Medical Policy Reference Manual
Medical Policy

1.01.030 Dynamic Splinting Systems

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Description

Dynamic splinting systems are devices that create a spring-tension, low-load, prolonged stretch (LLPS) designed to improve range of motion (ROM) and reduce joint contractures while patients are asleep or at rest. Dynamic splinting systems include, but are not limited to, such products as Dynasplint®, Ultraflex®. LMB Pro-glide®, EMPI Advance® and SaeboFlex®.

Policy

Dynamic splinting systems are considered **medically necessary** after major open surgery or trauma to a joint when one of the following criteria is met:

- as an adjunct to an active treatment plan that includes physical or occupational therapy in members with documented signs and symptoms of significant motion stiffness/ loss in the sub-acute injury or post-operative period (at least 3 weeks after injury or surgery); or
- in the acute post-operative period for patients who have a prior documented history of motion stiffness/ loss in a joint and are having additional surgery or procedures done to improve motion to that joint.

Prophylactic use of dynamic splinting systems is considered **not medically necessary** in the management of chronic contractures (no significant change in motion in a 4-month period).

The use of a Carpal Tunnel Dynasplint® system is considered **experimental/ investigational** in the management of carpal tunnel syndrome, as it does not meet TEC criteria # 2 - 5.

The Ankle Dorsiflexion Dynasplint® system is considered **experimental / investigational** for the treatment of chronic plantar fasciitis as it does not meet TEC criteria # 2 - 5.

The use of dynamic splinting systems, for all other conditions not listed above, are considered **experimental / investigational,** as it does not meet TEC criteria # 2 - 5.

Policy Guidelines

The spring-tension, low-load, prolonged stretch device must be ordered by the patient's treating physician.

If requested, the medical record must show supporting documentation of the medical necessity of the device.

Rationale:

There is a scarcity of current peer-reviewed literature through September 2007 to support the effectiveness of the Carpal Tunnel Dynasplint® system in the management of carpal tunnel syndrome.

2010 Update:

A search of the peer-reviewed literature was performed for the period of October 2007 through January 2010. Findings in the recent literature do not change the conclusions on the use of dynamic splinting systems. Therefore, the policy statements are unchanged.

2011 (January) Update: Dynamic splint for treatment of chronic plantar fasciitis:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

The Ankle Dorsiflexion Dynasplint® is considered a Class I device, so no pre-marketing approval by FDA is required.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

Only two studies were found that were specific to the Ankle Dorsiflexion Dynasplint®. A small (n=12) pilot study by Berlet et al (2002) documented symptomatic improvement in 75% of the patients after using the Dynasplint® for one month. Reported complaints from patients included disturbance of sleep, perspiration, numbness in the toes, and shifting of position of the splint. The authors concluded a randomized study with a comparison to other splint designs was warranted. A randomized, controlled trial was reported by Sheridan et al (2010). This was a fairly small study (n=60) where 30 patients were randomized to receive a dynamic tension splint along with the control treatment of NSAID, orthoses and corticosteroid injection if needed. No mention of blinding of results was made. Improvement was observed in both groups with significantly more improvement in the splint group. Overall the evidence does not permit conclusions regarding the outcomes of plantar fasciitis patients treated with the Dynasplint®.

3. The technology must improve the net health outcome:

The use of night splints is a tier 2 treatment option in the clinical practice guidelines of the American College of Foot and Ankle Surgeons, supported by level B evidence, defined as a "fair" rating. A level B evidence grade was also given by the clinical practice guide of the American Physical Therapy Association. Overall there is a limited amount of evidence supporting the use of night splints to improve outcomes, and results from the studies are mixed. No mention is made of the Dynasplint® device by name. No evidence was found that the Dynasplint® device accounted for any improvement over the standard night splint designs, many of which are widely available without prescription.

4. The technology must be as effective as any established alternatives:

The use of dorsiflexion night splints with stretching of the Achilles tendon is considered a treatment option for those who do not respond to the usual tier 1 therapies of padding and strapping, steroid injection, orthotics and NSAIDs. There is insufficient evidence to conclude that the Ankle Dorsiflexion Dynasplint® confers any advantage over conventional night splint designs.

5. The improvement must be attainable outside the investigational settings:

Because criteria 2-4 are not met, this criterion cannot be met.

Update 2013:

A search of the peer-reviewed literature was performed from January 2011 through January 2013. Findings in the literature do not change the medically necessary indications for dynamic splinting systems listed in the policy. Therefore, the policy statements are unchanged.

Update 2015:

A search of the peer-reviewed literature was performed from February 2013 through January 2015. Findings in the literature do not change the medically necessary indications for dynamic splint systems listed in the policy. Therefore, the policy statements are unchanged.

Update 2017:

A search of the peer-reviewed literature was performed from February 2015 through January 2017. Findings in the literature do not change the medically necessary indications listed in the policy for dynamic splint systems. Therefore, the policy statements are unchanged.

Update 2019:

A search of the peer-reviewed literature was performed from February 2017 through February 2019. Findings in the literature do not change the medically necessary indications for dynamic splint systems listed in the policy. Therefore, the policy statements are unchanged.

Update 2021:

A search of the peer-reviewed literature was performed from February 2019 through March 2021. Findings in the literature do not change the medically necessary indications for dynamic splint systems listed in the policy. Therefore, the policy statements are unchanged.

Benefit Applications

Check the member's contract for specific benefits for Durable Medical Equipment (DME).

Benefits **are provided** for the spring-tension, low-load, prolonged stretch device as a rental item. Repairs are *included in* the rental fee.

Benefits **are provided** for dynamic splinting systems to be reported twice only when two distinct devices are used (e.g., one for flexion, one for extension).

Benefits **are provided** for the replacement of a dynamic splinting system when there is documented change in the physical condition of the member.

For member-owned dynamic splinting systems, benefits **are provided** for the replacement padding when medically appropriate.

Benefits **are provided** for the rental only for the dynamic adjustable finger extension/flexion device.

NOTE: For FEP members, check the member's contract for benefits.

Provider Guidelines

The use of dynamic splinting systems for more than 3 months may require submission of medical records.

The spring-tension, low-load, prolonged stretch devices (These items are considered immediate needs. The appropriate documentation from the treating practitioner establishing the severity of the patient's condition and the immediate need for the durable medical equipment, and the therapeutic benefits the patient is expected to realize from its use is needed for the medical necessity determination).

Cross References to Related Policies and Procedures

Durable Medical Equipment with Attached Table, 1.01.001
Orthotic Devices and Orthopedic Appliances, Policy 01.03.001

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own, and may or may not be in agreement with those of CareFirst.

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