a reasonable expectation of the ability to correct the contracture, and d. The patient has a plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a non-fixed contracture). If an ankle contracture splint is used for the treatment of a plantar flexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the health record. There must be documentation of an appropriate stretching program carried out by professional staff.

<table>
<tr><td></td><td colspan="3">For ambulatory patients:

1. Ankle Foot Orthoses - medically necessary for ambulatory patients with weakness or deformity of the foot and ankle, which require stabilization for medical reasons, and have the potential to benefit functionally.
2. Knee-ankle-foot orthoses (KAFO) - medically necessary for ambulatory patients for whom an ankle-foot orthosis is clinically indicated and for whom additional knee stability is required.
3. Molded-to-patient model AFO's and KAFO's - Custom-made AFOs and KAFOs that are “molded-to-patient-model” are considered medically necessary for ambulatory patients when the basic medical necessity criteria are met and one of the following criteria is met:
a. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or
b. There is a need to control the knee, ankle or foot in more than one plane; or
c. The patient could not be fit with a pre-fabricated (off-the-shelf) AFO; or
d. The patient has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or
e. The patient has a healing fracture that lacks normal anatomical integrity or anthropometric proportions.</td></tr>
<tr><td>Trial Period</td><td colspan="2">☐ Yes ☒ No</td><td>Time Frame ≥:</td></tr>
<tr><td>Prescription vs. Authorization</td><td colspan="2">☒ Prescription Requirement</td><td>☐ Authorization</td></tr>
<tr><td colspan="2">☐ Reusable</td><td colspan="2">☒ Single Patient Only</td></tr>
<tr><td colspan="2">☐ Able to Loan</td><td colspan="2">☐ Must be purchased by patient</td></tr>
<tr><td colspan="2">☐ Manufactures User Manual</td><td colspan="2">☐ Patient Education Handout</td></tr>
<tr><td rowspan="7">Expected Refresh Period</td><td>Item Name</td><td colspan="2">Lifespan/Replacement Schedule</td></tr>
<tr><td>AFO/KAFO</td><td colspan="2">When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.</td></tr>
<tr><td>Replacement interface</td><td colspan="2">Up to one replacement interface per six months is considered medically necessary.</td></tr>
<tr><td>Accessories</td><td colspan="2">Lifespan/Replacement Schedule</td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td></td><td colspan="2"></td></tr>
<tr><td>Clinical References</td><td colspan="3">CMS National Coverage Determination (NCD)InterQual/Durable Medical Equipment/General/Orthoses, Lower Extremity, Ankle-Foot</td></tr>
<tr><td>Quantity</td><td colspan="3">1</td></tr>
</table>

Par Levels (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
	$38- $50
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Foot Orthoses
(See also InterQual/Durable Medical Equipment/General/Orthoses, Lower Extremity, Ankle-Foot)

Reference Brands, Sources, and Relative Prices:		Reference Brands	Sources	Relative Prices
Symbol	**Cost**			
$	$0 - 50	Example: Sole Supports		$9.99 – 20.99
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	Associated Supplies
Walkfit	

Indications	Contraindications
See Establishment of Medical Necessity	

Establishment of Medical Necessity:	Medically necessary when there is failure, contraindication, or intolerance to prefabricated foot orthosis for ANY of the following conditions: 1. The foot orthosis is an integral part of a leg brace and is necessary for the proper functioning of the brace. 2. The foot orthosis is used to compensate for a missing portion of the foot (e.g., amputation) and is necessary for the alleviation or correction of illness, injury or congenital defect. 3. Neurologic or neuromuscular condition (e.g., cerebral palsy, hemiplegia, spina bifida) producing spasticity, mal-alignment or pathological positioning of the foot where there is reasonable expectation of improvement.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☒ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Sole support	**When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
	Walkfit	

	Accessories	Lifespan/Replacement Schedule
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)	**Medical supply**	
Special Procurement	**(anticipated annual usage/cost)**	
	$10- $20	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

<table>
<tr><td colspan="5">Knee Braces</td></tr>
<tr><td colspan="2">Reference Brands, Sources, and Relative Prices:</td><td>Reference Brands</td><td>Sources</td><td>Relative Prices</td></tr>
<tr><td>Symbol</td><td>Cost</td><td></td><td></td><td></td></tr>
<tr><td>$</td><td>$0 - 50</td><td></td><td></td><td></td></tr>
<tr><td>$$</td><td>$51 - 500</td><td>Example: Elastic knee brace</td><td></td><td>$24.99 to 59.00</td></tr>
<tr><td>$$$</td><td>$501 - 1000</td><td></td><td></td><td></td></tr>
<tr><td>$$$$</td><td>$1000+</td><td></td><td></td><td></td></tr>
<tr><td colspan="3">Variations</td><td colspan="2">Associated Supplies</td></tr>
<tr><td colspan="3">Hinged composite knee brace</td><td colspan="2"><u>Heavy duty knee joints</u> - when medical necessity criteria for the knee brace has been met and the individual weighs greater than 300 pounds.

<u>High-strength, lightweight material</u> - for patient who meets medical necessity criteria for a custom-fabricated knee brace with EITHER of the following indications:

1. Daily activity level - requires a brace designed for high-impact/high-stress activities
2. Weight greater than 250 lbs</td></tr>
<tr><td colspan="3">Indications</td><td colspan="2">Contraindications</td></tr>
<tr><td colspan="3">1. Support for ligament tears & instabilities
2. Osteoarthritis
3. Post-op Knee surgery for support
4. Meniscal Injuries & instability
5. Patellar Support & stability
6. Knee pain</td><td colspan="2">1. Prophylactic knee braces
2. Functional knee braces utilized solely for participation in sports or to improve athletic performance
3. Patellofemoral knee braces/sleeves for the treatment of postoperative knee effusion or patellofemoral syndrome without subluxation or dislocation
4. Functional knee braces after successful reconstructive ligament surgery
5. Socks and brace sleeves used in conjunction with the orthotic device
6. Additional removable or non removable interface dispensed with the initial device
7. Prefabricated knee brace with inflatable air bladder</td></tr>
</table>

Establishment of Medical Necessity:	Fracture Knee Brace/Rehabilitative Brace - medically necessary when applied at the time of initial stabilization (e.g., post-surgery, post-injury, post- fracture). Patellofemoral Knee Brace - medically necessary for the treatment of patellofemoral dislocations or chronic patellar symptomatic subluxation for EITHER of the following indications: 1. Following reduction for an acute (initial) patellar dislocation 2. Recurrent dislocation/subluxation of the patella following failure of a 3 month exercise and strengthening Functional Knee Brace (prefabricated, i.e., off-the-shelf, custom-fitted) - medically necessary when there is documented knee instability and the individual is not considered a surgical candidate for ligament reconstruction. Custom-fabricated functional knee brace is medically necessary when the criteria for a prefabricated functional knee brace have been met and the patient is unable to be fitted with a prefabricated device as a result of ANY of the following (this list may not be all-inclusive): 1. Abnormal limb contour (e.g., disproportionate size/shape) 2. Knee deformity (e.g., valgus, varus deformity) 3. Minimal mass upon which to suspend the orthosis Unloading/Offloading Knee Brace (prefabricated) - medically necessary for the treatment of moderate to severe osteoarthritis of the knee when **ALL** of the following criteria are met: 1. Unicompartmental disease that requires load reduction to an affected compartment 2. Documented failure of prior medical treatment modalities (e.g., nonsteroidal anti-inflammatory medications, steroid injections, viscoelastic supplementation) 3. Radiographic documentation of single-compartment osteoarthritis with or without varus/valgus deformity 4. Persistent knee pain limiting activities of daily living Custom-fabricated unloading/offloading knee brace is medically necessary when criteria for a prefabricated unloading/offloading brace have been met and the patient is unable to be fitted with a prefabricated device as a result of ANY of the following (this list may not be all-inclusive): 1. Abnormal limb contour (e.g., disproportionate size/shape) 2. Knee deformity (e.g., valgus, varus deformity) 3. Minimal mass upon which to suspend the orthosis

Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	
☐ **Reusable**		☒ **Single Patient Only**	
☐ **Able to Loan**		☐ **Must be purchased by patient**	
☐ **Manufactures User Manual**		☐ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)	**Medical supply**	
Special Procurement	**(anticipated annual usage/cost)**	
	$50.00	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Spinal Orthoses
(See InterQual/Durable Medical Equipment/General/Orthoses, Spinal)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500	Example: ITA –med posture corrector		$59.99
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Rigid Spine Orthosis	
Flexible Spinal Orthosis	

Indications	**Contraindications**

Establishment of Medical Necessity:	See InterQual/Durable Medical Equipment/General/Orthoses, Spinal		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☒ **Manufactures User Manual**	☒ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	**InterQual/Durable Medical Equipment/General/Orthoses, Spinal**
Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Wrist Support Brace				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50		http://www.dme-direct.com	$15-30
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**
Carpal tunnel syndrome, Wrist injury	

Establishment of Medical Necessity:			
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	
Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Canes				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Standard	*Cane tips
Forearm	
Tripod	
Quad or retractable stud on the ground end	

Indications	**Contraindications**
See Medical Necessity section	

Establishment of Medical Necessity:	A patient has a mobility limitation that: 1. Prevents the patient from accomplishing the ADL entirely, 2. Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform the ADL, or 3. Prevents the patient from completing the ADL within a reasonable time frame. Canes are medically necessary when prescribed by a physician for a patient with a condition that is causing impaired ambulation, and when there is a potential for ambulation. The patient is normally ambulatory but suffers from a condition that impairs ambulation.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Cane	**Reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
	Accessories	**Lifespan/Replacement Schedule**
	***Cane Tips**	**Prior to each patient's use and annually if required at maintenance inspection**
Clinical References	**CMS National Coverage Determination (NCD) (280.3)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)	**4**	
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Commode Chair				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Standard Stationary Commode Chair	
Extra-wide, heavy-duty stationary commode chair	
Stationary commode chair with detachable arms	

Indications	**Contraindications**
When patient is confined to a bed or room due to a medical or surgical condition and cannot access a standard toilet.	

Establishment of Medical Necessity:	**Standard stationary commode chair** - due to a medical or surgical condition, the patient is confined to a room or lacking a toilet or unable to use standard bathroom facilities. **Extra-wide, heavy-duty stationary commode chair** - the patient meets medical necessity criteria for a standard commode chair and weighs ≥ 300 pounds. **Stationary commode chair with detachable arms -** the patient meets medical necessity criteria for a standard commode chair but requires either extra width or detachable arms to facilitate transfers.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		When anatomical change or reasonable wear and tear renders the DME **nonfunctioning.**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Compression Stocking				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	Associated Supplies

Indications	Contraindications
A gradient compression stocking may be indicated when used to secure a primary dressing over an open venous stasis ulcer that has been treated by a physician or other healthcare professional requiring medically necessary debridement, and when the gradient stocking can be proven to deliver compression greater than 30 mm Hg and less than 50 mm Hg. Compression garments with a pressure gradient of > 20 mm Hg that provide a medical benefit to the patient for a specific medical condition. 1. Venous insufficiency without stasis ulcers 2. Prevention of stasis ulcer 3. Prevention of reoccurrence of stasis ulcers that have healed 4. Treatment of lymphedema	1. Advanced arterial disease 2. Uncontrolled CHF 3. Neuropathy 4. Septic thrombophlebitis 5. Wet skin lesion or ulceration 6. Gangrene secondary to venous thrombosis

Establishment of Medical Necessity:	Medically necessary when garment provides specific medical benefit to the patient.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufacturer's User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Compression Garment	**When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.** **Limit to 2 every 365 days**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**2 every 365 days**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Requires Utilization Management approval.
Contact UM prior to ordering.

Continuous Passive Motion Device, Lower Extremity (See InterQual/Durable Medical Equipment/General/Lower Extremity)				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**

Establishment of Medical Necessity:	See InterQual/Durable Medical Equipment/General/Lower Extremity		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **UM Authorization Required**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	CPM Lower Extremity	**10 years or when no longer repairable**
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	**InterQual/Durable Medical Equipment/General/Lower Extremity**
Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**
	Inspect for clinical performance and safety prior to each patient's use

Requires Utilization Management approval.
Contact UM prior to ordering.

Continuous Passive Motion Device, Upper Extremity (See InterQual/Durable Medical Equipment/General/Upper Extremity)				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**

Establishment of Medical Necessity:	See InterQual/Durable Medical Equipment/General/Upper Extremity		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☐ **Prescription Requirement**	☒ **UM Authorization Required**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	CPM	**10 years or when no longer repairable**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**InterQual/Durable Medical Equipment/General/Upper Extremity**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	
	Review for clinical performance and safety prior to each patient's use.	

Crutches				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Axillary (underarm) - wooden or aluminum models can be adjusted easily to overall height and hand height with the elbow about 30°.	
Forearm crutch - allows flexion of the elbow at 15–30°. The increased flexion allows the arm to bear greater weight. The cuff on the crutch should sit below the back of the elbow.	
Platform or triceps crutch - contacts the skin fold of the armpit. The lower cuff should lie below the back of the elbow to avoid bony contact on the arm, yet provide stability.	
Indications	**Contraindications**
See Establishment of Medical Necessity section	

Establishment of Medical Necessity:	A patient has a mobility limitation that: 1. Prevents the patient from accomplishing the ADL entirely, 2. Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform the ADL, or 3. Prevents the patient from completing the ADL within a reasonable time frame. Crutches are medically necessary when prescribed by a physician for a patient with a condition that is causing impaired ambulation, and when there is a potential for ambulation.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Crutches	**Reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
	Accessories	**Lifespan/Replacement Schedule**
	Crutch Tip and Pads	**Reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
Clinical References	**CMS National Coverage Determination (NCD) (280.3)**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	
	Inspect for clinical performance and safety prior to each patient's use	

Mobility Impaired Disability Vest				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**

Indications	**Contraindications**

Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References		
Quantity:		

Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

Prosthetic Limbs - Lower extremity				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**	Example: Ottobock		
$	$0 - 50	Example: Ossur		
$$	$51 - 500			
$$$	$501 – 1000			
$$$$	$1000+		Medicaid fee schedule	$1684- $5370 +

Variations	**Associated Supplies**
	*Stump stockings
	*Harness
	*Prosthetic sheaths
	*Prosthetic socks
	*Gel stockings

Indications	**Contraindications**
The use of lower limb prosthesis required to replace the function of a lower limb loss due to trauma, disease or a congenital condition.	Contraindicated if patient does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance their quality of life or mobility.

Establishment of Medical Necessity:	Prosthesis is prescribed by physician and patient will maintain a defined functional state within a reasonable period of time; Patient needs prosthetic for ambulation.		
Trial Period:	☒ **Yes** ☐ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**Aetna: lower limb prosthesis**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Prosthetic Limbs - Upper Extremity				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			$1707.41 +

Variations	**Associated Supplies**
	*Socket
	*Sheath
	*Suspension system

Indications	**Contraindications**
Amputation of arm, forearm, hand	

Establishment of Medical Necessity:	When the patient has an amputation or missing limb at the wrist or above and patient has demonstrated sufficient neurological and cognitive function to operate prosthesis effectively and meets functional evaluation indicating that the use of the prosthesis will meet the functional needs of the individual when performing activities of daily living.		
Trial Period:	☒ **Yes** ☐ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**Interqual, Medicaid**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Requires Utilization Management approval.
Contact UM prior to ordering.

Standing Frames
(See InterQual/Durable Medical Equipment/General/Standing Frames)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+	Example: Adult Easystand Evolv		$1885.52

Variations	**Associated Supplies**

Indications	**Contraindications**
Paraplegic, quadriplegic, spinal cord injuries, muscular dystrophy, MS, Traumatic brain injury, CP	Hip subluxation, severe contracture, osteogenesis, impaired skeletal structure, orthostatic intolerance syndrome, orthostatic hypotension, Cardiovascular disease

Establishment of Medical Necessity:	See InterQual/Durable Medical Equipment/General/Standing Frames		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☐ **Prescription Requirement**	☒ **UM Authorization Required**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Adult Easystand Evolve	**N/A**

	Accessories	Lifespan/Replacement Schedule
	Hip support	**N/A**
	Lateral Support	**N/A**
	Head support	**N/A**
Clinical References	InterQual/Durable Medical Equipment/General/Standing Frames	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)	**Institutional use. Physical therapy clinic**	
Special Procurement	**(anticipated annual usage/cost)**	
	Purchase price $1885.52	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	
	Need a visual inspection of straps, locking canister before each use by the patient Annual safety inspection Weight capacity adhesion	

Therapeutic Shoes/Orthotics
(See InterQual/Durable Medical Equipment/General/Orthoses or Shoes for Persons with Diabetes)

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500	Example: Propet Cafe Walker, Propet Tour Walker II		$65-146.49
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
	*Inlays
	*Inserts

Indications	**Contraindications**
Also Refer to InterQual/Durable Medical Equipment/ Guidelines for Shoes for Persons with Diabetes	

Establishment of Medical Necessity:

Maybe medically necessary under the following conditions:

1. A shoe that is an integral part of a leg brace, and its expense is included as part of the cost of the brace.
2. Therapeutic shoes furnished to selected diabetic patients.

The diabetic patient must have one or more of the following conditions affecting one or both feet:

   a. History of partial or complete foot amputation
   b. History of previous foot ulceration
   c. History of preulcerative callus
   d. Foot deformity and peripheral neuropathy with evidence of callus formation
   e. Diminished blood supply to the foot or is being treated under a comprehensive diabetic care plan

3. Therapeutic shoes for certain peripheral vascular and neuropathic conditions.
   a. History of previous ulceration
   b. Diabetes
   c. Buerger's disease (thromboangiitis obliterans)
   d. Chronic thrombophlebitis
   e. Peripheral neuropathies involving the feet

f. Neuropathy associated with diabetes, carcinoma, drugs, toxins, and chronic renal disease

4. Rehabilitative foot orthotics as part of postsurgical or post-traumatic casting care.
5. Prosthetic shoes - used when all or a substantial portion of the front part of the foot is missing. A prosthetic shoe can be used as a terminal device; i.e., a structural supplement replacing a totally or substantially absent hand or foot.

The following items may be included under the diabetic shoe criteria:

1. Depth shoes, including a shoe with or without an internally seamless toe, with the following characteristics:
   a. Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16th inch of additional depth used to accommodate custom-molded or customized inserts;
   b. Are made of leather or other suitable material of equal quality;
   c. Have some sort of shoe closure; and
   d. Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard sizing schedule or its equivalent.
2. Custom-molded shoes, including a shoe with or without an internally seamless toe, with the following characteristics are covered when the patient has a foot deformity that cannot be accommodated by a depth shoe:
   a. Constructed over a positive model of the patient's foot;
   b. Made from leather or other suitable material of equal quality;
   c. Have removable inserts that can be altered or replaced as the patient's condition warrants; and
   d. Have some sort of shoe closure.
3. Modifications of custom-molded and depth shoes: Patient may substitute modifications of custom-molded or depth shoes instead of obtaining a pair of inserts in any combination.
4. Inclusion is provided for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease.

Foot orthotics (non-prescription or non-customized) may be medically necessary when medical necessity is established per Title 15. The following conditions may be medically necessary for foot orthotics.

1. Acute plantar fasciitis
2. Acute sport-related injuries (including: diagnoses related to inflammatory problems; e.g., bursitis, tendonitis)
3. Calcaneal bursitis (acute or chronic)
4. Calcaneal spurs (heel spurs)

	5. Conditions related to diabetes (see section above on therapeutic shoes for diabetes for a complete list of covered diagnoses) 6. Inflammatory conditions (i.e., sesamoiditis; submetatarsal bursitis; synovitis; tenosynovitis; synovial cyst; osteomyelitis; and plantar fascial fibromatosis) 7. Musculoskeletal/arthropathic deformities (including: deformities of the joint or skeleton that impair walking in a normal shoe; e.g. bunions, hallux valgus, talipes deformities, pes deformities, anomalies of toes) 8. Neurologically impaired feet (e.g., neuroma; tarsal tunnel syndrome; ganglionic cyst; and neuropathies involving the feet, including those associated with peripheral vascular disease, diabetes, carcinoma, drugs, toxins, and chronic renal disease) 9. Vascular conditions (including: ulceration, poor circulation, peripheral vascular disease, Buerger's disease (thromboangiitis obliterans), chronic thrombophlebitis **Exclusions** can include pes planus (flat feet), pronation, corns and calluses and hammertoes. Foot orthotics are not considered medically necessary when the foot condition does not cause symptoms *and p*atient has failed to respond to a course of appropriate conservative treatment (e.g., physical therapy, injections, strapping, and/or anti-inflammatory medications as may be reasonable and appropriate for the condition). Orthotics should not be considered first line therapy. **Additional exclusions:** 1. Orthotic devices made on the same date as an open cutting surgical procedure (e.g. bunionectomy). 2. Only one orthotic per foot is allowed. Separate orthotics for each pair of shoes are not considered medically necessary. 3. Replacement of a pair of shoes, or modifications, should be based on necessity (e.g., worn out, loss of effectiveness) not for convenience or style change. 4. Replacement of orthotics is generally not necessary more than every two years.

Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☒ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		When anatomical change and reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.
	Accessories	**Lifespan/Replacement Schedule**
Clinical References	**CMS National Coverage Determination (NCD) InterQual/Durable Medical Equipment/General/Orthoses of Shoes for Persons with Diabetes**	
Quantity:	**1 pair**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Toilet Seat Lift (Erector)				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Seat lift mechanism incorporated into a commode chair	

Indications	**Contraindications**
Patients unable to rise from toilet without assistance	

Establishment of Medical Necessity:	1. Medically necessary only when patient is unable to rise from toilet seat without assistance. 2. Seat lift mechanism incorporated into a commode chair may be medically necessary when patient meets criteria for commode chair and unable to rise from toilet seat without assistance.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Toilet Seat Lift	**When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Walkers				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 – 50			
$$	$51 – 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Standard walkers	Leg extensions for walkers for patients who are 6 feet tall or more.
Heavy-duty walkers (with or without multiple-braking systems or variable resistance)	Arm-rest attachments when the patient's ability to grip is impaired.
Walkers with trunk support	
Knee crutch/hands-free walkers	

Indications	**Contraindications**
See Medical Necessity section	

Establishment of Medical Necessity:	Standard walker - patient has a mobility limitation that significantly impairs ability to participate in one or more ADL, patient is able to safely use the walker; and the functional mobility deficit can be sufficiently resolved with use of a walker. A mobility limitation is ANY one that: 1. Prevents the patient from accomplishing the ADL entirely, or 2. Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform the ADL, or 3. Prevents the patient from completing the ADL within a reasonable time frame. Heavy-duty walker - for patients who meet criteria for standard walker and weigh more than 300 pounds. Multiple braking system, variable resistance walker - for patients who meet the mobility limitation criteria for a standard walker and who are unable to use a standard walker due to a severe neurologic disorder or other condition causing the restricted use of one hand. Heavy-duty, multiple-braking system, variable-resistance walker - for patients who meet criteria for a multiple braking system, variable resistance walker and weigh more than 300 lbs.

	Walker with trunk support - for patients who meet criteria for standard walker and require moderate to maximum support for walking and are capable of walking with the device.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	
☒ **Reusable**		☐ **Single Patient Only**	
☒ **Able to Loan**		☐ **Must be purchased by patient**	
☐ **Manufactures User Manual**		☐ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		Reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.
	Accessories	**Lifespan/Replacement Schedule**
	Tennis balls	**Reasonable wear and tear renders the accessory nonfunctioning.**
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

Wheelchair
(See InterQual/Durable Medical Equipment /General /Wheelchair, Manual)

Reference Brands, Sources, and Relative Prices:		Reference Brands	Sources	Relative Prices
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Standard hemi-wheelchair - patient requires a lower seat height (17"-18") due to short stature or cannot otherwise place feet on the ground for propulsion. Lightweight wheelchair - patient cannot self propel in a standard wheelchair but able to self propel in a lightweight wheelchair. High strength, lightweight wheelchair - patient can self-propel a high strength lightweight wheelchair while engaging in frequently performed activities that otherwise cannot be completed in a standard or lightweight wheelchair or, the patient requires a seat width, depth or height that cannot be accommodated in a standard, lightweight or hemi-wheelchair and spends at least 2 hours/day in the wheelchair. Ultra-lightweight - patient meets criteria for a lightweight wheelchair but requires adjustability in the axle, seat, and riggings of an ultra-lightweight wheelchair. Heavy-duty wheelchair - patient weighs more than 300 lbs.	*Anti-rollback device - patient propels himself/herself and needs the device because of ramps. *Safety belt/pelvic strap - patient has weak upper body muscles, upper body instability or muscle spasticity that requires use of the item for proper positioning. *Fully reclining back option - patient is high risk for development of pressure ulcer and unable to perform functional weight shift or, patient needs intermitted catheterization for bladder management and is unable to independently transfer from wheelchair to bed. *Shock absorber - patient at risk of spasm/myoclonus in an individual with myoclonic condition (e.g., spastic cerebral palsy). Customized Options: *Adjustable arm height - requires an arm height that is different from the arm height of nonadjustable arms, and the patient spends at least 2 hrs/day in the wheelchair. *Arm trough - patient has quadriplegia, hemiplegia or uncontrolled arm movements. *Footrest/Legrest - patient has musculoskeletal condition requiring elevation of one or both legs or, patient has a cast or brace that prevent 90-degree flexion at the knee or, individual has significant edema of the lower extremities. *Nonstandard seat depth or width - patient's body habitus justifies the need.

Indications	Contraindications

Establishment of Medical Necessity:	1. Patient has a mobility limitation that significantly impairs his/her ability to participate in 1-2 mobility related activities of daily living (MRADL) such as toileting, feeding, dressing, grooming and bathing. 2. Patient has other conditions that limit his/her ability to participate in MRADLs such as significant impairment in cognition, judgment, or vision. 3. Patient has the capability and willingness to safely operate the wheelchair. 4. Patient has sufficient upper extremity function to propel a manual wheelchair. 5. Patient has a disease process or injury for which weight bearing and/or ambulation is contraindicated. 6. Patient has a disease process or injury that precludes the use of the lower extremities (i.e., neuromuscular disease).		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☒ **Reusable**	☐ **Single Patient Only**
☒ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Wheelchair	**10 years or when can no longer be repaired**
	Accessories	**Lifespan/Replacement Schedule**
	Seat cushion, tires, and gloves	**When anatomical change or reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
Clinical References	**CMS National Coverage Determination (NCD) InterQual/Durable Medical Equipment/General/Wheelchair, Manual**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		

Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**
	Assess for safety and clinical performance monthly.

Non-invasive Airway Assistive Devices (CPAP, BiPAP)
(See Interqual/Durable Medical Equipment/Non-invasive Airway Assistive Devices)

Reference Brands, Sources, and Relative Prices:		Reference Brands	Sources	Relative Prices
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	Associated Supplies
CPAP	*CPAP base
BiPAP	*CPAP autotraining
	*tubing
	*mask
	*headgear
	*filter
	*Uninterruptible power supply
	*chinstrap
	*Nasal interface
	*Oral interface
	*Replacement cushions and pillows for nasal application device
	*Distilled water

Indications	Contraindications
See InterQual/ Durable Medical Equipment/Non-invasive Airway Assistive Devices	

Establishment of Medical Necessity:	See InterQual/ Durable Medical Equipment/Non-invasive Airway Assistive Devices		
Trial Period:	☒ **Yes** ☐ **No**	Time Frame ≥:	30 Days
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☐ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☒ **Manufactures User Manual**	☒ **Patient Education Handout**

<table>
<tr><td rowspan="8">Expected Refresh Period:</td><td>Item Name</td><td>Lifespan/Replacement Schedule</td></tr>
<tr><td>CPAP</td><td rowspan="2">When reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.</td></tr>
<tr><td>BiPAP</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Accessories</td><td>Lifespan/Replacement Schedule</td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td>Clinical References</td><td colspan="2">See InterQual: CP: Durable Medical Equipment
Non-invasive Airway Assistive Devices</td></tr>
<tr><td>Quantity:</td><td colspan="2"></td></tr>
<tr><td>Par Levels: (if any, at warehouse, clinic, medical supply area)</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Special Procurement</td><td colspan="2">(anticipated annual usage/cost)</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="2">Maintenance</td><td colspan="2">(Service contracts, inspections for clinical performance, safety and compliance)</td></tr>
<tr><td colspan="2">CPAP Cleaning Patient Education - English
CPAP Cleaning Patient Education - Spanish</td></tr>
</table>

Oxygen Concentrators				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Bedside	
Portable	

Indications	**Contraindications**
1. Patients with severe lung disease such as chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, or widespread pulmonary neoplasm. 2. Patients with hypoxia-related symptoms, such as pulmonary hypertension, erythrocytosis and recurrent congestive heart failure due to chronic cor pulmonale. 3. Short-term oxygen therapy may be indicated for conditions such as pneumonia, asthma, bronchitis or bronchiolitis.	

Establishment of Medical Necessity:	Portable oxygen concentrators are medically necessary as documented by the presence of ANY of the following combinations of clinical findings and oxygenation results (performed on room air unless medically contraindicated): 1. Arterial PaO2 ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% at rest 2. Arterial PaO2 ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% for at least five minutes taken during sleep for a patient who demonstrates an arterial PaO2 ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% while awake 3. Decrease in arterial PaO2 of more than 10 mm Hg, or a decrease in arterial oxygen saturation of more than 5% for at least five minutes taken during sleep, associated with symptoms or signs reasonably attributable to hypoxemia, including but not limited to cor pulmonale, “p” pulmonale on ECG, documented pulmonary hypertension and erythrocytosis

	4. Arterial PaO2 ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% during exercise for a patient who demonstrates arterial PaO2 ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% during the day at rest (when documented that oxygen improves hypoxemia during exercise) 5. Arterial PaO2 of 56-59 mm Hg or arterial blood oxygen saturation of ≤ 89% at rest, during sleep for at least five minutes, or during exercise (as described in preceding bullet) and ONE of the following: dependent edema secondary to congestive heart failure, pulmonary hypertension, chronic cor pulmonale, or congestive heart failure with hypoxemia, erythrocythemia with hematocrit > 56% Proof of Continued Need: The medical necessity for ongoing oxygen must be demonstrated via either blood gas results or pulse oximetry performed by the individual's attending physician or an independent respiratory practitioner one month after initiation of therapy for conditions that may be expected to be short-term, such as pneumonia, asthma, bronchitis or bronchiolitis, and three months after initiation of therapy for other conditions. Following the three month initial evaluation, pulse oximetry or arterial blood gas results must be reported within 12 months of the initiation of oxygen and whenever there is an increase in the amount of oxygen or change in the type of oxygen equipment being requested.		
Trial Period:	☐ Yes ☒ No	Time Frame ≥:	
Prescription vs. Authorization	☒ Prescription Requirement	☐ Authorization	
☐ **Reusable**		☒ **Single Patient Only**	
☒ **Able to Loan**		☐ **Must be purchased by patient**	
☐ **Manufactures User Manual**		☐ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**
Clinical References		

Quantity:	
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

***Tracheostomy Care Supplies**				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Tracheostomy care kit	*Trach brush
Tracheostomy care or cleaning starter kit	*Trach speaking valve
	*Trach outer tube
	*Trach tube holder
	*Trach cover
	*Trach collar
	*Trach vent and moisture exchanger
	*Connecting tubing
	*Breathing filter

Indications	**Contraindications**
Tracheostomy self care/nursing care	

Establishment of Medical Necessity:	1. A tracheostomy care kit is medically necessary for a patient following a surgical tracheostomy which has been open or is expected to remain open for at least three months. 2. A tracheostomy care or cleaning starter kit is medically necessary following an open surgical tracheostomy. One tracheostomy care kit per day is considered necessary for routine care of a tracheostomy.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Tracheostomy care kit	**Change daily**
	Accessories	**Lifespan/Replacement Schedule**
	See list on page 100	
	1 Trach Care Kit per day or 30 per month	
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:		
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	

<table>
<tr><th colspan="5">Voice Prostheses/Augmentative Communication/Speech Generating Device</th></tr>
<tr><td colspan="2">Reference Brands, Sources, and Relative Prices:</td><td>Reference Brands</td><td>Sources</td><td>Relative Prices</td></tr>
<tr><td>Symbol</td><td>Cost</td><td>Example: Provox 2</td><td></td><td></td></tr>
<tr><td>$</td><td>$0 - 50</td><td>Example: Voice prosthesis 8 mm model 7218</td><td></td><td></td></tr>
<tr><td>$$</td><td>$51 - 500</td><td></td><td></td><td></td></tr>
<tr><td>$$$</td><td>$501 - 1000</td><td></td><td></td><td></td></tr>
<tr><td>$$$$</td><td>$1000+</td><td></td><td></td><td></td></tr>
<tr><td colspan="3">Variations</td><td colspan="2">Associated Supplies</td></tr>
<tr><td colspan="3">Adeva Bigflow</td><td colspan="2">*Insertion tool</td></tr>
<tr><td colspan="3">Blom Singer</td><td colspan="2">*Provox brush</td></tr>
<tr><td colspan="3">Newvox</td><td colspan="2">*Provox plug</td></tr>
<tr><td colspan="3">Eska</td><td colspan="2">*Skin prep wipes</td></tr>
<tr><td colspan="3">Tracoe</td><td colspan="2">*Batteries</td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td colspan="3">Indications</td><td colspan="2">Contraindications</td></tr>
<tr><td colspan="3">Post Laryngectomy vocal rehabilitation</td><td colspan="2"></td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Establishment of Medical Necessity:</td><td colspan="3">Communication aids (also known as alternative or augmentative communication (AAC) devices) assist patients who are unable to speak due to a disease, injury, or a congenital condition. They may be appropriate if medical staff determines that the patient suffers from severe speech impairment and that the medical condition warrants the use of a device.

Speech generating devices are defined as speech aids that provide a patient who has severe speech impairment with the ability to meet his functional speaking needs. Speech generating devices are characterized by:

1. Being a dedicated speech device, used solely by a person who has a severe speech impairment;
2. May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time;
3. May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time;
4. May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
5. May have synthesized speech output, which permits multiple methods of message formulation and multiple methods of device access; or</td></tr>
</table>

6. May be software that allows a laptop computer, desktop computer, or personal digital assistant (PDA) to function as a speech generating device.

A speech generating device (SGD) may be considered medically necessary when all the following criteria are met:

1. Prior to delivery of the SGD, the patient has had a formal evaluation of cognitive and communication abilities by a speech-language pathologist. The formal written evaluation must include, at a minimum, the following elements.
   a. Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
   b. An assessment of whether the individual's daily communication needs could be met using other natural modes of communication (gestural, speech, and/or written communication);
   c. A description of the functional communication goals expected to be achieved and treatment options;
   d. Rationale for selection of a specific device and any accessories;
   e. Demonstration that the patient possesses a treatment plan that includes a training schedule for the selected device;
   f. Patient has the cognitive and physical abilities to effectively use the selected device and any accessories to communicate; and
   g. Any request for upgrading from a previously issued SGD must provide information regarding the functional benefit to the patient.
2. The patient's medical condition is one resulting in a severe expressive speech impairment.
3. The patient's speaking needs cannot be meet using gestural, speech, and/or written communication.
4. Other forms of treatment have been considered and ruled out.
5. The patient will gain intelligible speech with the device despite the patient's severe communication impairment demonstrated by a one month trial therapy utilizing the device prior to purchase.

<u>Tracheo-esophageal Voice Prosthesis</u>

Tracheo-esophageal (TE) voice prostheses are surgically placed to permit laryngectomized and other non-vocal (e.g., ALS) patients TE speech by shunting inhaled air from the lungs into the esophagus - resulting in a vibration of the esophageal tissue. TE voice prostheses provide adequate speech following total laryngectomy.

An indwelling tracheo-esophageal voice prosthesis *or* handheld artificial larynx may be medically necessary when recommended by a laryngologist or a speech-language pathologist for voice rehabilitation following total laryngectomy, or the larynx is permanently non-functional for speech following trauma or disease.

	The patient must meet **ALL** of the following criteria: 1. Patient must have the manual dexterity to care for the prosthesis several times daily. 2. Patient must have adequate pulmonary function to force air from the trachea through the prosthesis into the esophagus. 3. Patient must be motivated to use the device and have well-defined treatment goals. 4. Patient must be unable to meet daily communication needs without the use of an augmentative communication device and, 5. Patient has the cognitive, motor, and receptive language skills to use an augmentative communication device to meet daily communication needs and achieve functional communication goals. A trachea tube has been determined to satisfy the definition of a prosthetic device, and the **tracheostomy speaking valve** is an add-on to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words, it makes the system a better prosthesis. As such, a tracheostomy speaking valve is covered as an element of the trachea tube which makes the tube more effective. (CMS NCD) Replacement every 3 to 6 months is consistent with the documented life span of most voice prostheses. It is usually carried out as an outpatient procedure. Leakage of fluid (saliva, reflux) through or around a voice prosthesis as well as increased airflow resistance are the main indications to remove the prosthesis for inspection and, if necessary, replacement. Replacement of TE voice prosthesis should only be carried out by a physician or a speech-language pathologist; and is usually performed in an outpatient setting.

Trial Period:	☒ **Yes** ☐ **No**	Time Frame ≥:	4 weeks
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☒ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
		Reasonable wear and tear renders the DME nonfunctioning.

	Accessories	Lifespan/Replacement Schedule
	Batteries	**Reasonable wear and tear renders the Durable Medical Equipment nonfunctioning.**
Clinical References	**CMS National Coverage Determination (NCD) for Speech Generating Devices (50.1) Publication Number 100-3**	
Quantity:	**1**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	
	Regular cleaning, brushing, and flushing.	

***Incontinence Supplies**				
Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Disposable diapers	*Disposable washcloths
	*Cleaning wipes

Indications	**Contraindications**
Loss of bowel or bladder control; for hygiene use	

Establishment of Medical Necessity:	Patients with an underlying medical condition that involves loss of bladder or bowel control.		
Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	

☐ **Reusable**	☒ **Single Patient Only**
☐ **Able to Loan**	☐ **Must be purchased by patient**
☐ **Manufactures User Manual**	☐ **Patient Education Handout**

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Accessories	**Lifespan/Replacement Schedule**

Clinical References	**CMS National Coverage Determination (NCD)**

Quantity:	**1 week supply**
Par Levels: (if any, at warehouse, clinic, medical supply area)	
Special Procurement	**(anticipated annual usage/cost)**
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**

***Urologic Supplies**

Reference Brands, Sources, and Relative Prices:		**Reference Brands**	**Sources**	**Relative Prices**
Symbol	**Cost**			
$	$0 - 50			
$$	$51 - 500			
$$$	$501 - 1000			
$$$$	$1000+			

Variations	**Associated Supplies**
Single Use Drainage System	*Indwelling catheter
Multi Use Drainage Bags	*Insertion tray
	*External catheter (condom type)
	*Leg bags
	*Intermittent irrigation supplies
	*Continuous irrigation supplies
	*Lubricating gels
	*External urethral clamp
	*Tape
	*Appliance cleaner
	*Adhesive catheter anchoring device
	*Catheter leg strap

Indications	**Contraindications**
Replace bladder function in the case of permanent urinary incontinence (retention that is not expected to be medically or surgically corrected in that patient within 3 months).	

Establishment of Medical Necessity:	No more than 1 indwelling catheter per month is allowed for routine catheter maintenance. Non-routine catheter changes are indicated when documentation substantiates medical necessity, such as for: 1. Catheter is accidentally removed (e.g., pulled out by patient). 2. Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter). 3. Catheter is obstructed by encrustation, mucous plug, or blood clot. 4. History of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change frequency of more than once per month.

	Leg bags are indicated for patients who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden patients is not medically necessary. Supplies for **intermittent irrigation** of an indwelling catheter are necessary when they are used on an as needed (non-routine) basis in the presence of acute obstruction of the catheter. Supplies for **continuous irrigation** of a catheter are necessary when there is a history of obstruction of the catheter and the patency of the catheter cannot be maintained by intermittent irrigation in conjunction with medically necessary catheter changes. Continuous irrigation as a primary preventative measure (i.e., no history of obstruction) is not medically necessary. **Intermittent catheterization** is medically necessary when the patient can perform the procedure. Non-sterile lubricating gel is indicated for use with clean, non-sterile catheterization technique. Eight oz. would be included per month. Intermittent catheterization using sterile technique is medically necessary when the patient requires catheterization, and the patient meets one of the following criteria: 1. Patient is immunosuppressed, for example (not all inclusive): on a regimen of immunosuppressive drugs post-transplant, or on cancer chemotherapy, or has AIDS, or has a drug-induced state such as chronic oral corticosteroid use, or 2. Has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization, or is 3. A spinal-cord injured female with neurogenic bladder who is pregnant (duration of pregnancy only), or 4. Has had distinct, recurrent urinary tract infections, while on a program of clean intermittent catheterization, twice within the 12 months prior to the initiation of sterile intermittent catheterization. For this policy, a urinary tract infection is considered to be present if a urine culture with greater than 10,000 colony forming units of a urinary pathogen AND concurrent presence of 1 or more of the following signs, symptoms or laboratory findings is documented: a. Fever (oral temperature greater than 38° C [100.4° F]) b. Systemic leukocytosis c. Change in urinary urgency, frequency, or incontinence d. Appearance of new or increase in autonomic dysreflexia (sweating, bradycardia, blood pressure elevation) e. Physical signs of prostatitis, epididymitis, orchitis f. Increased muscle spasms g. Pyuria (greater than 5 white blood cells per high-powered field)

	External Catheters/Urinary Collection Devices 1. Male external catheters (condom-type) or female external urinary collection devices are medically necessary for patients who have permanent urinary incontinence when used as an alternative to an indwelling catheter. The utilization of male external catheters generally should not exceed 35 per month. Greater utilization of these devices must be accompanied by documentation of medical necessity. 2. Specialty type male external catheters (e.g., inflate or include a faceplate) are medically necessary only when documentation substantiates the medical necessity for such a catheter. For female external urinary collection devices, more than one metal cup per week, or more than one pouch per day are not medically necessary. **Miscellaneous Urinary Drainage Supplies** 1. Appliance cleaner is allowed when used to clean the inside of certain urinary collecting appliances. More than 1 unit of service (16 oz.) per month is rarely medically necessary. 2. One external urethral clamp or compression device is appropriate every 3 months or sooner if the rubber/foam casing deteriorates. 3. Tape used to secure an indwelling catheter to the patient's body is included. More than 10 units (1 unit = 18 sq. in.; 10 units = 180 sq. in. = 5 yds. of 1 inch tape) per month is not medically necessary unless the request is accompanied by documentation justifying a larger quantity in the individual case. 4. Adhesive catheter anchoring devices (3 per week) and catheter leg straps (1 per month) for indwelling urethral catheters.

Trial Period:	☐ **Yes** ☒ **No**	Time Frame ≥:	
Prescription vs. Authorization	☒ **Prescription Requirement**	☐ **Authorization**	
☐ **Reusable**		☒ **Single Patient Only**	
☐ **Able to Loan**		☐ **Must be purchased by patient**	
☐ **Manufactures User Manual**		☐ **Patient Education Handout**	

Expected Refresh Period:	**Item Name**	**Lifespan/Replacement Schedule**
	Urologic Supplies	**IC - one month** **Male external cath - one day** **Female external cath - one week** **Leg bag replacement as needed**

	Accessories	Lifespan/Replacement Schedule
Clinical References	**CMS National Coverage Determination (NCD)**	
Quantity:	**IC - 1/month; Male external cath - 35/month;** **Female external cath - 1 metal cup/week** **Insertion Tray - 1 per IC insertion or sterile intermittent cath insertion** **Appliance cleaner - 16 oz/month** **External urethral clamp - 1 per 3 months** **Tape - 10 units of 1 inch tape per month** **Adhesive catheter anchoring device - 3 per week** **Catheter leg strap - 1/week** **Leg bag - 1 as needed**	
Par Levels: (if any, at warehouse, clinic, medical supply area)		
Special Procurement	**(anticipated annual usage/cost)**	
Maintenance	**(Service contracts, inspections for clinical performance, safety and compliance)**	