Select Health Medical Policies
Durable Medical Equipment Policies

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Select Health

MEDICAL POLICY

BONE GROWTH STIMULATORS: ULTRASOUND

Policy # 201

Implementation Date:6/1/03

Review Dates: 6/24/04, 5/20/05, 5/17/07, 4/24/08, 4/23/09, 4/22/10, 9/15/11, 11/29/12, 10/24/13, 10/23/14, 10/15/15, 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/15/20, 11/18/21, 9/15/22, 10/19/23, 10/17/24

Revision Dates: 6/30/06, 8/14/06, 1/21/22, 7/14/23, 7/10/25

Description

Ultrasound (US) is a form of mechanical energy that is transmitted into the body as high-frequency acoustic pressure waves. The pressure waves provide micromechanical stress and strain to the bone and surrounding tissues. While the exact mechanism by which US exerts its healing effects are unclear, it has been hypothesized that its application leads to biochemical changes at the cellular level that result in enhanced bone formation.

The ultrasound bone growth stimulator consists of a signal generator and a small transducer, which are applied externally. Treatment is continued once daily for 20 weeks or until the fracture is sufficiently healed. In addition to the noninvasive aspect of the system, ultrasound stimulation has the advantages of portability and minimal daily treatment time required.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers ultrasound bone growth stimulators for traumatic fractures and surgical nonunions of all bones, excluding skull, vertebrae, and scapular, in skeletally mature patients, and excluding those that are related to malignancy when the following three conditions are present:

1. Documented evidence of nonunion (> 3 months since fracture or surgery)
2. The patient has failed other more conservative therapies (coverage for patients who cannot undergo surgery due to comorbidities, or who refuse surgery, will be considered on a case-by-case basis)
3. The patient can be adequately immobilized and is of an age where they are likely to comply with non-weight bearing requirements

Exclusions

- Tibial stress fractures
- Fractures in which the gap exceeds 1 cm or is greater than half the diameter of the bone
- Fractures that are open, grade II or III, unstable; require surgical intervention or internal or external fixation, or have post-reduction displacement of > 50%, or post-reduction angulation or malalignment

- Delayed or nonunion fractures associated with malignancy or other bone pathology
- For malaligned nonunion, since the device will not correct or alter displacement, angulation, or other malalignment
- Failed fusions of spinal or non-spinal arthrodesis

Contraindications

- Skeletally immature individuals
- Fractures which are not sufficiently stable for closed reduction and cast immobilization
- Patients with documented evidence of thrombophlebitis, vascular insufficiency, sensory paralysis, alcoholism and/or nutritional deficiency
- Pregnancy
- Patients who are receiving drugs which alter bone metabolism

Note: Patients who have implanted devices such as active cardiac pacemakers should consult their cardiologist prior to using this device.

Select Health does NOT cover ultrasound bone stimulation for acute (≤ 3 months) fractures. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Low-intensity pulsed ultrasound (US) is an alternative to electrical stimulation. According to both the Hayes ('A' rating) and CMS reports, use of low-intensity pulsed US is effective for nonunions of bones other than the skull or vertebrae in skeletally mature patients and excluding those that are related to malignancy when: 1) the fracture is 9 months old; 2) there is documentation that healing has ceased or is not progressing; and 3) the patient has failed one surgery and other medical therapies. In the last several years CMS has adjusted their timeframe for allowing bone growth stimulation downward to 3 months (90 days). The rationale for this change was that limited available evidence suggests delaying therapy beyond 3 months is not likely to alter the long-term outcomes. Given the high cost of fracture non-unions, it was felt that earlier intervention was reasonable despite the limited evidence to support this change.

In November 1998, CMS revisited ultrasound for the treatment of fresh fractures. The national noncoverage decision was officially reviewed and re-issued. HCFA determined that there was a lack of functional benefits attributable to ultrasound therapy, a failure to determine effectiveness in the elderly population, and a failure to demonstrate the prevention of delayed union or non-union.

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design study by Busse et al., in 2016 further calls into question the effectiveness of pulsed low intensity ultrasound in accelerating functional recovery and radiographic healing in patients with operatively managed tibial fractures. This study in 501 mature men or women with an open or closed tibial fracture amenable to intramedullary nail fixation showed no impact on SF-36PCS scores between LIPUS and control groups

(mean difference 0.55, 95% confidence interval −0.75 to 1.84; P=0.41) or for the interaction between time and treatment (P=0.30); minimal important difference is 3−5 points or in other functional measures. There was also no difference in time to radiographic healing (hazard ratio 1.07, 95% confidence interval 0.86 to 1.34; P=0.55). There were no differences in safety outcomes between treatment groups. Patient compliance was moderate; 73% of patients administered ≥ 50% of all recommended treatments. The study found that postoperative use of LIPUS after tibial fracture fixation does not accelerate radiographic healing and fails to improve functional recovery.

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

20979 Low intensity ultrasound stimulation to aid bone healing, non-invasive (nonoperative)

HCPCS CODES

E0760 Osteogenesis stimulator, low intensity ultrasound, non-invasive

Key References

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Bone Growth Stimulators: Ultrasound, continued

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Revision History

Revision Date	Summary of Changes
7/14/23	For Commercial Plan Policy, modified requirements in criteria #1: "Documented evidence of nonunion (> 3 months since fracture ***or surgery***)."
7/10/25	For Commercial Plan Policy, included scapular bones as part of bones excluded from this treatment: "Select Health covers ultrasound bone growth stimulators for traumatic fractures and surgical nonunions of all bones, excluding skull, vertebrae, ***and scapular*** …"

Select Health

MEDICAL POLICY

BREAST PUMPS

Policy # 108
Implementation Date:11/30/00
Review Dates: 1/27/01, 3/29/02, 8/27/03, 8/26/04, 8/23/07, 8/21/08, 8/13/09, 9/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 10/10/18, 10/2/19, 10/14/20, 11/17/21, 9/15/22, 10/10/23, 10/8/24
Revision Dates: 9/15/06, 1/13/11, 12/31/12, 11/15/18, 1/24/19, 2/6/24

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Breast pumps are primarily used to ensure continued production of breast milk when the mother cannot nurse the baby. Several types are commercially available. Manual breast pumps are designed to use the strength of the hand or arm muscles for pumping one breast at a time. Handheld battery-operated breast pumps use batteries for creating suction minimizing muscle fatigue. Most battery-operated pumps are designed for pumping one breast at a time and are suggested for occasional use. Electric breast pumps usually plug directly into an outlet and are designed for pumping both breasts at one time; and are intended for frequent use. Hospital-grade quality breast pumps are the most efficient for initiating and maintaining the milk supply and are available for rent or purchase. Professional quality breast pumps are efficient for maintaining the milk supply and tend to be available for purchase only.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers the purchase of only 1 electric portable breast pump [HCPCS E0603] per pregnancy.

Select Health does NOT cover the *purchase* of "hospital-grade" breast pumps [HCPCS E0604]. These devices are considered not medically necessary.

Select Health covers the *rental* of hospital-grade breast pumps up to 9 months. After this period, coverage will be allowed in *limited* circumstances when the *infant* meets criteria*.

*Select Health may give special consideration to coverage beyond 9 months for extenuating circumstances (e.g., infants who fail to adequately grow, infants who have suck/swallow issues, or infants with cardiac problems). In such cases, coverage will be evaluated on a case-by-case basis.

Select Health does NOT cover breast pump rentals for mothers who are hospitalized, regardless of the infant's weight or gestational age, as the hospital is able to provide the pump and it is a duplication of services.

SELECT HEALTH MEDICARE (CMS)

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Breast Pumps, continued

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

E0602 Breast pump, manual, any type

E0603 Breast pump, electric (AC and /or DC), any type

E0604 Breast pump, heavy duty, hospital grade, piston operated, pulsatile vacuum suction/release cycles, vacuum regulator, supplies, transformer, electric (AC and/or DC)

Revision History

Revision Date	Summary of Changes
2/6/24	For Commercial Plan Policy, modified timeframe for approval of hospital-grade rentals from 6 months to 9 months: "Select Health covers the *rental* of hospital-grade breast pumps up to 9 months. After this period, coverage will be allowed in *limited* circumstances when the *infant* meets criteria."

Select Health

Select Health

MEDICAL POLICY

BREAST PUMPS

Policy # 108

Implementation Date:11/30/00

Review Dates: 1/27/01, 3/29/02, 8/27/03, 8/26/04, 8/23/07, 8/21/08, 8/13/09, 9/15/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 10/10/18, 10/2/19, 10/14/20, 11/17/21, 9/15/22, 10/10/23, 10/8/24

Revision Dates: 9/15/06, 1/13/11, 12/31/12, 11/15/18, 1/24/19, 2/6/24

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Select Health

MEDICAL POLICY

CLOSED-LOOP INSULIN DELIVERY SYSTEM

Policy # 548
Implementation Date: 1/7/14
Review Dates: 10/20/16, 10/19/17, 10/15/18, 10/15/19, 10/20/20, 11/2/21, 9/8/22, 10/18/23, 9/27/24
Revision Dates: 4/24/14, 3/13/15, 10/7/15, 11/2/16, 12/30/19, 11/23/20

Related Medical Policies:
#133 Insulin Pumps

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The standard approach to the management of diabetes mellitus begins with lifestyle and dietary management. For patients with Type 1 diabetes, this approach also requires insulin replacement therapy. This is done using either intermittent dosing of both short- and long-acting insulin, the basal-bolus method, or continuous infusion of rapid-acting insulin using insulin pump devices.

Currently, patients may administer insulin via intermittent subcutaneous injections or through a continuous insulin pump. The pump provides continuous low volumes of insulin with the ability to bolus larger volumes of rapid acting insulin to meet meal-related needs. There are multiple models of insulin pumps available, all of which allow for small dosage adjustments. Patients monitor their blood sugar using continuous glucose monitoring (CGM) or finger-stick blood sugar measurements and base dosage adjustments accordingly.

Recently, efforts have been made to automate the insulin dose adjustment process, reducing the need for patients or providers to intervene in management of blood sugar trends in real-time. These "closed-loop" systems contain computer-controlled algorithms that connect the CGM and insulin infusion pump to allow continuous communication between the two devices.

There are currently five FDA approved closed-loop insulin delivery systems available in the United States. The Medtronic MiniMed SmartGuard system consists of the MiniMed 670G, 770G, and 780G insulin pump in combination with the Guardian (3) and (4) sensors. The t:slim Basal-IQ technology is comprised of the t:slim insulin pump in combination with the Dexcom G6 sensor. Tandem Diabetes has also developed the Tandem Mobi insulin pump to be used with their Control-IQ software and a compatible CGM device (details on CGM compatibility were not available at the time of writing). Insulet's Omnipod 5 is a tubeless automated insulin delivery system in combination with the Dexcom G6 sensor. Beta Bionics' iLet Bionic Pancreas consists of the iLET ACE pump and is also compatible with the Dexcom G6 sensor.

These systems continuously monitor interstitial blood glucose and can automatically suspend insulin delivery when sensor glucose values reach a preset level and resume delivery when glucose returns to a preset threshold. Safety and efficacy data for these closed loop systems is discussed in the Summary of Medical Information below. This policy is intended to summarize coverage for these systems. For insulin pump coverage, see policy #133.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Closed-Loop Insulin Delivery System, continued

Coverage Criteria

Select Health covers insulin pump therapy on all persons with Type 1 diabetes regardless of the adequacy of their current insulin regimen. Current benefit limitations for replacement of insulin pumps continue to apply.

Select Health covers insulin pump therapy on persons with Type 2 diabetes who fail to demonstrate satisfactory diabetic control despite documentation of strict compliance to an aggressive treatment standard regimen (i.e., frequent glucose monitoring-minimum of 4 times a day), multiple daily injections (3 or more), and formal diabetic education.

AND

Member must have attended 2 medical provider visits for persons with diabetes within 12 months at least one of which must be with a prescribing provider and demonstrated compliance with therapeutic regimen.

Select Health covers insulin pump therapy as an adjunct to kidney transplant in persons with Type 1 and Type 2 diabetes.

Select Health covers insulin pump therapy in pregnancy regardless of the member's previous efforts at diabetic control or whether they have Type 1 or Type 2 diabetes.

Replacements will only be allowed when ALL the following criteria are met:

1. The device is out of warranty.
2. Damage was not due to patient neglect or abuse.
3. Member must have attended 2 medical provider visits for persons with diabetes within 12 months, at least one of which must be with a prescribing provider and must have demonstrated compliance with therapeutic regimen.

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Summary of Medical Information

Originally approved in 2016, the MiniMed SmartGuard technology system is indicated for adults and adolescents age 7 and older with type 1 diabetes mellitus. Approval was based on two pivotal clinical trials demonstrating safety and efficacy. The first trial was a single arm prospective study conducted in 124 patients with type 1 diabetes age 14 to 75 years to evaluate the safety of the 670G system and insulin dosing algorithm. An additional trial of similar design extended the safety and effectiveness data to expand the indication to include patients age 7 to 13 years of age. The primary test for efficacy was in a multicenter single arm 3-month study consisting of a 2-week in-home run-in period during which subjects used the system in Manual Mode followed by a 3-month in-home study phase during which Auto Mode

Closed-Loop Insulin Delivery System, continued

was enabled. The primary endpoint for the study was to demonstrate safety of the system so all statistical analyses were considered exploratory and P-values presented without multiplicity adjustment. Auto Mode was enabled for a median of 75.8% of the time or 18.2 h/day for adolescents and a median 88.0% of the time or 21.1 h/day for adults. There was an increase in within target glucose values 70-180 mg/dL, a reduction in values below 70 mg/dL, and values above 180 mg/dL between the study phase and the run-in phase. Glucose variability was also reduced from the run-in phase to the study phase. For the pediatric study in patients ages 7 to 13, similar results were seen. The Auto Mode feature was used a median of 80.6% of the time or 19.3 h/day. Mean percentage of sensor glucose values below and above the target range of 70-180 mg/dL were reduced, while increase in time in range and decrease in variability were also seen.

The Medtronic 780G pump was approved in 2023. The 780G pump contains meal detection technology and will automatically adjust insulin doses to compensate for an inadequate mealtime bolus or missed dose. The Guardian (4) sensor will be used in combination with the 780G pump and will not require finger sticks while the system is in SmartGuard technology mode. However, to enter the SmartGuard mode, a finger stick is required.

Approved in 2018, the t:slim Basal IQ system is indicated for use in individuals 6 years of age and older. Approval was based on a pivotal study in 107 subjects with type 1 diabetes. The study was a crossover design consisting of two 3-week periods with the predictive low glucose suspend (PLGS) system used during one period and sensor augmented pump (SAP) used during the other period. The primary efficacy outcome was CGM-measured time < 70 mg/dL. Median time spent in hypoglycemia (BG < 70 mg/dL) was reduced from 3.6% at baseline to 2.6% during the 3-week PLGS period compared with 3.2% in the SAP period (difference [PLGS 2 SAP] = 20.8%, 95% CI 21.1 to 20.5, P < 0.001). This corresponds to a mean value of 4.4% at baseline, 3.1% in the PLGS arm, and 4.5% in the SAP arm, representing a 31% reduction in time < 70 mg/dL with PLGS. Other outcomes included mean time in range 70-180 mg/dL which increased in the PLGS arm compared with the SAP arm (64% at baseline, 65% with PLGS, 63% with SAP; P < 0.001). Glucose variability measured as coefficient of variation showed a greater reduction in the PLGS arm compared with the SAP arm (difference [PLGS-SAP] = -1%, 95% ci -2 TO 0, p = 0.007).

Tandem Mobi was approved in 2023 via FDA 510(k) clearance. No new clinical data was needed for this submission as it was compared to its predicate device, t:slim X2 insulin pump (K203234). The Tandem Mobi is half the size of t:slim X2 pump and can be controlled through a mobile app.

Approved in 2022, Omnipod 5 is indicated for use in individuals 6 years of age and older. The approval was based off a single-arm, multicenter, prospective study that enrolled 112 children (age 6–13.9 years) and 129 adults (age 14–70 years). Participants were trained on the investigational system, which consisted of a tubeless insulin pump (Pod) with an embedded automated insulin delivery algorithm (Omnipod 5), an interoperable glucose sensor (Dexcom G6), and a mobile app (Omnipod 5 app). The primary safety outcomes were incidence rates of severe hypoglycemia and diabetic ketoacidosis. The primary effectiveness outcomes were change in HbA1c and percentage of time in glucose target range 70–180 mg/dL (“time in range”) measured by the glucose sensor during the 3-month automated insulin delivery phase compared with the 2-week standard therapy phase. HbA1c was reduced in children by 0.71% (7.8 mmol/mol) (7.67 ± 0.95% to 6.99 ± 0.63% [60 ± 10.4 to 53 ± 6.9 mmol/mol], P < 0.0001) and in adults by 0.38% (4.2 mmol/mol) (7.16 ± 0.86% to 6.78 ± 0.68% [55 ± 9.4 to 51 ± 7.4 mmol/mol], P < 0.0001). Time in range increased by 15.6% in children (52.5 ± 15.6% to 68.0 ± 8.1%, P < 0.0001) and 9.3% in adults (64.7 ± 16.6% to 73.9 ± 11.0%, P < 0.0001). Improvement in time in range was achieved rapidly, with adults achieving 73.5% over days 1–3 after system initiation and children achieving 62.6% in days 1–3 and 68.0% in days 4–6. Time in range remained stable thereafter.

The iLet insulin pump was approved in 2023. The iLet bionic pancreas does not require data from the patient’s insulin regimen. The device is initialized only on the basis of body weight and automates all insulin doses immediately after body-weight data have been entered, with no warm-up period. Meal announcements consist of a qualitative estimate of carbohydrate content (“usual for me,” “more,” or “less”) as compared with a typical meal of that type (“breakfast,” “lunch,” or “dinner”). It is not possible for the user to determine or modify insulin doses as this is handled by the software’s algorithm. Approval was based off a 13-week, multicenter, randomized trial that enrolled 219 participants at least 6 years of age with type 1 diabetes. Patients received bionic pancreas treatment with insulin aspart or insulin lispro or the standard of care (defined as any insulin-delivery method with unblinded, real-time continuous glucose monitoring). The primary outcome was the glycated hemoglobin level at 13 weeks. The key secondary

outcome was the percentage of time that the glucose level as assessed by continuous glucose monitoring was below 54 mg per deciliter; the prespecified noninferiority limit for this outcome was 1 percentage point. The glycated hemoglobin level decreased from 7.9% to 7.3% in the bionic-pancreas group and did not change (was at 7.7% at both time points) in the standard-care group (mean adjusted difference at 13 weeks, −0.5 percentage points; 95% confidence interval [CI], −0.6 to −0.3; P<0.001). The percentage of time that the glucose level as assessed by continuous glucose monitoring was below 54 mg per deciliter did not differ significantly between the two groups (13-week adjusted difference, 0.0 percentage points; 95% CI, −0.1 to 0.04; P<0.001 for noninferiority).

These closed loop systems provide an additional tool to patients with diabetes and their caregivers to improve glucose management, reduce glucose variability and increase time in range.

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

S1034	Artificial pancreas device system (e.g., low glucose suspend (lgs) feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous) disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system

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Select Health

MEDICAL POLICY

CONTINUOUS PASSIVE MOTION (CPM) DEVICES

Policy # 542
Implementation Date:4/1/13
Review Dates: 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/25/18, 6/20/19, 6/14/20, 6/1/21, 5/4/22, 6/2/23, 6/3/24, 6/3/25
Revision Dates:

Description

Continuous passive motion (CPM) devices continuously move the affected joint (e.g., flexion/extension) without assistance on a 24-hour basis, or as prescribed. The CPM device is held in place across the affected joint by Velcro straps. An electrical power unit is used to set the variable range of motion (ROM) and speed. The initial settings for ROM are based on the level of comfort of the individual receiving therapy and other factors that are assessed intra-operatively. The initial settings are made by a physical therapist or by other health professionals familiar with the device. The ROM is increased by three to five degrees per day as tolerated. The speed and range of motion can vary depending on joint stability. An emergency stop-switch immediately halts the device if necessary.

The goal of CPM is to promote diffusion of joint fluid, reduce edema, and maintain or improve range of joint motion to facilitate healing of the cartilage tissue. This therapy is based on observations of the adverse effects of immobilization of joints, such as joint capsule contracture and cartilage degeneration, and on the theory that movement and circulation of synovial fluid is essential for promoting repair and maintaining the health of articular cartilage. CPM is used during the first few days or weeks following surgery, or injury, and is often an adjunct to conventional active physical therapy. CPM devices are available for treatment of the joints in the leg (principally the knee), arm, hand, and the temporomandibular joint (TMJ). They are designed to be used either in a hospital or home environment.

A wide variety of CPM devices are available for rehabilitation of specific joints. CPM devices are available for synovial joints (hip, knee, ankle, shoulder, elbow, and wrist) following surgery or trauma (including fracture, infection, etc.).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers the continuous passive motion device (CPM) *in limited circumstances.*

Conditions for which CPM is covered:

- Arthrofibrosis of knee
- Elbow fracture with open reduction
- Postoperatively, after joint manipulation under anesthesia for adhesions or arthrofibrosis (shoulder or knee)
- Post-ACL repair

Continuous Passive Motion (CPM) Devices, continued

- Post-total joint arthroplasty (shoulder or knee)
- Tibial plateau fracture

CPM coverage is limited to a maximum of 21 days for all covered conditions.

Contraindications:

- Documentation indicates excessive laxity of joint
- Documentation indicates malalignment of joint axis
- When rigid fixation of the fracture has not been attained
- Patients who are unable to turn the device on and off, or who are not willing to participate in a course of rehabilitation

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Joint rehabilitation involves multiple treatment components and multiple options for delivery of these components. One component of joint rehab, passive motion, may be performed by a physical therapist or with the use of a CPM device. This rehabilitation usually begins inpatient and continues in an outpatient setting. To some extent, CPM devices and physical therapists are an interchangeable means of delivering passive motion. The preference for one or the other mode of delivery may be determined by considerations related to the organization of services or resource allocation (e.g., staffing, timing of discharge, patient access to physical therapy) and the need for treatment beyond the time allotted for active physical therapy. Use of CPM devices as a substitute for physical therapists in the delivery of passive motion should be distinguished from use of these devices as an adjunct to physical therapy when the objective is to increase the duration and intensity of passive motion in order to achieve outcomes superior to that achieved by conventional physical therapy programs.

The body of published literature on the use of CPM is extremely heterogeneous, relatively old, poorly coordinated, and poorly executed. Most of the available studies are composed of case reports and case series (uncontrolled, unblended, and non-randomized), and the few RCTs available report inconsistent results (including CPM for TKA). It is safe to say that there is currently too little useable evidence to permit conclusive statements about the value of CPM, for any indication. Though widely disseminated in orthopedic practice, it is despite the lack of supporting evidence or consensus support.

For articular tibia or femur fractures, thorough search of available peer-reviewed medical literature identified only 3 articles on the use of CPM with tibial fractures and none involving the femur. All 3 articles are either case reports or very small case series that provide no quality information to substantiate the use of CPM for either of these indications. In fact, the largest of the series (Biyani, et al.) reported that there was no difference between CPM and cast, vs. cast only in an older group (mean age = 72 yrs) with displaced tibial plateau fractures. A case report (Graham and Loomer) suggested that the development of "compartment syndrome" of the knee was likely due to the use of CPM. According to the BCBS of

Continuous Passive Motion (CPM) Devices, continued

Massachusetts policy on CPM, Hoffman reported no difference between cast and CPM post high tibial osteotomy (this article could not be identified to verify its conclusion). Thus, the literature does not directly support the use of CPM to promote healing of fractures involving the knee and seems to contradict its use (though this evidence is poor).

Most of the available information regarding the use of CPM comes from retrospective and prospective controlled studies involving patients who have undergone total knee arthroplasty (TKA) or anterior cruciate ligament (ACL) repair. There are relatively few published studies on the use of CPM for the upper extremity, ankle, foot, or TMJ, and most of these studies involved limited numbers of patients. While a few studies compared CPM with manual passive motion, most used conventional active physical therapy (APT) administered by a physical therapist as the control; in a few cases, immobilization was the alternative treatment. The outcome measures varied among studies included: pain, various measures of joint range of motion (ROM) such as strength, and function, length of hospital stay (LOS), cost, patient compliance, and patient satisfaction.

Many of the studies were flawed by use of subjective outcome measures and the unblinded evaluation of patients. There is a moderate level of evidence that CPM, used as an adjunct to active physical therapy, decreases knee swelling, improves flexion, and decreases the need for knee manipulation in the early postoperative period following TKA. The optimal treatment regimen for these patients has not been well-defined. Altering the duration and intensity of CPM therapy does not appear to affect results. There is no evidence of a long-term benefit of CPM. By 6 weeks after surgery there were no significant differences between CPM and APT treatment groups in knee ROM or function. Results of CPM in patients who have undergone ACL repair are less convincing. One randomized controlled study reported no significant difference between CPM and APT, while another reported decreased analgesic use and less postoperative joint swelling; however, this latter study suffered from lack of blinding and other design flaws.

Studies involving the use of CPM in joints of the upper extremity suggest that CPM may decrease pain associated with shoulder movement after rotator cuff repair, elbow capsulotomy, and digital flexor tendon surgery, and may also improve ROM. Several of these studies indicated that CPM may provide better results than passive manual therapy; however, differences in manual therapy techniques or shorter duration of manual therapy may explain these results. In most studies, the overall outcome was not affected by type of rehabilitation therapy, although CPM appeared to provide long-term improved ROM compared with immobilization or with intermittent passive motion exercises. The effects of CPM on other joints in the body, such as the TMJ, the hip, or joints in the foot, have not been studied adequately in a systematic fashion, and there is insufficient evidence to conclude that CPM is beneficial for these indications. Preliminary studies indicate that CPM provides no benefit for patients following surgical treatment of degenerative conditions such as Dupuytren's disease or rheumatoid arthritis; however, one small pilot study indicated that CPM might facilitate joint movement in patients with osteoarthritis by decreasing pain and perception of disability.

It seems clear from the evidence that CPM provides superior results to immobilization in the rehabilitation of synovial joints and associated tissues. In addition, short-term benefits include decreased postoperative pain and swelling, and an early increase in joint ROM following TKA and certain surgical procedures on joints of the upper extremity. However, it remains to be proven that this form of therapy provides a better long-term outcome than standard active physical therapy or adequately performed manual passive motion.

There is insufficient evidence to formulate definitive recommendations regarding duration and intensity of therapy, or to evaluate the different design features of the various CPM devices. CPM is generally considered safe for most patients, and no major adverse events have been reported. Some authors caution that CPM devices have the potential to loosen internal fixation devices used for fracture repair if not applied correctly.

The literature for indication other than ACL or TKA is comprised of case studies and small clinical series, which do not compare CPM to established rehab methods such as cast immobilization and active exercise. Sampson evaluated patients, post-op Dupuytren's surgery, and found no difference in hand motion from controls; Galberman on hand flexor tendon repair reported increased digit motion at 11 months, but the randomization method may have been flawed. Hoffman saw no difference between cast and CPM post high tibial osteotomy.

Continuous Passive Motion (CPM) Devices, continued

Studies by Salter and Salter, and Graham, reported elbow and other joints are inadequate due to lack of controls. A retrospective report by Letsch on intra-articular distal humerus fractures included subjective information without appropriate comparisons, as is true for reports by Soffer and Yahiro. Appropriate controls were also lacking in the Hastings and Caroll report on closed intra-articular fractures of the MCP and PIP joints; Lewis and Foster's 1990 report on acute osteochondral knee fractures; Grumbine's report on post-op partial ankle arthroplasty; Homminga's report after periosteal/ perichondrial grafting; Craig's report on post-op shoulder reconstruction, and Fontenot and Kent's 1989 study post prosthetic TMJ arthroplasty. Similarly, Guidera's study of a variety of pediatric orthopedic conditions lacked controls and standardized protocols. Coutts and Stenstrom reported on CPM post-op intertrochanteric femur fracture, suggesting a 6-day decrease in LOS, but this was published in abstract form only.

Additional indirect reasons to question the evidence/effectiveness of CPM include the observation in the available literature that the duration of CPM use does not seem to significantly impact patient outcomes. No studies currently available suggest that a longer interval of CPM leads to improved patient outcomes. A 7–10-day period was most often cited in the literature.

There is little consensus regarding the cost-effectiveness of CPM therapy; some studies cite a reduction in required joint manipulations as a major area of cost-savings attributable to CPM, while others report that CPM was more expensive than therapy delivered by a physical therapist.

A literature review in December 2009 identified a systematic review by Wright et al., who reviewed CPM in the rehabilitation of ACL reconstructions. In a review of 6 studies, they found every study had at least 1 parameter that was determined not to be statistically different between groups. Blinding of the examiners, dropouts, and patient compliance were not identified. Wright et al. concluded by stating: "Based on this review, there is no substantial advantage for CPM use except for a possible decrease in pain. Therefore, its use cannot be justified with its additional insurance and patients' costs."

Billing/Coding Information

Covered: For the conditions outlined above

CPT CODES

No specific codes identified

HCPCS CODES

E0935 Continuous passive motion exercise device for use on knee only

E0936 Continuous passive motion exercise device for use other than knee

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Continuous Passive Motion (CPM) Devices, continued

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MEDICAL POLICY

COOLING DEVICES FOR THE TREATMENT OF MULTIPLE SCLEROSIS (MS)

Policy # 345

Implementation Date:4/19/07

Review Dates: 4/21/08, 4/23/09, 4/22/10, 8/16/11, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 9/12/18, 8/7/19, 8/20/20, 8/19/21, 7/21/22, 8/17/23, 8/22/24

Revision Dates: 7/1/12

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Multiple Sclerosis (MS) is a disease of the central nervous system (CNS) that causes destruction of the myelin sheath surrounding nerve fibers. Patches of demyelination disseminate throughout the brain and spinal cord and sclerotic plaques (scar-like lesions) with perivascular inflammation form in the de-myelinated parts of the nerve, blocking or distorting normal transmission of nerve impulses. They may occur anywhere within the CNS and frequently in the periventricular areas of the cerebral hemispheres, the optic nerves, the brainstem, the cerebellum, and the spinal cord.

Symptoms of MS vary widely across patients. Common early symptoms include weakness in limbs, incontinence, retrobulbar or optic neuritis (causing temporary or partial loss of vision), and bladder dysfunction. Other symptoms include fatigue, spasticity, pain, tremor, vertigo, ataxia, alteration of sensations, depression, and cognitive changes, which may be exacerbated by heat. MS patients use a variety of techniques to mitigate the effects of heat. One such strategy is to use cooling devices to reduce body temperature.

Cooling devices range from bandanas, scarves, and neck wraps to vests and full bodysuits. Active cooling devices contain a network of small tubes through which a chilled liquid such as ice water is circulated via an external pump. Active cooling devices require both a doctor's prescription and supervision. Passive cooling relies on evaporation from water-soaked garments or ice, or gel-pack inserts to produce cooling.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover cooling devices for the treatment of multiple sclerosis. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Cooling Devices for the Treatment of Multiple Sclerosis (MS), continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

The evidence for cooling therapy for MS is based almost exclusively on small cohort studies of sample sizes < 20. These studies utilized a heterogeneous set of cooling procedures that limit comparisons across studies. For example, cooling durations varied from 15−45 minutes across studies. Depending on the particular aim of the study, treatment effects were either measured immediately following cooling or after several days or weeks of treatment. Wide variability in treatment outcomes was also observed. Five studies focused on physiological outcomes of cooling such as intracranial blood flow, skin temperature, cortical somatosensory evoked potentials, or mean leukocyte nitric oxide. The remaining studies measured specific symptoms or functional outcomes such as tremors or fatigue or physical activity. Two studies measured quality of life associated with participation in a cooling regimen. Thus, while most of these studies observe a clinical benefit to cooling, the poor understanding of even the mechanism underlying the health effects of body cooling, the heterogeneity across studies, and a general lack of scientific rigor may limit confidence in the reliability of these results. The only study with any scientific rigor basically found no effect of cooling on therapeutic outcomes.

A Medical Technology Assessment performed in June 2012 identified only 2 new systematic and 2 peer-reviewed articles concerning cooling devices for the treatment of MS symptoms since the last review in 2007. Notably, a consensus statement published in 2006, but not available until after the last review, stated cooling garments can result in an improvement in symptoms that may endure for hours. No additional information was given pertaining to the type of cooling, how long the cooling technique was employed, or which device in particular was used during treatment or treatment protocols.

Subsequently, Grahn et al. published a study which illustrated a novel cooling technique where only the hands were cooled. The group reported increased exercise durations for MS patients when this method was used, but concluded with this admission, that systematic longitudinal studies with larger groups of patients is needed to confirm their findings. Similarly, Reynolds et al. in 2011 reported a well-conducted, sham-controlled trial where cooling of the head and neck decreased core temperatures by 0.37°C. The authors note that this decrease in temperature over a 60-minute interval improved the performance of the patients' 6-minute walk test; no additional benefits were noted.

In conclusion, little new evidence demonstrating appropriate patent selection criteria, treatment protocol, improvement of health outcomes, or duration of effectiveness have been published since the previous review.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

No specific codes identified

HCPCS CODES

E0218	Water circulating cold pad with pump
E0236	Pump for water circulating pad

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Cooling Devices for the Treatment of Multiple Sclerosis (MS), continued

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Select Health

MEDICAL POLICY

FREESTANDING OR HOME CERVICAL TRACTION DEVICES FOR MUSCULOSKELETAL CONDITIONS

Policy # 283
Implementation Date:9/30/05
Review Dates: 7/27/06, 7/12/07, 6/11/09, 5/19/11, 6/21/12, 6/20/13, 4/17/14, 5/7/15, 4/14/16, 4/27/17, 6/20/18, 4/11/19, 4/13/20, 4/5/21, 2/22/22, 2/16/23, 2/15/24, 2/20/25
Revision Dates: 6/19/08, 11/9/09

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1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

The prevalence of non-traumatic mechanical neck disorders (neck pain) in the United States is 10%. The anatomic source may be facetogenic, discogenic, myofacial, ligamentous, osseous, neurologic, cutaneous, or visceral. Compression of neural structures may cause radicular pain, spasms, weakness, and numbness. Acute treatment of neck pain includes physical therapy with mobilization, active stretching and lengthening, modalities, and medications. Patients with herniated discs are usually treated with medications, exercise, injections, and/or surgery. For chronic neck pain, an active exercise program, radiofrequency rhizotomy, mobilizations, and medications may be utilized. Chiropractic care has some proof of benefit for neck pain without radiculopathy but is not without risk. Cervical soft collars and bed rest have not been shown to be helpful.

For decades, cervical traction has been applied widely for pain relief of neck muscle spasm or nerve root compression. Traction is thought to relieve neck pain by reducing cervical neuromuscular activity, muscle spasms, and disc lesion or myofascial adhesions, and improving blood flow. It is a technique in which force is applied to a part of the body to reduce paravertebral muscle spasms by stretching soft tissues, and in certain circumstances separating facet joint surfaces or bony structures. Cervical traction is administered by various techniques ranging from supine mechanical motorized cervical traction to seated cervical traction using an over-the-door pulley support with attached weights. Studies have shown that traction must be constant so that the muscles tire and reduce the strain on the joints. It generally takes 2 minutes of sustained traction before the intervertebral spaces begin to widen. Forces between 20−50 lbs. are commonly used to achieve intervertebral separation. Studies have shown that optimum weight for cervical traction to accomplish intervertebral separation is 25 lbs. Additional pounds for cervical traction are usually utilized in hospitals or clinics for temporary use, and in certain situations and under observation with occasional imaging, making sure to not destabilize the spine. Duration of cervical traction can range from a few minutes to 30 minutes, once or twice weekly to several times per day.

Anecdotal evidence suggests efficacy and safety, but there is no documentation of efficacy of cervical traction beyond short-term pain reduction. In general, over-the-door traction at home is limited to providing less than 20 lbs. of traction. However, the optimal weight and duration of traction has not been clearly demonstrated.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover freestanding or home cervical traction devices as current evidence suggests use of this therapy lacks efficacy over standard physical therapy. This therapy fails to meet the standard of medical necessity required for coverage.

Freestanding or Home Cervical Tractions Devices for Musculoskeletal Conditions, continued

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information

Few controlled trials of cervical traction have been published in the medical literature. Most studies have been reports of case series. The few reports of controlled trials had several problems that limit their comparability to other studies and generalizability to a wider clinical population: 1) dated studies (i.e., before 1980) that did not examine current advances in cervical traction technology; 2) vague criteria for study inclusion that did not account for multiple types of neck pain; 3) mixing traction with other therapy modalities, making it difficult to estimate the unique effect of traction on therapeutic outcomes; 4) multiple operational definitions of successful treatment outcomes; and 5) limited trials of in-home traction devices.

Additionally, several careful reviews of common therapeutic techniques for neck pain have included cervical traction. Every review concluded that research methodology of the empirical literature was of marginal quality and that the effect of cervical traction on clinical outcomes is inconclusive.

In October 2009, the Medical Technology Committee reviewed the literature and found 2 systematic reviews and 3 clinical trials published since the initial September 2005 review. A 2006 systematic review of 10 studies by Graham et al. found inconclusive results, with some support for intermittent traction but none for continuous traction. However, only 1 of these studies was considered to be of high quality (randomized study with blinding and intent-to treat analysis). A 2008 Cochrane review by the same authors evaluated seven randomized placebo-controlled trials, rating each on degree of methodological bias. The authors concluded that only 1 study had low risk of bias and that the literature did not support or refute the efficacy or effectiveness of continuous or intermittent traction for pain reduction, improved function, or global perceived effect when compared to placebo traction, tablet or heat, or other conservative treatments in patients with chronic neck disorders.

The 3 empirical studies offer minimal support for this procedure. Cleland et al. treated 11 patients with cervical radiculopathy with manual physical therapy, cervical traction, and strengthening exercises of the deep neck flexors and scapulothoracic muscles. After 6 months, 91% of patients experienced a clinically significant improvement in pain and functioning. However, the authors noted that without randomized trials, the effectiveness of these therapies cannot be determined. Borman et al. randomly assigned 42 patients to a standard course of traction therapy plus physical therapy or physical therapy alone. After 2 weeks of therapy, both groups improved significantly in pain intensity and the scores of neck-disability and quality of life. However, there was no difference between the groups in these outcomes. Similar results were reported by Young et al. In a multicenter randomized clinical trial of 81 patients with cervical radiculopathy. Patients were assigned to manual therapy, exercise, and intermittent cervical traction (MTEXTraction group) or to manual therapy, exercise, and sham intermittent cervical traction (MTEX group). After 4 weeks, there was no difference between groups on measures of pain, disability, and functioning.

In summary, there remains little new evidence to conclude that cervical traction offers any benefit over physical therapy and strength training in treatment for neck pain and some studies would suggest no advantage in this therapy over standard physical therapy modalities.

Freestanding or Home Cervical Traction Devices for Musculoskeletal Conditions, continued

Billing/Coding Information
CPT CODES
No specific codes identified

HCPCS CODES
Not covered: Investigational/Experimental/Unproven for this indication

E0849 Traction equipment, cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible

E0850 Traction stand, freestanding, cervical traction

E0855 Cervical traction equipment not requiring additional stand or frame

E0856 Cervical traction device, cervical collar with inflatable air bladder

E0860 Traction equipment, overdoor, cervical

M99.50 Intervertebral disc stenosis of neural canal of head region

M99.51 Intervertebral disc stenosis of neural canal of cervical region

M99.60 Osseous and subluxation stenosis of intervertebral foramina of head region

M99.61 Osseous and subluxation stenosis of intervertebral foramina of cervical region

M99.70 Connective tissue and disc stenosis of intervertebral foramina of head region

M99.71 Connective tissue and disc stenosis of intervertebral foramina of cervical region

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Freestanding or Home Cervical Traction Devices for Musculoskeletal Conditions, continued

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MEDICAL POLICY

INSULIN PUMPS

Policy # 133
Implementation Date: 1/4/00
Review Dates: 3/23/01, 6/28/02, 1/02/0, 9/15/03, 8/26/04, 8/25/05, 8/17/06, 2/21/08, 2/26/09, 2/18/10, 2/17/11, 5/7/15, 10/19/17, 10/15/18, 10/15/19, 10/20/20, 11/2/21, 9/8/22, 10/6/23, 9/27/24
Revision Dates: 9/15/03, 1/16/07, 10/7/11, 9/24/13, 3/26/14, 10/7/15, 1/14/16, 11/1/16, 12/30/19, 11/23/20

Related Medical Policies:
#548 Closed-Loop Insulin Delivery System
#609 Infusion Pumps (External or Implantable)

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Description

Approximately 30 million Americans, or 9% of the population suffers from diabetes mellitus, a condition in which a person does not make enough insulin, or their body cannot use its own insulin to effectively control blood glucose levels. Without proper management, diabetes can lead to a myriad of health issues, which include heart disease, blindness, stroke, kidney disease, limb loss, nerve damage, death, etc. Diabetes, often referred to as the "silent epidemic," has tripled in incidence in the United States between 1990 and 2010, likely caused by increased rates of obesity, an aging population who is living longer, and growth in minority groups who have higher risk for developing diabetes.

Especially concerning is that diabetes prevalence is expected to increase by 54% to nearly 55 million Americans, with annual mortality growing by 38% to nearly 385,000, and total medical and societal cost attributed to this disease expected to swell by 53% to over $622 billion by 2030. Diagnosis and treatment of diabetes comprises $1 in every $7 of U.S. healthcare expenditures, and spending is more than double for those with this disease. New tools and technologies are needed to address the societal, economic, and quality-of-life hardships caused by diabetes.

For people living with diabetes who are tired of injections, an insulin pump can bring welcome relief. Insulin pumps are small, computerized devices that deliver insulin in two ways:

- In a steady measured and continuous dose (the "basal" insulin), or
- As a surge ("bolus") dose, at the patient's direction, around mealtime

Doses are delivered through a flexible plastic tube called a catheter. With the aid of a small needle, the catheter is inserted through the skin into the fatty tissue and is taped in place. The tube/needle combination is called an infusion set.

Insulin pumps have been used successfully across the age spectrum. Whether or not to use a pump is an individual decision. Patients can manage their diabetes equally well with pumps or multiple injections, so it really comes down to preference.

A pump is just a tool: patients can reach their blood sugar goals with a pump or injections. Choosing one method over the other is not a lifelong commitment. Some people go on and off their pumps (but this should always be done with instructions from a patient's diabetes care team).

Insulin Pumps, continued

The one requirement for using a pump is that a patient and/or their caregivers are ready and willing to do what it takes to use the pump safely. Checking blood sugar is important because it will warn if the pump stops working right, or the infusion set stops working. This can cause high blood sugar levels and cause diabetes ketoacidosis, which is very serious and dangerous. Checking blood sugar levels frequently will alert this possibility and will prevent the development of ketones.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers insulin pump therapy on all persons with Type 1 diabetes regardless of the adequacy of their current insulin regimen. Current benefit limitations for replacement of insulin pumps continue to apply.

Select Health covers insulin pump therapy on persons with Type 2 diabetes who fail to demonstrate satisfactory diabetic control despite documentation of strict compliance to an aggressive treatment standard regimen (i.e., frequent glucose monitoring-minimum of 4 times a day), multiple daily injections (3 or more), and formal diabetic education.

AND

Member must have attended 2 medical provider visits for persons with diabetes within 12 months at least one of which must be with a prescribing provider and demonstrated compliance with therapeutic regimen.

Select Health covers insulin pump therapy as an adjunct to kidney transplant in persons with Type 1 and Type 2 diabetes.

Select Health covers insulin pump therapy in pregnancy regardless of patients' previous efforts at diabetic control or whether they have Type 1 or Type 2.

Replacements will only be allowed when ALL the following criteria are met:

1. The device is out of warranty and the device is malfunctioning.
2. Damage was not due to patient neglect or abuse.
3. Member must have attended 2 medical provider visits for persons with diabetes within 12 months—at least one of which must be with a prescribing provider—and has demonstrated compliance with therapeutic regimen.

SELECT HEALTH MEDICARE (CMS)

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Insulin Pumps, continued

Summary of Medical Information
Since the completion of the Diabetes Control and Complications Trial (DCCT) in 1993 and the introduction of lispro (Humalog) insulin in 1996, children and adolescents with diabetes have increasingly turned to insulin pump therapy to maximize their diabetic control in an effort to slow the development of long-term complications of poorly controlled diabetes.

The theoretical advantage of insulin pump therapy is its ability to mimic physiological insulin release and meet physiological insulin needs in people with insulin diabetes mellitus. The basal and bolus functions of the pump allow separate determination and adjustment of both these insulin requirements and also allow flexibility in timing and amounts of nutritional intake and physical activity, allowing wide variation in lifestyles. This flexibility allows for improved patient compliance and adherence to their diabetic regimen allowing for improved diabetic control.

In addition, use of the newer short-acting (Novolog or Humalog) or ultra-short acting insulins makes coverage of the early morning glucose rise ("Dawn phenomenon") easier, eases sick day management, and matches nutrient absorption more physiologically, thereby, reducing the risk of hypoglycemic complications.

Prior studies of pump users show a high degree of satisfaction, and most show a decreased risk of severe hypoglycemia. Recent studies, additionally, have demonstrated improved effectiveness of diabetic control even in patients who have achieved good control (HgbA1C) using standard therapies.

Billing/Coding Information
CPT CODES

95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor (includes hook-up, calibration, patient initiation and training, recording disconnection, downloading with printout of data)

95251 ; physician interpretation and report

HCPCS CODES

A4220 Refill kit for implantable infusion pump

A4221 Supplies for maintenance of drug infusion catheter

A4222 Infusion supplies for external drug infusion pump, per cassette or bag (LDS)

A4223 Infusion supplies not used with external infusion pump, per cassette or bag (LDS)

A4224 Supplies for maintenance of insulin infusion catheter, per week

A4225 Supplies for external insulin infusion pump, syringe type cartridge, sterile, each

A4230 Infusion set for external insulin pump, non-needle cannula type

A4231 Infusion set for external insulin pump, needle type

A4232 Syringe with needle for external insulin pump, sterile, 3cc

A9274 External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories

E0784 External ambulatory infusion pump, insulin

E1399 Durable medical equipment, miscellaneous

J1817 Insulin for administration through DME (i.e., insulin pump) per 50 units

K0552 Supplies for external drug infusion pump, syringe type cartridge, sterile, each

S9145 Insulin pump initiation, instruction in initial use of pump (pump not included)

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Insulin Pumps, continued

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Insulin Pumps, continued

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MEDICAL POLICY

KNEE EXTENDER DEVICES

Policy # 300
Implementation Date:3/7/06
Review Dates: 5/17/07, 4/24/08, 4/23/09, 4/22/10, 8/16/11, 8/16/12, 8/15/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/11/19, 6/2/20, 6/3/21, 5/4/22, 6/2/23, 6/3/24, 6/3/25
Revision Dates:

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description
Patients sometimes experience reduced range of motion in their knee due to extreme overuse, failed knee surgery, adhesions, or weakness with resultant "favoring" of the weakened or painful knee. This can result in a flexion contracture, making further straightening of the knee difficult. This can result in further pain and weakness, leading to a progressive cycle of worsening disability. Patients will often seek treatment including medication, physical therapy, braces, and arthroscopic or open surgery to try and alleviate this problem. Many of these treatments can be quite successful.

Recently, a new device has become available as a nonoperative treatment of degenerative knee conditions, called Elite Seat. This device is purported to reduce pain and improve range of motion in knees experiencing flexion contractures. The patient straps the affected leg into the device, and then uses a crank handle to apply tension to the straps forcing the leg to extend. This therapy is recommended to be done 3−5 times a day with each session lasting 10 minutes (increasing the strap tension every 2 to 3 minutes). There is no published literature demonstrating effectiveness of this therapy.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover knee extender devices. These devices meet the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Knee Extender Devices, continued

Summary of Medical Information

A search for any published peer-reviewed literature regarding the Elite Seat knee extender device, using various search parameters did not reveal any publications. A search of the manufacturer's website, www.kneebourne.com, also failed to identify any published study. It mentioned "an on-going study" being conducted by the Shelbourne Clinic at Methodist Hospital. The study involves 41 patients with "deconditioned knees," defined as a loss of leg strength and knee-range of motion due to the lack of treatment or proper rehabilitation after surgery or from another source of pain that resulted in the patient reducing the use of the affected knee. They note "interim" findings, demonstrating "significant improvement" in IKDC evaluation scores, increasing from a baseline of 36.3 to 52.3 at 1 month, 64.5 at 3 months, and 67.5 at 6 months. Study parameters such as randomization, sham-controls, or blinding were not reported. No other studies or other research-oriented information was found.

Billing/Coding Information

Not covered: Investigational/Experimental/Unproven for this indication

CPT CODES

No specific codes identified

HCPCS CODES

E1399 Durable medical equipment, miscellaneous

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2. www.kneebourne.com

Select Health

Select Health

MEDICAL POLICY

ORAL APPLIANCES FOR SLEEP APNEA

Policy # 492
Implementation Date:12/12/11
Review Dates: 7/18/13, 6/11/15, 6/16/16, 12/13/18, 12/18/19, 12/17/20, 11/18/21, 1/17/23, 12/15/23, 12/2/24
Revision Dates: 5/8/14, 5/7/15, 11/9/16, 10/5/17, 2/21/20, 9/2/20, 5/16/24, 5/2/25, 7/3/25

Related Medical Policies:
#631 Orthognathic Surgery

Disclaimer:
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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Sleep apnea is a common disorder in which a patient will have one or more pauses in breathing or shallow breaths while they sleep. Breathing pauses can last from a few seconds to minutes. They often occur 30 times or more an hour. Typically, normal breathing then starts again, sometimes with a loud snort or choking sound.

The obstruction that occurs in obstructive sleep apnea (OSA) results from collapse of the pharyngeal airway during sleep. It is largely due to the interaction of an easily collapsible upper airway with the relaxation of the pharyngeal dilator muscles, which happens during sleep. Obesity, soft tissue hypertrophy, and craniofacial characteristics add to this propensity for collapse. Untreated, sleep apnea can cause high blood pressure (50% or more of patients with sleep apnea have systemic hypertension) and other cardiovascular diseases, memory problems, weight gain, impotency, and headaches. Moreover, untreated sleep apnea may be responsible for job impairment and motor vehicle crashes. Fortunately, sleep apnea can be diagnosed and treated. Several treatment options exist, and research into additional options continues.

One such treatment is an oral appliance, which is a dental mouthpiece that fits much like a sports mouthguard or a removable orthodontic retainer. They are used to treat snoring and obstructive sleep apnea (OSA). This device prevents the airway from collapsing by either holding the tongue or supporting the jaw in a forward position. Since oral appliances are non-invasive and easy to use, they are sometimes considered as an early treatment option. Oral appliance therapy (OAT), or mandibular advancement devices (MAD), involves the customization, selection, fabrication, fitting, adjustments, and long-term follow-up care of specially designed oral devices, worn during sleep, which reposition the lower jaw and tongue base forward to maintain an open airway. Oral appliance therapy can be used as an alternative to CPAP therapy for the treatment of mild-to-moderate sleep apnea.

Apnea Hypopnea Index (AHI)

The AHI is the number of apneas or hypopneas recorded during the study per hour of sleep. It is generally expressed as the number of events per hour. Based on the AHI, the severity of OSA is classified as follows:

- None/Minimal: AHI < 5 per hour
- Mild: AHI ≥ 5, but < 15 per hour
- Moderate: AHI ≥ 15, but < 30 per hour
- Severe: AHI ≥ 30 per hour

Oral Appliances for Sleep Apnea, continued

Respiratory Disturbance Index (RDI)

This is a commonly utilized index specifying the degree of apnea and is calculated based on a sleep study. The RDI cannot be calculated in the office setting, nor can it be predicted by a physician. An **overnight sleep stud**y, termed a polysomnogram is the gold standard test to determine whether one has apnea, and the RDI is a numeric index which helps to define the degree of the apnea.

- Normal sleep study: RDI < 5 events/hour
- Mild apnea: RDI 5−15 events/hour
- Moderate apnea: RDI between 15−30 events/hour
- Severe apnea: RDI > 30 events/hour

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health considers custom fabricated oral appliances in the treatment of obstructive sleep apnea to be medically necessary, when either of the following criteria are met (A or B):

Criteria for coverage:

A. The patient has diagnosis of mild sleep apnea (Apnea Hypopnea Index (AHI) or a Respiratory Disturbance Index (RDI) of 5 to 15) obstructive sleep apnea verified by a certified sleep specialist;

OR

B. The patient has diagnosis of moderate sleep apnea (AHI or RDI of 15 to 30) or severe sleep apnea (AHI or RDI of > 30), with all the following:

1. The patient has attempted an adequate trial of CPAP or BiPAP and has demonstrated intolerance, failure, or incomplete treatment, which must be documented; and
2. The patient is under the care of a sleep specialist* who has attempted alternative therapies and who has ordered the oral appliance; and

*Sleep specialist is defined as a physician who is a diplomate of the American Board of Sleep Medicine (ABSM) or is sleep medicine certified through one of the following:

- American Board of Internal Medicine (ABIM)
- American Board of Family Medicine (ABFM)
- American Board of Pediatrics (ABP)
- American Board of Psychiatry and Neurology (ABPN)
- American Board of Otolaryngology – Head and Neck Surgery (ABOHNS)
- American Osteopathic Board of Neurology and Psychiatry (AOBNP)
- American Osteopathic Board of Family Medicine, (AOBFP)
- American Osteopathic Board of Internal Medicine, (AOBIM)
- American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO)
- American Board of Anesthesia (ABA) [*ABA certification not recognized by CMS*]

3. The patient does not have any of the following conditions, which may be exacerbated by chronic use of an oral appliance:
   - Temporal Mandibular Joint Syndrome, or other TMJ-related pathological processes, causing insufficient dentition to support device stability
   - Periodontal compromise (e.g., tooth mobility, limited protrusive distance)
   - Significant component of central apnea

Note: For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds with at least a 3% oxygen desaturation. Hypopnea is defined as an abnormal respiratory event

Oral Appliances for Sleep Apnea, continued

lasting at least 10 seconds with at least a 30% reduction in thoraco-abdominal movement or airflow as compared to baseline, and with at least a 3% oxygen desaturation.

Limitations/Exclusions:

Select Health does NOT cover oral appliances that are available over-the-counter without a prescription. They have not been shown to be as effective as prefabricated or custom-fitted oral appliances in the treatment of OSA.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

SELECT HEALTH COMMUNITY CARE (MEDICAID)

Select Health Community Care policies typically align with State of Utah Medicaid policy, including use of InterQual. There may be situations where NCD/LCD criteria or Select Health commercial policies are used. For the most up-to-date Medicaid policies and coverage, please visit their website http://health.utah.gov/medicaid/manuals/directory.php or the Utah Medicaid code Look-Up tool

Summary of Medical Information
A Medical Technology Assessment performed in September 2011 identified 5 systematic reviews and 23 peer-reviewed journal articles concerning oral sleep appliances for the treatment of obstructive sleep apnea. The systematic reviews and primary literature addressed: 1) OA vs. CPAP, 2) OA vs. surgery, 3) OA and blood pressure changes, and 4) OA and craniofacial changes in patients using oral appliances. No literature was found comparing the various devices. No standardized method was used between studies that would be useful to draw global conclusions concerning OA for sleep apnea. Each primary literature study used different follow-up times, primary endpoints, and patient demographics. Cost-effectiveness was not discussed in any of the literature.

OA vs. CPAP
The reviewed literature establishes that minimum oxygen saturation, subjective daytime sleepiness, and AHI levels are all significantly better in CPAP patient populations than in OA populations for those with mild-to-moderate sleep apnea. Patients treated with OA were more likely to withdraw from studies than those treated with CPAP (however, the Institute for Clinical Systems Improvement found patients preferred mandibular advancement devices (MAD) to that of nasal CPAP). Noticeable adverse effects such as jaw and oral pain occurred more frequently with OA. There were higher rates of excessive salivation and appliance removal during sleep with OA, while there were higher rates of leak, dry upper airway, stuffy nose, and inconvenience with CPAP.

OA vs. Surgery
When MAD was compared to surgery, MAD therapy resulted in significantly lower AHI levels than surgery at both the 1-year and 4-year follow-up times. Likewise, mean AHI is not different between OA and surgery at 6 months but is statistically better at 12 months in favor of OA. Symptoms of daytime sleepiness are initially lower with surgery, but differences disappear at 12 months.

OA and Blood Pressure Changes
Studies assessing the clinical variables intended to be impacted by treatment of OSA with oral appliances are nearly non-existent. One trial reported blood pressure outcomes, where active OA therapy led to lower blood pressure compared to control, particularly blood pressure taken for 24 hours and during the day. Three journal articles demonstrated statistical significance as it pertained to OA decreasing blood pressure. These significant reductions were seen after 24 hours, 3 months, 12 months, and 36 months.

Oral Appliances for Sleep Apnea, continued

When OA is compared to CPAP, no statistically significant differences on blood pressure are observed. Andren et al. (2009) and Lam et al. (2011) showed MAD treatment of OSA decreased patient's blood pressure in three-month and three-year perspectives.

OA and Craniofacial Changes

In 2010, Doff et al. published a paper concerning long-term OA therapy in OSA as it pertained to craniofacial changes. Fifty-one patients were randomized to oral appliance therapy and 52 patients to CPAP therapy. Compared with CPAP, long-term use of an oral appliance resulted in small but significant dental changes; overbite and overjet decreased. Furthermore, the group found a retroclination of the upper incisors and a proclination of the lower incisors. This leads to the question as to how often patients need to visit a dental specialist once they have begun OA therapy for OSA. Moreover, the lower and total anterior facial height increased significantly; no changes in skeletal variables were found.

This review concluded that there is increasing evidence suggesting that OA improves subjective sleepiness and sleep disordered breathing compared with a control. CPAP appears to be more effective in improving sleep disordered breathing than OA, but some patients refuse to use CPAP machines. OA appears to have equally as significant long-term results to surgery. There is no evidence that any particular brand of oral appliance is superior to another. As for decreasing blood pressure and AHI, it can be safely concluded that oral sleep appliances are non-inferior, if not superior, to CPAP, as demonstrated in various studies and systematic reviews.

Subsequent to the technology assessment completed in 2011, the American College of Physicians (ACP) developed guidelines intended to present the evidence and provide clinical recommendations on the management of obstructive sleep apnea (OSA) in adults in September 2013. The clinical outcomes evaluated for this guideline included cardiovascular disease (such as heart failure, hypertension, stroke, and myocardial infarction), type 2 diabetes, death, sleep study measures (such as the Apnea–Hypopnea Index), measures of cardiovascular status (such as blood pressure), measures of diabetes status (such as hemoglobin A1c levels), and quality of life. This guideline grades the evidence and recommendations using ACP's clinical practice guidelines grading system. Specific to oral appliances, the ACP recommended continuous positive airway pressure treatment as initial therapy for patients diagnosed with OSA with an evidence grade, strong recommendation, and moderate-quality evidence. The ACP also provided a weak recommendation for mandibular advancement devices as an alternative therapy to continuous positive airway pressure treatment for patients diagnosed with OSA who prefer mandibular advancement devices or for those with adverse effects associated with continuous positive airway pressure treatment. The ACP noted the evidence for mandibular advancement therapy to be of low-quality.

Billing/Coding Information

CPT CODES

Note: Bundled services; these services are not payable separately in addition to the appliance

21085	Impression and custom preparation; oral surgical splint
21089	Unlisted maxillofacial prosthetic procedure
21110	Application of interdental fixation device for conditions other than fracture or dislocation, includes removal

HCPCS CODES

Covered: For the conditions outlined above

E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

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Revision History

Revision Date	Summary of Changes
5/16/24	For Commercial Plan Policy, added the following clarification regarding requirements listed in the policy: "Note: For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds ***with at least a 3% oxygen desaturation***. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30% reduction in thoraco-abdominal movement or airflow as compared to baseline, ***and with at least a 3% oxygen desaturation***."
5/2/25	For Commercial Plan Policy, clarified requirements in criterion #B-2: "The patient is under the care of a sleep specialist ***(defined as a physician who is a diplomate of the American Board of Sleep Medicine (ABSM) or is sleep medicine certified through the ABA (American Board of Anesthesia)***, who has attempted alternative therapies and who has ordered the oral appliance; …"
7/3/25	For Commercial Plan Policy, added further clarification for requirements in criterion #B-2: "2. The patient is under the care of a sleep specialist* who has attempted alternative therapies and who has ordered the oral appliance; … *Sleep specialist is defined as a physician who is a diplomate of the American Board of Sleep Medicine (ABSM) or is sleep medicine certified through one of the following: - American Board of Internal Medicine (ABIM) - American Board of Family Medicine (ABFM) - American Board of Pediatrics (ABP) - American Board of Psychiatry and Neurology (ABPN) - American Board of Otolaryngology – Head and Neck Surgery (ABOHNS) - American Osteopathic Board of Neurology and Psychiatry (AOBNP) - American Osteopathic Board of Family Medicine, (AOBFP)

Select Health

Oral Appliances for Sleep Apnea, continued

	- American Osteopathic Board of Internal Medicine, (AOBIM) - American Osteopathic Board of Ophthalmology and Otorhinolaryngology (AOBOO) - American Board of Anesthesia (ABA) [ABA certification not recognized by CMS]"

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MEDICAL POLICY

OXYGEN COVERAGE

Policy # 158
Implementation Date:7/98
Review Dates: 1/4/00, 1/31/01, 10/1/02, 10/23/03, 11/18/04, 12/15/05, 12/20/07, 12/18/08, 12/17/09, 4/12/12, 6/20/13, 4/17/14, 12/21/17, 12/13/18, 12/16/19, 12/17/20, 11/18/21, 11/9/22, 12/28/23, 12/13/24
Revision Dates: 9/14/06, 11/12/08, 2/14/11, 5/7/15, 1/15/16, 3/24/16, 1/6/17, 2/21/20, 10/2/20

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2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Oxygen therapy is the administration of oxygen as part of the treatment of a variety of acute and chronic conditions. Oxygen is essential for all normal cellular physiological functions.

Room air only contains 21% oxygen and increasing the percentage of oxygen in the breathing gas increases the amount of oxygen in the blood. It is often only required to raise the percentage of oxygen delivered to 30%–35%, and this is done by use of a nasal cannula. When 100% oxygen is needed, it may be delivered via a tight-fitting face mask, or by supplying 100% oxygen to an incubator in the case of infants.

High blood and tissue levels of oxygen can be helpful or damaging depending on circumstances. Oxygen therapy should be used to benefit the patient by increasing the supply of oxygen to the body tissues to alleviate hypoxemia.

Home oxygen therapy is used to treat and prevent symptoms and manifestations of hypoxemia. Home oxygen may be indicated for patients with severe lung disease such as chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, or widespread pulmonary neoplasm. Oxygen therapy may also be indicated for patients with hypoxia-related symptoms, such as pulmonary hypertension, erythrocytosis and recurrent congestive heart failure due to chronic corpulmonale, which may be expected to improve with oxygen therapy. Short-term oxygen therapy may be indicated for conditions such as pneumonia, asthma, bronchitis, or bronchiolitis.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers home oxygen and oxygen equipment under the durable medical equipment (DME) benefit *when criteria are met.* For recertification, annual oxygen testing must be completed for continued coverage.

Criteria for oxygen therapy:

1. P_aO_2 < 55 mm Hg or $S_aO_2 \leq 88\%$; taken at rest while breathing room air, or alternatively either:
   a. Taken during exercise for a patient who demonstrates a higher PaO_2 or oxygen saturation at rest is acceptable for oxygen therapy approval. In this case, supplemental oxygen is provided for exercise periods if there is evidence that the use of oxygen supplementation improves the hypoxemia that was demonstrated during exercise on room air.
   b. Taken during sleep for a patient who demonstrates a higher PaO_2 or oxygen saturation while awake, or a greater than normal fall in oxygen level while asleep (> 5% decrease in

Select Health

Oxygen Coverage, continued

arterial PaO_2) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for the nocturnal use of oxygen.

2. P_aO_2 56~59 mm Hg OR S_aO_2 89%
   a. Requires secondary diagnosis of:
      1) Edema/congestive heart failure, or
      2) Cor pulmonale with P wave > 3 mm in lead II, III, and/or AVF, or
      3) Erythrocythemia with hematocrit > 56%
   b. Requires recertification and retesting 61−90 days after the initial start of therapy
3. P_aO_2 60 mm Hg OR P_aO_2 90%
   a. Coverage unlikely to be medically necessary; requires extensive physician documentation for review by physician advisor.
4. Guidelines for coverage:
   a. Flow rate in liters/minute
   b. Frequency of use
   c. Hours/day
   d. Minutes/hour (if applicable)
   e. Duration of need: Specific number of months
   f. Laboratory evidence:
   g. Blood gas or oximetry required while at rest on room air
   h. Acceptable P_aO_2 or S_aO_2
   i. Diagnosis
   j. Severe primary lung disease
   k. Secondary conditions related to lung disease
   l. Hypoxia-related symptoms that may improve with oxygen
   m. Additional medical documentation: Any other forms of treatment tried without success; oxygen therapy is still required
   n. Start of therapy: Within one month of last visit

Select Health covers portable oxygen concentrators *in limited circumstances*, where use of a standard home oxygen system with portable oxygen tanks is not feasible for member performance of activities of daily living.

Criteria for portable oxygen concentrators: (Must meet ALL, 1−3)

1. Patient requires continuous oxygen therapy; **and**
2. Portable oxygen concentrator is being used as primary oxygen delivery system, **or** as a supplement to an existing stationary home oxygen system; **and**
3. Patient has any ONE of the following clinical circumstances*:
   a. Patients who are still actively working despite their lung disease and whose needs cannot be met by other oxygen modalities (portable oxygen tanks, portable oxygen tanks with a conserving device as prescribed by the patient's physician, or the possibility of a stationary concentrator supplied to their place of employment). This group may include patients who are highly mobile in their jobs to include attending frequent meetings, frequently working off-site, high frequency of travel required, and any other situation where a stationary concentrator or a portable oxygen tank cannot meet their needs.
   b. Patients whose careers include frequent travel such as truck drivers, flight attendants, traveling business positions, etc., and whose needs cannot be met with other portability options.
   c. Highly mobile patients with physical disabilities that cause extreme difficulty with changing the regulator on their tanks

d. Highly mobile students whose needs cannot be met by other oxygen modalities (portable oxygen tanks, portable oxygen tanks with a conserving device as prescribed by the patient's physician, or the possibility of a stationary concentrator supplied).

e. Patients who frequently travel, or who reside outside of Intermountain Homecare and Hospices' service area [Utah plans, only], and whose needs cannot be met by other modalities (portable oxygen tanks, portable oxygen tanks with a conserving device as prescribed by the patient's physician, or the possibility of a stationary concentrator supplied) or a loaner/traveler portable oxygen concentrator.

*Requires submission of supporting documentation.

Select Health does not cover portable oxygen concentrators used solely for recreational purposes, travel to provider office visits, or short duration ADL activities, unless above criteria are met.

SELECT HEALTH MEDICARE (CMS)

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

Equipment

E0424	Stationary compressed gaseous oxygen system, *rental*; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adapter, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adapter
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing

Oxygen Coverage, continued

E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0550	Humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery
E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter
E0560	Humidifier, durable for supplemental humidification during IPPB treatment or oxygen delivery
E0580	Nebulizer, with compressor, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1353	Regulator
E1355	Stand/Rack
E1390	Oxygen concentrator, single delivery port, capable of delivering 85% or greater oxygen concentration at the prescribed flow rate
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85% or greater oxygen concentration at the prescribed flow rate, each
E1392	Portable oxygen concentrator, *rental*
E1405	Oxygen and water vapor enriching system with heated delivery
E1406	Oxygen and water vapor enriching system without heated delivery
Contents	
E0441	Oxygen contents, gaseous (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned), 1 month's supply = 1 unit
E0442	Oxygen contents, liquid (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned), 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit
S8120	Oxygen contents, gaseous, 1 unit = 1 cubic foot
S1821	Oxygen contents, liquid, 1 unit = 1 pound
IPPB	
E0500	IPPB machine, all types, with built-in nebulization; manual or automatic valves; internal or external power source
E0550	Humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery
E0560	Humidifier, durable for supplemental humidification during IPPB treatment or oxygen delivery
Modifiers	
QE	Prescribed amount of oxygen is less than one liter per minute (LPM)
QF	Prescribed amount of oxygen exceeds 4 liters per minute (LPM) and portable oxygen is prescribed
QG	Prescribed amount of oxygen is greater than 4 liters per minute (LPM)
QH	Oxygen conserving device is being used with an oxygen delivery system

Oxygen Coverage, continued

Key References
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2. Bell EC, Cox NS, Goh N, et al. Oxygen therapy for interstitial lung disease: a systematic review. Eur Respir Rev. 2017 Feb 21;26(143):160080.
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MEDICAL POLICY

PNEUMATIC COMPRESSION THERAPY FOR DVT PROPHYLAXIS

Policy # 525

Implementation Date:5/31/13
Review Dates: 4/17/14, 5/7/15, 4/14/16, 4/27/17, 7/16/18, 4/16/19, 4/9/20, 4/15/21, 3/7/22, 5/3/23, 4/18/24
Revision Dates: 11/1/18, 4/23/21

Related Medical Policies:
#147 Lymphedema Therapy

Disclaimer:
1. Policies are subject to change without notice.
2. Policies outline coverage determinations for Select Health Commercial, Select Health Medicare (CMS), and Select Health Community Care (Medicaid) plans. Refer to the "Policy" section for more information.

Description

Intermittent pneumatic compression therapy is designed to improve venous circulation in the limbs. An inflatable garment is put around the limb (affected area) and connected to an air pump. It intermittently inflates and deflates with cycle times and pressure. These devices are classified into three different types:

- Non-segmented (single compartment)
- Segmented (multi-chamber) with sequential inflation of each chamber with fixed pressure (no manual control of pressure) in each chamber
- Segmented (multi-chamber) with sequential inflation with manually calibrated pressure in each chamber

Patients that have undergone major surgery are put at a higher risk for developing deep vein thrombosis (DVT), pulmonary embolism (PE), and venous thromboembolism (VTE). Limb pneumatic compression devices are one option for thromboprophylaxis and are used in the hospital and/or home setting.

In patients that have undergone major orthopedic surgery (defined as total hip arthroplasty (THA), total knee arthroplasty (TKA), and hip fracture surgery (HFS)), risk of DVT is increased due to venous stasis of the lower limbs due to immobility during and after surgery. Damage to the venous wall associated with the surgical procedure may also occur and contribute to increased risk. Normal risk is often restored with mobility. The most serious adverse consequence of an acute DVT is a possible pulmonary embolism (PE).

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

Select Health covers only the rental of intermittent pneumatic compression devices for home use in the following circumstances:

- Venous thromboembolism prophylaxis after major orthopedic surgery* with contraindication to pharmacological agents (high risk for bleeding)#
- Venous thromboembolism prophylaxis after major non-orthopedic surgery in patients who are at moderate or high risk^ of venous thromboembolism with a contraindication to pharmacological agents.

Pneumatic Compression Therapy for DVT Prophylaxis, continued

Select Health will NOT cover intermittent or segmental pneumatic compression devices, with or without calibrated gradient pressure, for any other reasons; as this is considered not medically necessary for DVT Prophylaxis.

*Major orthopedic surgery is total hip arthroplasty, total knee arthroplasty, or hip fracture surgery.

#High bleeding risk is defined as patients with one of the following:

1. History of major bleeding
2. Renal failure
3. Antiplatelet agent
4. During current procedure: difficulty to control bleeding, extensive surgical dissection, and revision surgery

^Risk classification is as followed:

- Low: Surgery lasting less than 30 minutes in patients younger than 40 years with no additional risk factors.
- Moderate: Surgery lasting less than 30 minutes in patients with additional risk factors; surgery lasting less than 30 minutes in patients age 40–60 years with no additional risk factors; major surgery in patients younger than 40 years with no additional risk factors.
- High: Surgery lasting less than 30 minutes in patients older than 60 years or with additional risk factors; major surgery in patients older than 40 years or with additional risk factors.
- Highest: Major surgery in patients older than 60 years plus prior venous thromboembolism, cancer, or molecular hypercoagulable state.

Duration of Use

Use in major orthopedic surgery with intermittent pneumatic compression devices is limited to 14 days post-surgery, in patients with contraindications to pharmacologic prophylaxis. Exceptions will be considered on a case-by-case basis for patients continuing to demonstrate inadequate mobility/weight-bearing.

Non-orthopedic surgery should be no more than 4 weeks in patients at high risk for VTE. This determination is based upon the patient's ability to ambulate adequately.

SELECT HEALTH MEDICARE (CMS)

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SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

Many published studies have shown the benefit of pneumatic compression devices in a hospital setting. Due to the inability to control and monitor compliance in a home setting, many questions remain about the effectiveness of home therapy in preventing DVTs in many clinical settings. No studies were identified that focused on the use of pneumatic compression devices in the home. Published evidence demonstrates antithrombotic prophylaxis to be recommended for patients undergoing major orthopedic

surgery and other surgical patients at increased risk of VTE. The American College of Chest Physicians (ACCP) recommends that one of several pharmacologic agents or mechanical prophylaxis be provided rather than no thromboprophylaxis. These recommendations also support the use of pharmacologic prophylaxis during hospitalization, whether patients are using a pneumatic compression device or not. Concerns noted in the ACCP recommendations included the lack of evidence to support compliance as being a major issue with pneumatic compression devices used for thromboprophylaxis. ACCP recommend that, if this prophylactic option is selected, use should be limited to portable, battery-operated devices. It is recommended that devices be used for 18 hours per day.

With regards to the use of intermittent home compression therapy, ACCP recommends use only in patients who cannot tolerate pharmacologic therapy in non-orthopedic surgery and patients who are at high risk for VTE postoperatively. This is similar to the recommendation from the American Society of Hematology guidelines 2019. In patients undergoing general and abdominal-pelvic surgery, the risk of VTE varies depending on both patient-specific and procedure-specific factors. Examples of relatively low-risk procedures include laparoscopic cholecystectomy, appendectomy, transurethral prostatectomy, inguinal herniorrhaphy, and unilateral or bilateral mastectomy. Open abdominal and open-pelvic procedures are associated with a higher risk of VTE. VTE risk appears to be highest for patients undergoing abdominal or pelvic surgery for cancer. Patient-specific factors also determine the risk of VTE, as demonstrated in several relatively large studies of VTE in mixed surgical populations. Studies have identified independent risk factors including age of prior VTE, active cancer, age > 60 years, prior VTE, surgical anesthesia lasting at least 2 hours, bed rest at least 4 days in duration, male gender, longer length of hospital stay, higher Charlson comorbidity score, recent sepsis, pregnancy or postpartum state, central venous access, malignancy, and inpatient hospital stay more than 2 days. These findings were supported in another study which identified most of the moderate-to-strong independent risk factors for VTE were surgical complications, including urinary tract infection, acute renal insufficiency, postoperative transfusion, perioperative myocardial infarction, and pneumonia.

A Hayes review completed in August 2018 supports the current coverage position. It noted the available evidence suggests that pneumatic compression may be effective in reducing the incidence of deep vein thrombosis (DVT) in patients who have undergone knee surgery, particularly when used in combination with other mechanical or pharmacological interventions for prevention of DVT. However, the available studies provide limited and somewhat inconsistent evidence concerning the efficacy of pneumatic compression relative to other strategies for DVT prevention—and the optimal DVT prevention strategy for knee surgery patients remains unclear. Pneumatic compression therapy is reasonably safe and caused minor or no complications in the reviewed studies. The reviewed studies determined additional randomized trials are needed to determine the optimal strategy for DVT prevention, particularly in patients who cannot tolerate treatment with anticoagulants such as low-molecular-weight heparin (LMWH) and aspirin.

Billing/Coding Information

CPT CODES

No specific codes identified

HCPCS CODES

A4600	Sleeve for intermittent limb compression device, replacement only, each
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient Pressure
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full

Pneumatic Compression Therapy for DVT Prophylaxis, continued

	arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise

Key References

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2. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Gynecology. Prevention of Venous Thromboembolism in Gynecologic Surgery: ACOG Practice Bulletin, Number 232. Obstet Gynecol. 2021 Jul 1;138(1): e1-e15.
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5. Fisher WD. Impact of venous thromboembolism on clinical management and therapy after hip and knee arthroplasty. Can J Surg, 2011; 54(5):344-51.
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13. Torrejon Torres R, Saunders R, Ho KM. A comparative cost-effectiveness analysis of mechanical and pharmacological VTE prophylaxis after lower limb arthroplasty in Australia. J Orthop Surg Res. 2019 Apr 2;14(1):93.

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Pneumatic Compression Therapy for DVT Prophylaxis, continued

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Select Health

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MEDICAL POLICY

STRUTTER CRUTCH (EASY STRUTTER FUNCTIONAL ORTHOSIS SYSTEM)

Policy # 304

Implementation Date:5/20/06

Review Dates: 5/17/07, 4/24/08, 4/23/09, 4/22/10, 8/16/11, 7/18/13, 6/19/14, 6/11/15, 6/16/16, 6/15/17, 7/20/18, 6/18/19, 6/20/20, 7/2/21, 5/18/22, 8/21/23, 8/8/24

Revision Dates:

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Description

A crutch is a device of wood or metal, ordinarily long enough to reach from the armpit to the ground, with a concave surface fitting under the arm and a cross bar for the hand, used for supporting the weight of the body. Common types of crutches include axillary crutches, forearm crutches, and triceps (elbow) crutches; most crutches are adjustable. The height of the crutches should be set so that the top of each crutch falls just below the armpit (approximately three or four fingers-worth of space). To protect the delicate nerves under the arms, crutches should not extend all the way up to the armpits. Rather, patients should brace crutches against their ribs just below the armpits.

The Easy Strutter Functional Orthosis System (Orthotic Mobility Systems, Inc., Kensington, MD) was designed to alleviate upper limb forces and improve assistive device ambulation efficiency. Both the axillary support and the rubber soled, spring-loaded base (16.5 cm long × 7.6 cm wide, 125.8 cm^2) are believed to improve subject stability/security and comfort during gait on multiple surfaces. In addition to providing a greater floor contact surface area than the 2.54–4.45 cm^2 provided by standard axillary crutches, or the 6.99 cm^2 area provided by oversized crutch tips, the design of the Strutter enables the device-base to maintain ground contact over a longer duration, enabling greater stability, especially when the patient ambulates on wet, slippery, or uneven surfaces. The Strutter was designed as a rectangle with "articulated" pivot points at each corner. This articulated parallelogram configuration enables the orthotic support and the device-base to remain parallel as the long sides rotate during use. The articulated, spring-loaded base of the Strutter may help absorb impact shock and may also help facilitate forward propulsion during gait.

COMMERCIAL PLAN POLICY AND CHIP (CHILDREN'S HEALTH INSURANCE PROGRAM)

Select Health does NOT cover the Easy Strutter Functional Orthosis System as there is inadequate published clinical evidence supporting the utility of this device in preventing neurovascular dysfunction associated with crutch use. This meets the plan's definition of experimental/investigational.

SELECT HEALTH MEDICARE (CMS)

Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, and InterQual criteria are not available, the Select Health Commercial policy applies. For the most up-to-date Medicare policies and coverage, please visit their search website http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Strutter Crutch (Easy Strutter Functional Orthosis System™), continued

SELECT HEALTH COMMUNITY CARE (MEDICAID)

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Summary of Medical Information

The results from the only study on the Strutter crutch suggest that it does reduce biomechanical forces that may lead to neurovascular damage from axillary crutch use. However, the data from this single study need to be replicated by other studies with larger sample sizes and more diverse patient groups. More importantly, this study did not consider any long-term neurovascular outcomes of Strutter or axillary crutch use, nor did it include other traditional crutches (e.g., forearm crutches) that are designed to address some of the problems Strutter claims to ameliorate. Studies addressing these issues must be done before any firm conclusions can be drawn regarding the benefits of the Strutter on neurovascular outcomes. Moreover, there is scant literature to support the premise that neurovascular damage from crutch use is even a common or serious problem requiring correction through alternative crutch designs. A larger body of literature involving more diverse sample sizes is needed before any conclusions can be made regarding the prevalence of neurovascular damage and the impact of Strutter on neurovascular outcomes.

Billing/Coding Information

Not Covered: Investigational/Experimental/Unproved for this Indication

CPT CODES

No specific codes identified

HCPCS CODES

E0117 Crutch, underarm, articulating, spring assisted, each

Key References

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