

DURABLE MEDICAL EQUIPMENT CLINICAL CRITERIA

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Bi-Directional and Dynamic Adjustable Splints

Covered items (HCPCS):

- E1811 Bi-Directional Static Progressive Stretch Knee Device with Range of Motion Adjustment, Includes Cuffs
- E1806 Bi-Directional Static Progressive Stretch Wrist Device with Range of Motion Adjustment, Includes Cuffs
- E1815 Dynamic Adjustable Ankle Extension/Flexion Device, Includes Soft Interface Material
- E1800 Dynamic Adjustable Elbow Extension/Flexion Device, Includes Soft Interface Material
- E1825 Dynamic Adjustable Finger Extension/Flexion Device, Includes Soft Interface Material
- E1802 Dynamic Adjustable Forearm Pronation/Supination Device, Includes Soft Interface Material
- E1810 Dynamic Adjustable Knee Extension / Flexion Device, Includes Soft Interface Material
- E1840 Dynamic Adjustable Shoulder Flexion / Abduction / Rotation Device, Includes Soft Interface Material
- E1830 Dynamic Adjustable Toe Extension/Flexion Device, Includes Soft Interface Material
- E1805 Dynamic Adjustable Wrist Extension / Flexion Device, Includes Soft Interface Material

- E1700 Jaw Motion Rehabilitation System
- E1841 Multi-Directional Static Progressive Stretch Shoulder Device, With Range Of Motion Adjustability, Includes Cuffs
- E1701 Replacement Cushions For Jaw Motion Rehabilitation System, Pkg. Of 6
- E1820 Replacement Soft Interface Material, Dynamic Adjustable Extension/Flexion Device
- E1821 Replacement Soft Interface Material/Cuffs For Bi-Directional Static Progressive Stretch Device

Clinical Guidelines: Covered for the treatment of contractures following surgery and/or injury. Not covered in DME if used in lieu of casting.

Clinical review: Orthopedics or Physical Medicine review required.

Usage guidelines: one per affected joint/extremity

The above guideline is based upon the following references:

1. Aspinall SK, Bmaber ZA, Hignett SM, et al. Medical stretching devices are effective in the treatment of knee arthrofibrosis: A systematic review. *J Orthop Translat.* 2021; 27; 119-131.
2. Berner SH, Willis FB. Dynamic splinting in wrist extension following distal radius fractures. *J Orthop Surg Res* 2010;5:53.
3. Blair WF, Steyers CM. Extensor tendon injuries. *Orthop Clin North Am.* 1992;23(1):141-148
4. Bonutti P, Marulanda G, McGrath, et al. Static progressive stretch improves range of motion in arthrofibrosis following total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2010 Feb;18(2):194-9.
5. Bonutti PM, Marulanda GA, Ulrich SD, et al. Static progressive stretch improves range of motion in arthrofibrosis following total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2010;18(2):194-199.
6. Bonutti PM, McGrath, MS, Ulrich SD, et al. Static progressive stretch for the treatment of knee stiffness. *Knee* 2008;15(4):272-276.
7. Bonutti PM, Windau JE, Ables BA, et al. Static progressive stretch to reestablish elbow range of motion. *Clin Orthop.* 1994;303:128-134.
8. Branch TP, Karsch RE, Mills TJ, Pamer MT. Mechanical therapy for loss of knee flexion. *Am J Orthop.* 2003;32(4):195-200.
9. Browne Ez jr, Ribik CA. early dynamic splinting for extensor tendon injuries. *J Hand Surg[Am].*
10. Canter-Tellez R, Cuesta-Vargas A, Cuadros-Romero M. Treatment of proximal interphalangeal joint flexion contracture: combined static and dynamic orthotic intervention compared with other therapy intervention: a randomized controlled trial. *J Hand Surg Am.* 2015 May;40(5):951-5. doi: 10.1016/j.jhsa.2015.01.005. Epub 2015 Mar 11.

11. Chester DL, Beales S, Beveridge L, et al. A prospective, controlled, randomized trial comparing early active extension with passive extension using a dynamic splint in the rehabilitation of repaired extensor tendon. *J Hand Surg (Br)*. 2002; 27N(3):283-288
12. Chow JA, Dovel S, Thomas TJ, et al. A comparison of results of extensor tendon repair followed by early controlled mobilization versus static immobilization. *J Hand Surg*. 1989;70(4):591-595.
13. Cohen EJ. Adjunctive therapy devices: restoring ROM outside of the clinic. *Phys Ther Magazine*. 1995 Mar:10-13.
14. Costa C, McElroy M, Johnson A, et al. Use of a static progressive stretch orthosis to treat post-traumatic ankle stiffness. *BMC Res Notes*. 2012 Jul 4:5:348.
15. Costa C, McElroy M, Johnson A, et al. Use of a static progressive stretch orthosis to treat post-traumatic ankle stiffness. *BMC Res Notes*. 2012 Jul 4:5:348.
16. Dempsey AL, Mills T, Karsch RM, Branch Tp. Maximizing total end range time is safe and effective for the conservative treatment of frozen shoulder patients. *Am J Phys Med Rehabil*. 2011;90(9):738-745.
17. Doornberg JM, RingD Jupiter JB. Static progressive splinting for posttraumatic elbow stiffness. *J Orthop trauma*. 2006;20(6):400-404.
18. Evan PJ, Nandi S, Maschke S, et al. Prevention and treatment of elbow stiffness. *J Hand Surg Am*. 2009;34(4):769-778.
19. Farmer SE, Woollam PJ, Patrick JH, et al. Dynamic orthoses in management of joint contracture. *J Bone Joint Surg br*. 2005;87(3):291-295
20. Furia J, Willis F, Shanmuggam R, Curran S. Systematic review of contracture reduction in the lower extremity with dynamic splinting. *Adv Ther*. 2013 Aug;30(8):763-70.
21. Furia JP, Willis FB, Shanmugam R, Curran SA. Systematic review of contracture reduction in the lower extremity with dynamic splinting. *Adv Ther*. 2013;30(8):763-770.
22. Greer MA, Miklos-Essenber ME. Early mobilization using dynamic splinting with acute triceps tendon avulsion. *J Hand Ther*. 2005;18:365-371.
23. Ibrahim M, Donatelli R, Hellman M, et al. Efficacy of a static progressive stretch device as an adjunct to physical therapy in treating adhesive capsulitis of the shoulder: a prospective, randomized study. *Physiotherapy*. 2014 Sep;100(3):228-34.
24. Ibrahim M, Johnson A, Pivec R, et al. Treatment of adhesive capsulitis of the shoulder with a static progressive stretch device: a prospective, randomized study. *J Long Term Eff Med Implants*. 2012;22(4):281-91.
25. John M, Kalish S, Perns S, et al. Dynamic splinting for postoperative hallux limitus: a randomized, controlled trial. *J Am Podiatr Med Assoc*. 2011 Jul-Aug;101(4):285-8.
26. Johnson A, McKenzie S, Ulrich S, et al. Assessment of static progressive stretch for the treatment of shoulder stiffness: a prospective case series. *J Long Term Eff Med Implants*. 2012;22(4):293-303.
27. Kamstra J, Reinstema H, Roodenburg J, et al. Dynasplint trismus system exercise for trismus secondary to head and neck cancer: a prospective study. *Support Care Cancer*. 2016 Aug;24(8):3315-23.
28. Li Y, Chang W, Chiang T, et al. Mouth-opening device as a treatment modality in trismus patients with head and neck cancer and oral submucous fibrosis: a prospective study. *Clin Oral Investig*. 2019 Jan;23(1):469-476.

29. Lindenhovius A, Doornberg J, Brouwer K, et al. A prospective randomized controlled trial of dynamic versus static progressive elbow splinting for posttraumatic elbow stiffness. *J Bone Joint Surg Am.* 2012 Apr 18;94(8):694-700.
30. Lucado A, Zhonguy L. Static progressive splinting to improve wrist stiffness after distal radius fracture: a prospective case series study. *Physiother Theory Pract.* 2009 May;25(4):297-309.
31. Lucado AM, Li Z. Static progressive splinting to improve wrist stiffness after distal radius fracture: A prospective, case series study. *Physiother Theory Pract.* 2009;25:297-309.
32. Mcgrath MS, Bonutti PM, Marker DR, et al. Static progressive splinting for restoration of rotational motion of the forearm. *J Hand Ther.* 2009;22(1);3-9.
33. Merolla G, Bianchi P, Porcellini G. Efficacy, usability and tolerability of a dynamic elbow orthosis after collateral ligament reconstruction: a prospective randomized study. *Musculoskelet Surg.* 2014 Dec;98(3):209-16.
34. Michlovitz SL, Harris BA, Watkins MP. Therapy interventions for improving joint range of motion: A systematic review. *J Hand Ther.* 2004;17(2): 118-131.
35. Miller A, Sadoghi P, Lucas R, et al. Effectiveness of bracing in the treatment of nonosseous restriction of elbow mobility: a systematic review and meta-analysis of 13 studies. *J Shoulder Elbow Surg.* 2013 Aug;22(8):1146-52.
36. Moulodi N, Kamyab M, Farzadi M. A comparison of the hallx valgus angle, range of motion, and patient satisfaction after use of dynamic and static orthoses. *Foot (Edinb).* 2019 Dec;41:6-11.
37. Sharma N, London J. Static progressive stretch brace as a treatment of pain and functional limitations associated with plantar fasciitis; a pilot study. *Foot Ankle Spec.* 2010 Jun;3(3):117-24.
38. Sodhi N, Khlopas A, Vaughn M, et al. Manufactured brace modalities for elbow stiffness. *Orthopedics.* 2018 Jan 1;41(1):e127-e135.
39. Suksathien R, Suksathien Y. A new static progressive splint for treatment of knee and elbow flexion contractures. *J Med Assoc Thai.* 2010 Jul;93(7):799-804.
40. Ulrich S, Bonutti P, Seyler T, et al. Restoring range of motion via stress relaxation and static progressive stretch in posttraumatic elbow contractures. *J Shoulder Elbow Surg.* 2010 Mar;19(2):196-201.
41. Van der Heide L, Gelderblom G, de Witte, L. Effects and effectiveness of dynamic arm supports: a technical review. *Am J Phys Med Rehabil.* 2015 Jan;94(1):44-62
42. Veltman E, Doornberg J, Eyegendaal D, et al. Static progressive versus dynamic splinting for posttraumatic elbow stiffness: a systematic review of 232 patients. *Arch Orthop Trauma Surg.* 2015 May;135(5):613-7.
43. Willis F, Fowler B. Longitudinal outcomes following a randomized controlled trial of dynamic splint stretching for carpal tunnel syndrome. *Hand (N Y).* 2016 Sep;11(3):290-29

External Female Urine Collection Device

Covered Items (HCPCS):

- E2001 Electric Urine Suction Device

- A6590 External Urine Catheters; Disposable, with Wicking Material Device, For use with Suction Pump, Per Month
- A7001 Canister, Non-disposable, Used with Suction Pump
- A7002 Tubing, Used with Suction Pump

Patient must meet criteria 1 to 4:

1. Patients must have female genitalia with urinary incontinence AND
2. Deemed at risk for indwelling catheterization AND
3. Bed confined/immobile, requiring full assist from bed to chair AND
4. Must have one of the following:
 1. Patient has a history of current or previous decubitus ulcers, skin breakdown or injury in the sacral or gluteal area OR
 2. History of catheter associated urinary tract infection.

Contraindications:

1. Has a known allergy to one or more components of the device
2. Has urinary retention

Clinical Review:

No specialist required.

Usage Guidelines:

- E2001 – One at a time
- A6590- External Urine Catheters; Disposable – 30 per month. Quantities of 31-90 per month require medical justification
- A7001 – None
- A7002- None

Clinical guidelines were based upon the following references:

1. Bagley K, Severud L. Preventing catheter- associated urinary tract infections with incontinence management alternatives. Nursing Clin of NA, 2021; 56 (3):413-425.
2. McRae A, Kennelly M. Outpatient purewick female external catheter system performance: healthy volunteer study. Continence, 2023, 7 (9): 100712

Non-invasive Vagus Nerve Stimulator

Covered items (HCPCS):

E0735 – Non-invasive Vagus Nerve Stimulator – Components, Accessories and Supplies

Clinical Guidelines:

- Member has a diagnosis of Cluster Headaches and
- Documented non-responsiveness, failure of, or contraindication to use of triptans, CGRP inhibitors and/or Dihydroergotamine -DHE (unless contraindicated).

Not covered:

- Migraine
- Other headache types

Clinical Review:

- Neurologist

Usage Guideline:

- One month at a time.
- New order is required for each monthly usage

Clinical guidelines were based upon the following references:

1. Barbanti P, Brazzi L, Egeo G, et al. Non-invasive vagus nerve stimulation for acute treatment of high-frequency and chronic migraine: an open-label study. *The Journal of Headache and Pain*. 2015;16:61.
2. Diener HC, Goadsby PJ, Ashina M, et al. Non-invasive vague nerve stimulation (nVNS) for the preventive treatment of episodic migraine: the mulicentre, double-blind, randomised, sham-controlled PREMIUM trial. *Cephalalgia*. 2019 Oct;39(12):1475-87.
3. Gaul C, Diener HC, Silver N, et al. PREVA Study Group. Non-invasive vagus nerve stimulation for prevention and acute treatment of chronic cluster headache (PREVA): a randomized controlled study. *Cephalalgia*. 2016May;; 36(6): 534-46.
4. Goadsby Pj, de Coo IF, Silver N, et al. ACT2 Study Group. Non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A randomized, double-blind, sham-controlled ACT2 study. *Cephalalgia*. 2018 April;38(5): 959-69
5. Grazi L, Egeo G, Calhoun AH, et al. Non-invasive vagus nerve stimulation (nVNS) as mini-prophylaxis for menstrual/menstrually related migraine: an open-label study. *The Journal of Headache and Pain*. 2016 Dec; 17(1):91
6. Marin J, Giffin, N, Consiglio E, et al. Noninvasive vagus nerve stimulation for treatment of cluster headache early UK clinical experience. *The Journal of headache and pain*. 2018 Nov 12: 19(1):114.
7. Silberstein SD, Calhoun AH, Lipton RB, et al. Chronic migraine headache prevention with noninvasive vagus nerve stimulation: the EVENT study. *Neurology*. 2016 Aug 2;87(5):529-38.
8. Silberstein SD, Mechtler LL, Kudrow DB, et al. ACT1 Study Group. Non-invasive vagus nerve stimulation for the acute treatment of cluster headache: finding from the randomized, double-blind, sham-controlled ACT1 study. *Headache*. 2016 Sep; 56(8):1317-32.
9. Tassorelli C, Grazi L, d Tommaso M, et al. Noninvasive vagus nerve stimulation as acute therapy of migraine: the randomized PRESTO study. *Neurology*. 2018 Jul 24;91(4):e364-73.

