

# **DURABLE MEDICAL EQUIPMENT**

## **Federal Bureau of Prisons Clinical Guidance**

**June 2018**

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## PURPOSE OF THIS CLINICAL GUIDANCE

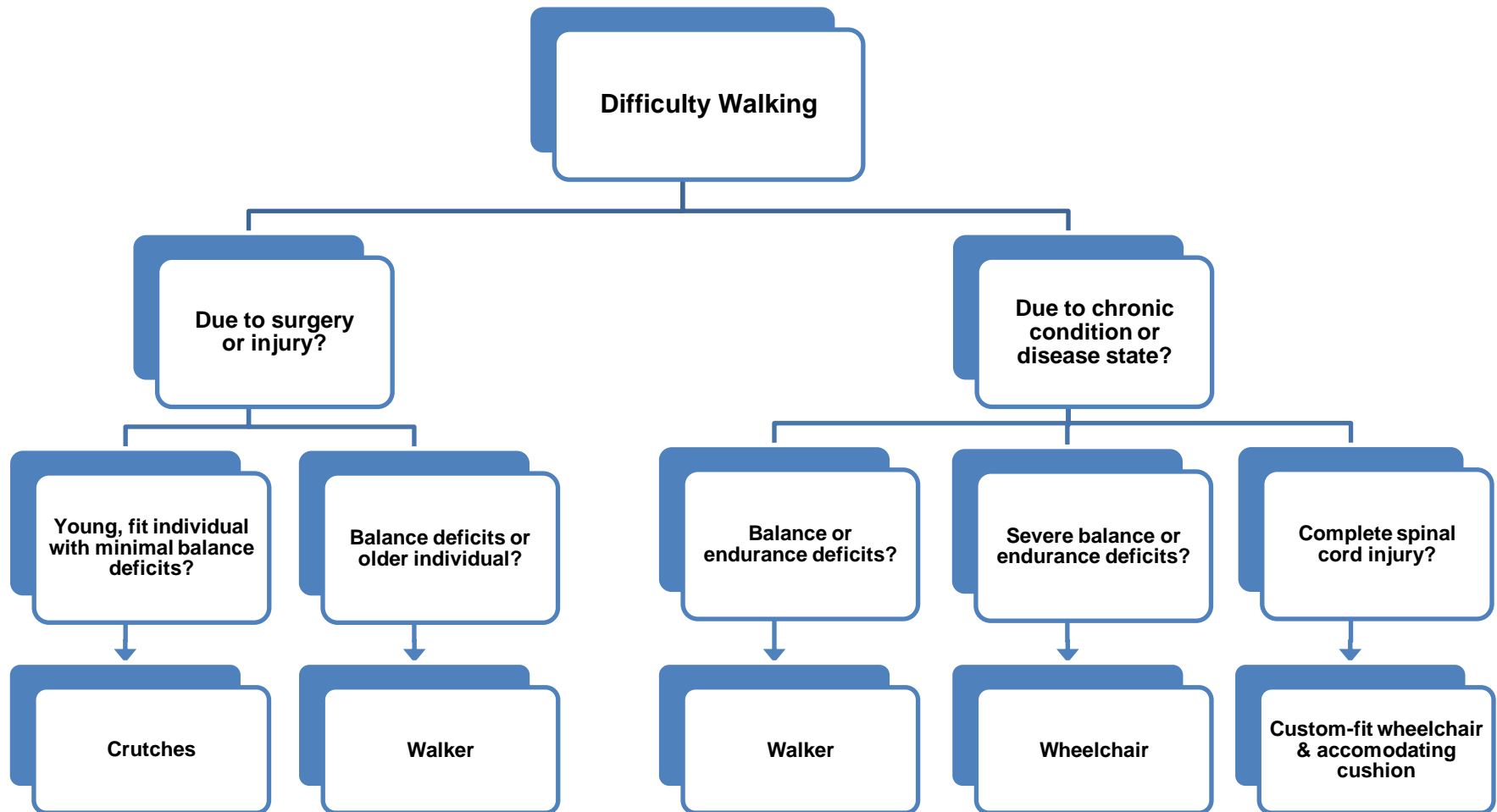
Pain management may include use of Durable Medical Equipment (DME) to aid in reducing pain, enhancing balance/kinesthetic sense and improving functionality. DME includes wheelchairs, walking assistive devices, braces, orthotics, and splints. The BOP *Clinical Guidance on Durable Medical Equipment* is designed to provide consistent and clinically sound information to support and justify decisions about the usefulness of DME for individual patients, particularly those within the correctional environment.

**This guidance is divided into three sections to assist health care providers in determining the most appropriate DME choice for a given individual, based on the best available evidence:**

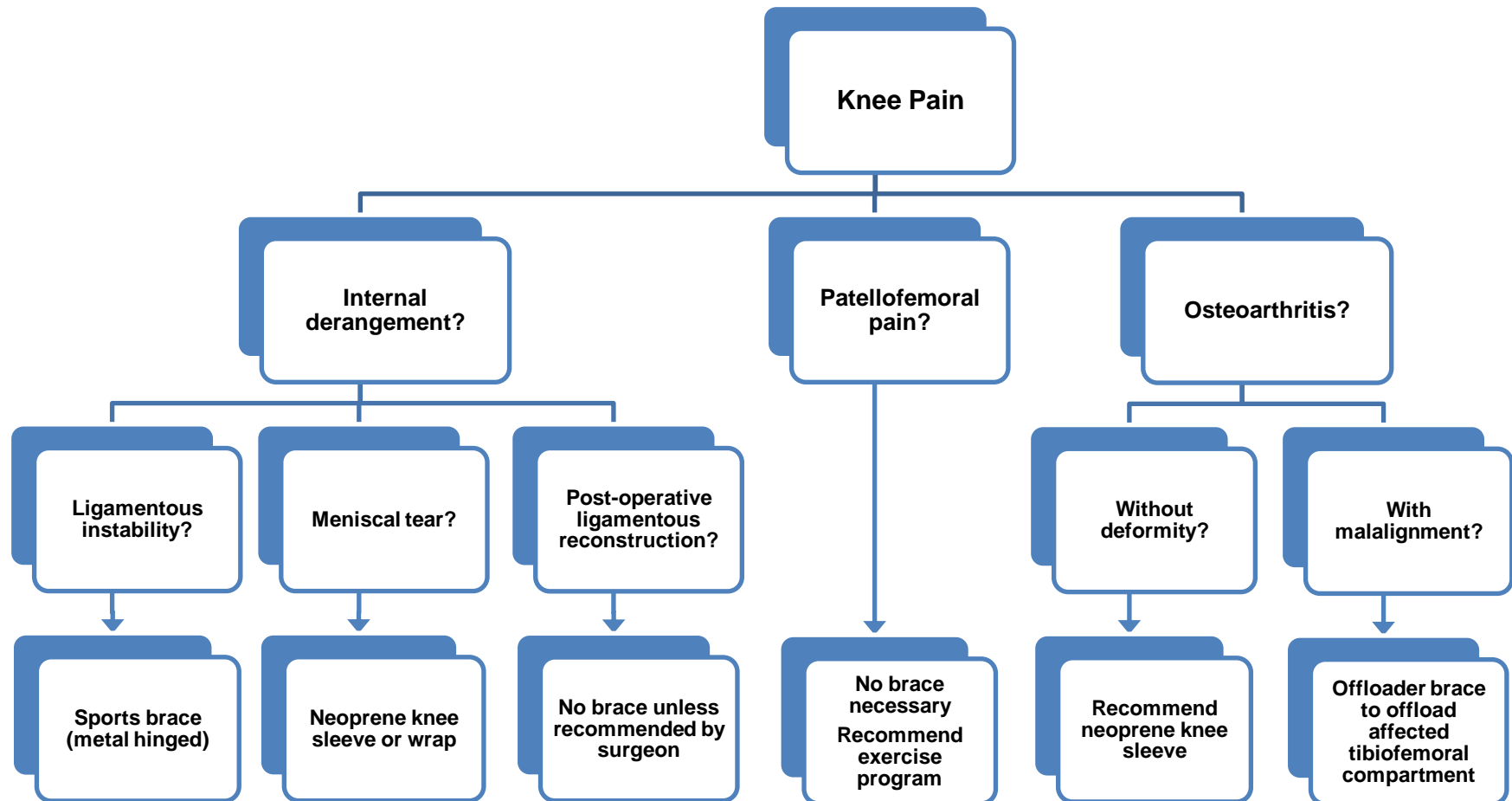
- **SECTION 1** contains a series of “ready-decision” charts, organized by the affected body part and/or the nature of the individual’s complaint.
- **SECTION 2** contains a series of “ready-decision” charts organized by type of DME.
- **SECTION 3** provides more complete information on indications, clinical guidance, and evidence for using each type of device.

## SECTION 1. APPROPRIATE DME ISSUE, BASED ON BODY PART OR COMPLAINT

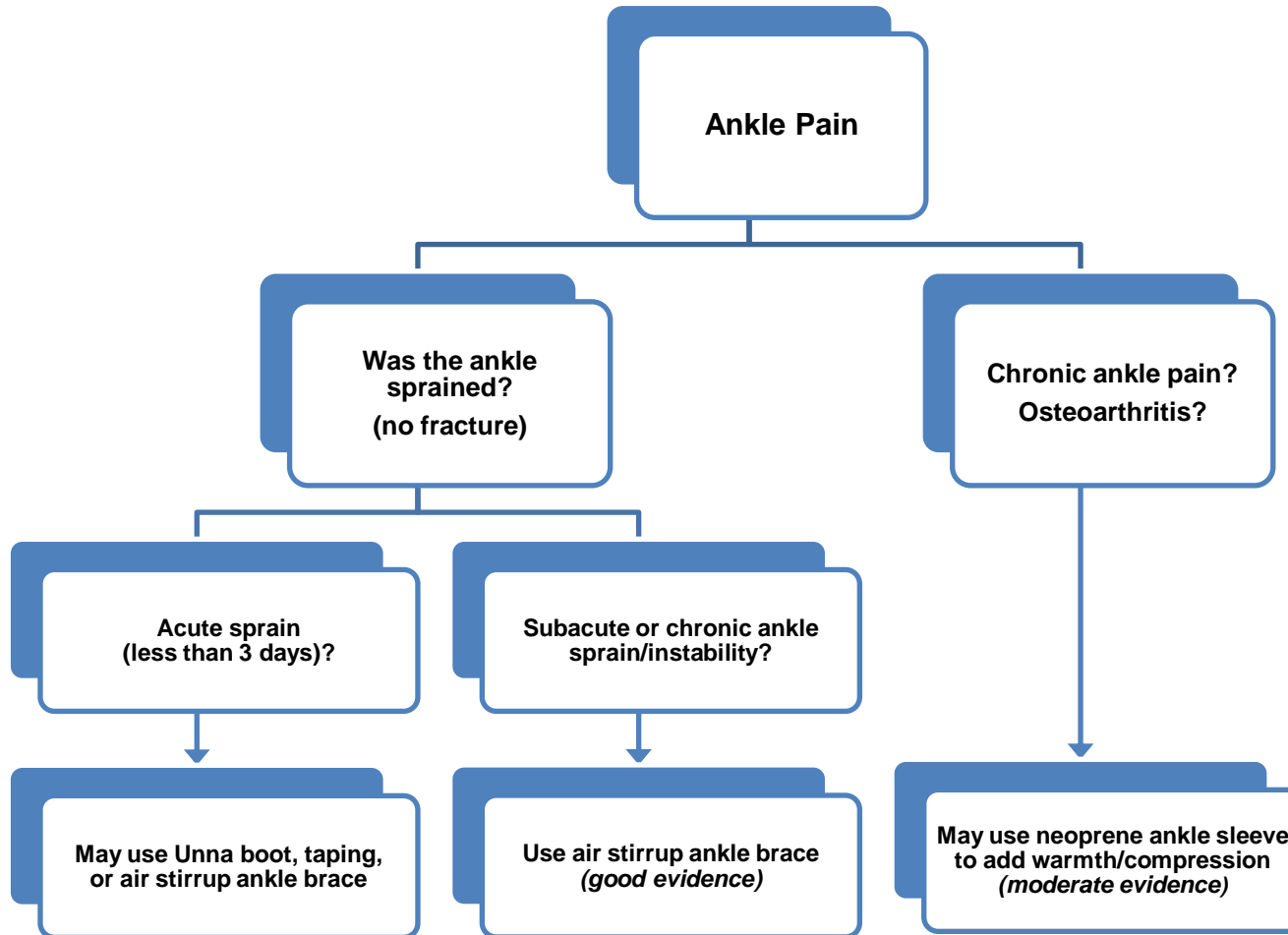
### 1A. MOBILITY ASSISTIVE DEVICES



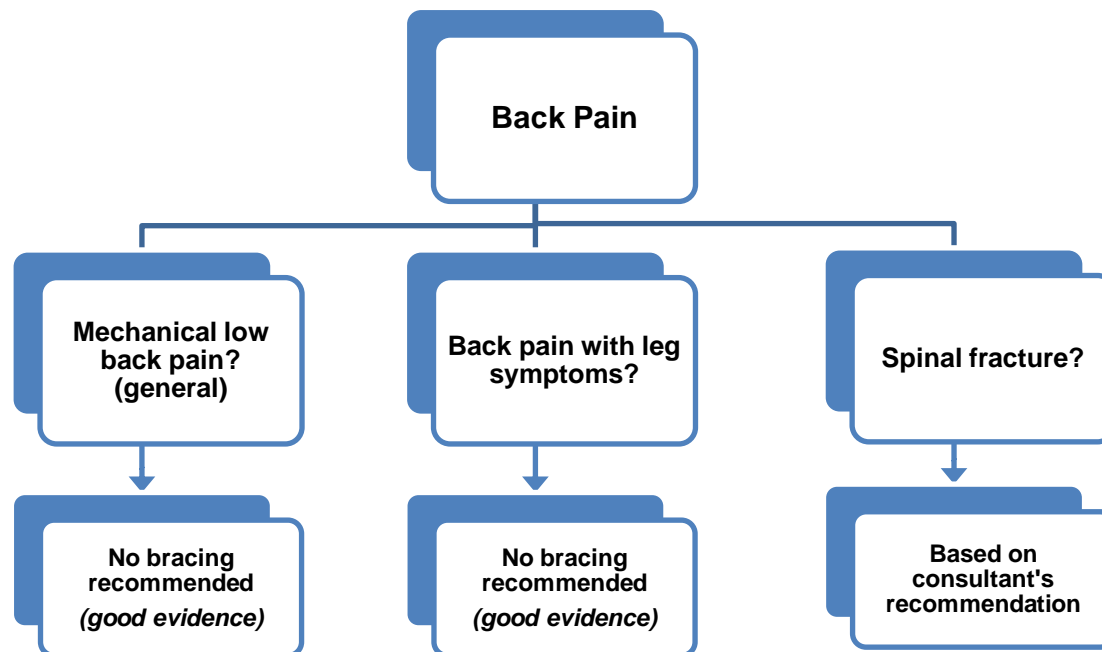
## 1B. KNEE PAIN



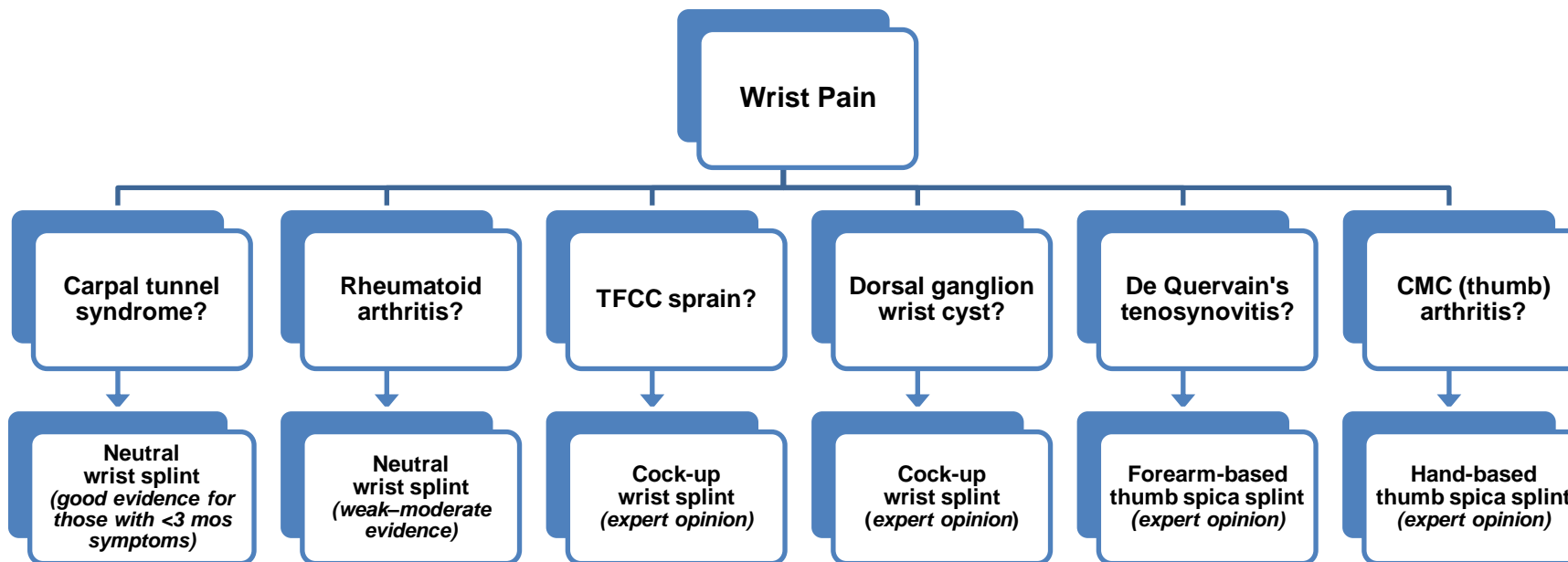
### 1C. ANKLE PAIN



## 1D. BACK PAIN



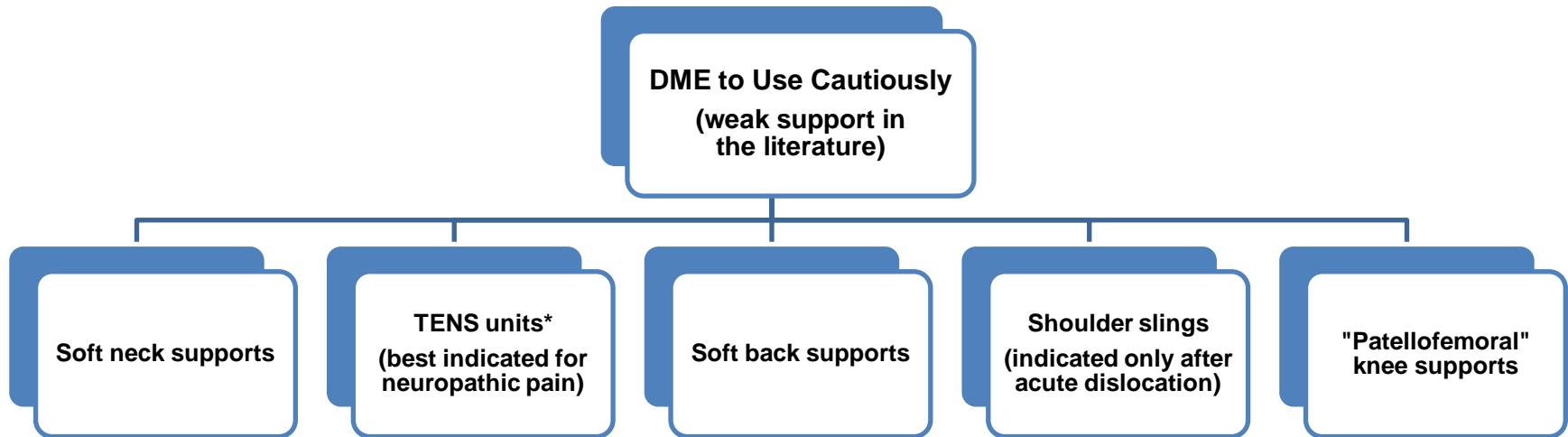
## 1E. WRIST PAIN





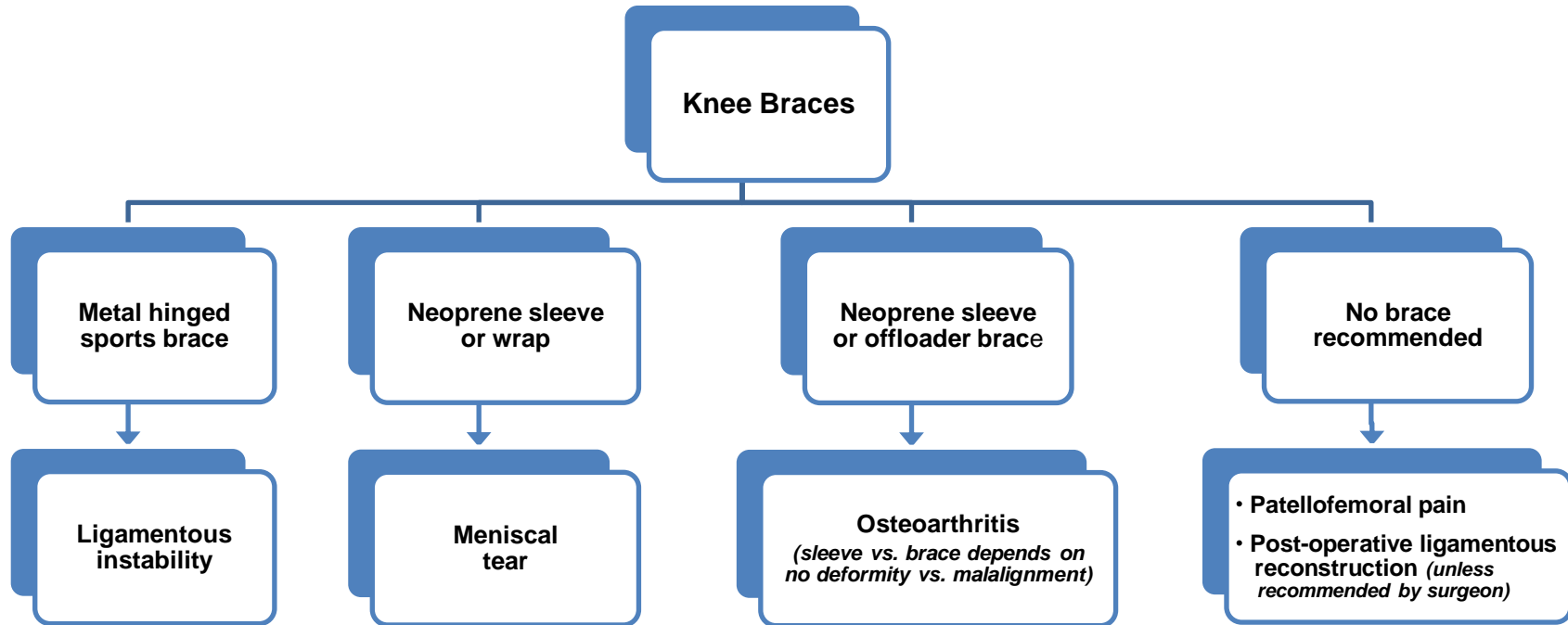
## SECTION 2. TYPES OF DME DEVICES AND RECOMMENDED USE

### 2A. DME TO USE WITH CAUTION

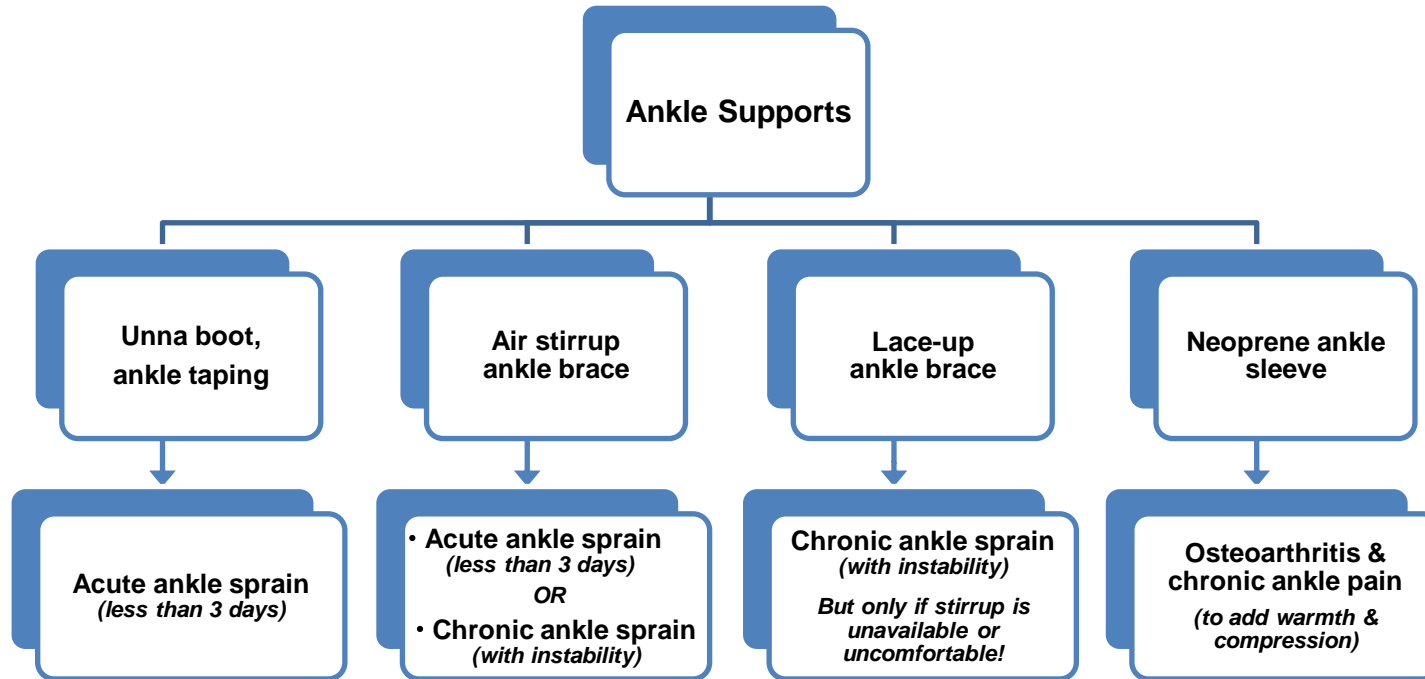


\* See Section 2F. [TENS UNITS: RECOMMENDED USES](#).

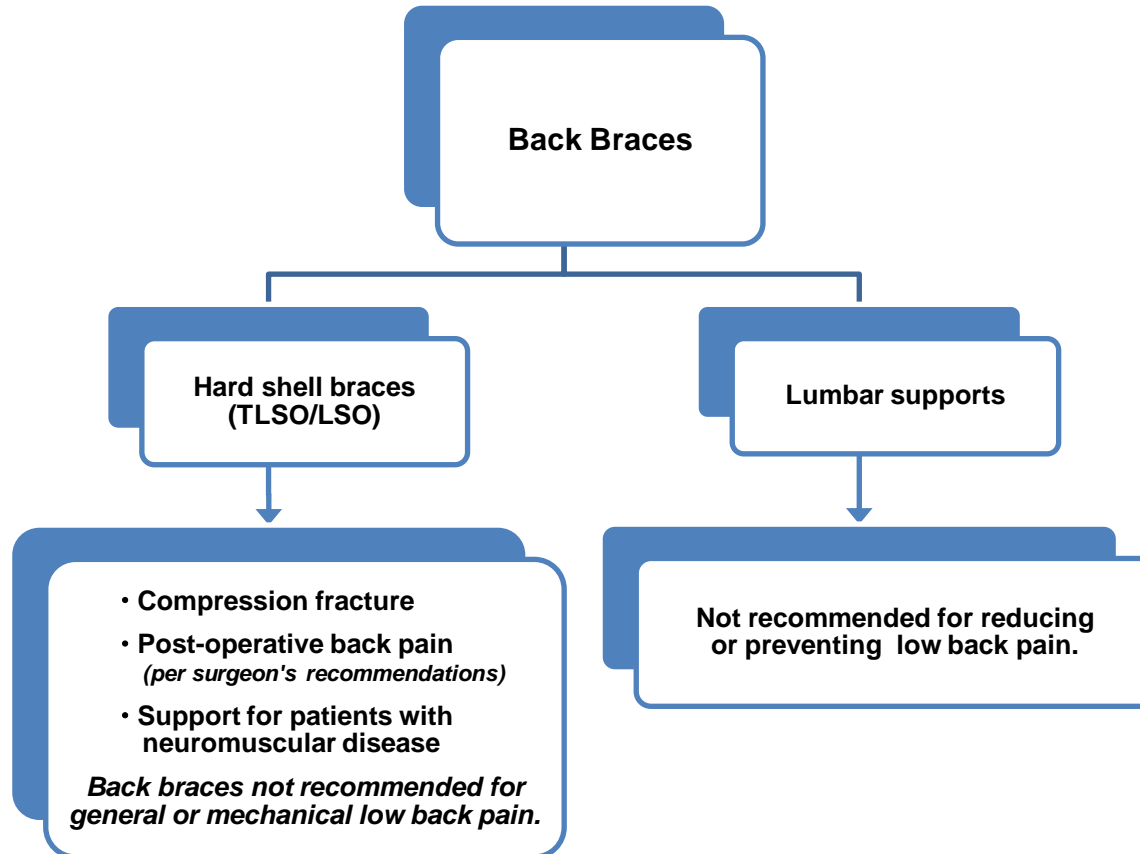
## 2B. KNEE BRACES



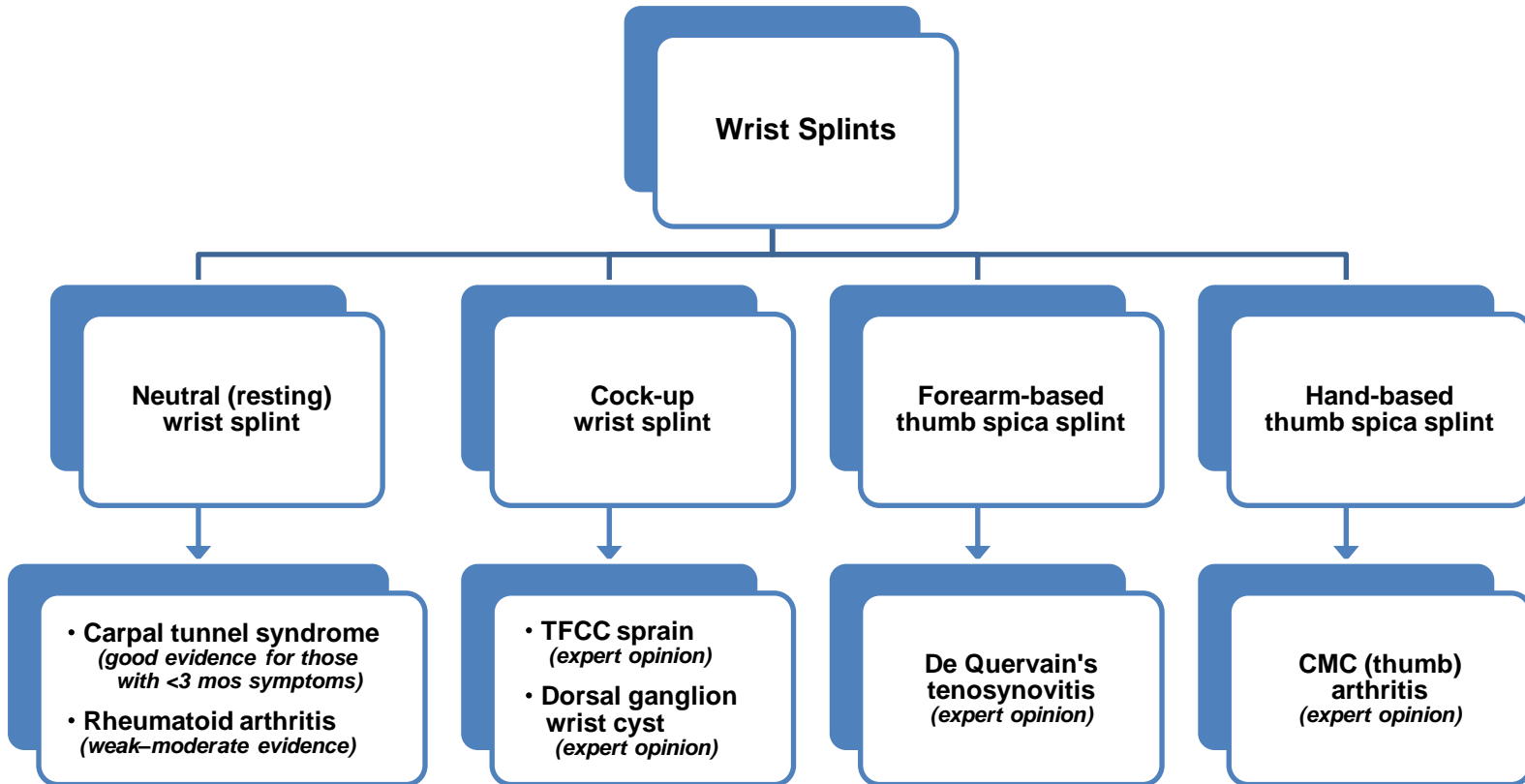
## 2C. ANKLE SUPPORTS



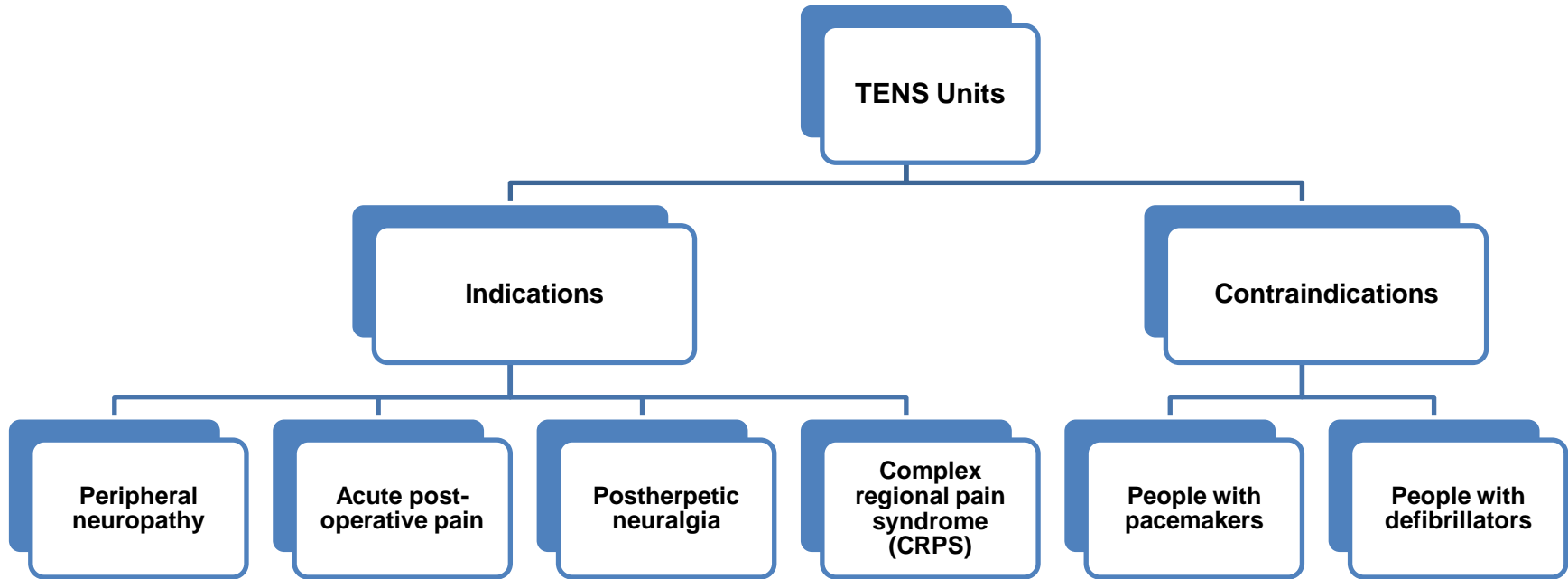
## 2D. BACK BRACES



## 2E. WRIST SPLINTS



## 2F. TENS UNITS: RECOMMENDED USES



## SECTION 3. DURABLE MEDICAL EQUIPMENT: INDICATIONS, CLINICAL GUIDANCE, AND EVIDENCE

This guide offers information on the indications, clinical guidance, and evidence for a range of DME categories:

- **Indications** for use are based on the best available evidence.
  - **Clinical guidance** is based on the current standard of care and expert opinion.
  - A summary of the best available **evidence** for each type of DME is provided, when available, based on Sackett's hierarchy of evidence.
  - The **referenced studies** are listed by number in the [References](#) section.
- ➔ Please note that the Federal Bureau of Prisons does not endorse any specific DME companies or product lines.

### ANKLE SUPPORTS AND BRACES

#### ❖ General Ankle Support (e.g., Neoprene sleeve):

- **Indications:** Typically used for mild, generalized ankle pain without sprain. May aid in warming and compressing the ankle joint.
- **Clinical Guidance:** General ankle supports do not aid in stabilizing the ankle, but may aid in providing compression and warmth, while enhancing kinesthetic sense. May assist those with osteoarthritis.
- **Evidence:** General ankle supports have not been systematically studied.



#### ❖ Lace-Up Ankle Brace:

- **Indications:** Typically used in the subacute and chronic phases after an ankle sprain.
- **Clinical Guidance:** All lace-up and semi-rigid stirrup braces significantly reduce passive motion, compared to no brace being used. It is recommended for all activities on unlevel surfaces for at least three months status-post ankle sprain requiring medical evaluation. The stirrup brace is best for preventing inversion sprains, but the lace-up can be used if a person is wearing shin guards. (See [Stirrup Ankle Brace](#) below.)
- **Evidence:**
  - Research is inconclusive about whether ankle supports are helpful with chronic instability or in preventing ankle sprains.<sup>19,49</sup>
  - Lace-up braces limit passive mobility in all directions; however, they are not as limiting in rapidly induced real-time situations.<sup>19,48</sup>



### ❖ **Stirrup Ankle Brace:**

- **Indications:** Typically used after an acute ankle sprain or in patients with chronic ankle instability.
- **Clinical Guidance:** This type of ankle brace may reduce the risk of re-injury if used prophylactically.
- **Evidence:**
  - There is good evidence in Cochrane Systematic Reviews that semi-rigid ankle braces or air-cast braces decrease the risk of ankle sprains during high-risk sporting activities.<sup>19,25</sup>
  - A study of 10 different types of ankle braces found that semi-rigid braces with a stirrup design restrict inversion under passive and rapidly induced conditions. May be used prophylactically in sports to prevent inversion sprains.<sup>21,49</sup>
  - For severe ankle sprains, a 10-day below-the-knee cast is recommended to accelerate healing and clinical outcomes. However, the stirrup brace pictured above is also suitable and less time-intensive.<sup>35</sup>
  - Use of a stirrup brace in the treatment of lateral ankle sprains significantly improves ankle joint function at 10 days and 1 month after injury, compared with standard elastic support management.<sup>6</sup>
  - Use of an elastic support combined with a stirrup brace demonstrates an earlier return to pre-injury function in those with first-time Grade I and II ankle sprains, compared to either treatment used alone.<sup>3</sup>



### ❖ **Ankle Foot Orthosis (AFO):**

- **Indications:** An ankle foot orthosis is most appropriate for a patient with noted weakness of the ankle stabilizer muscles that is likely due to an orthopedic or neurologic condition. An AFO will help stabilize and support the ankle, especially for those patients with foot drop, allowing them to ambulate. An ankle foot orthosis may be used for patients with multiple sclerosis, cerebral palsy, cerebrovascular accident, spina bifida, traumatic brain injury, peripheral neuropathy, or spinal cord injury.

AFOs can also be used to prevent contractures in those who cannot actively flex their ankle upwards repetitively. AFOs have some use in contracture management for those who have a non-fixed ankle plantarflexion contracture.
- **Clinical Guidance:** A pre-fabricated or “off the shelf” AFO is not custom-molded for the patient. They are available in multiple sizes and can be accommodated or adjusted to meet patient needs. AFOs are generally used to assist patients who have weakness of their ankle dorsiflexor muscles to allow ambulation without foot drop.





## BACK BRACES

### ❖ General Supports/Binders

- **Indications:** No specific indications.
- **Clinical Guidance:** Back supports do not appear to aid in reducing back pain or preventing back injury.
- **Evidence:**
  - In a Cochrane Systematic Review, it was noted that there is moderate evidence that lumbar supports are not more effective than no intervention or preventative training in preventing or reducing low back pain. It remains unclear whether lumbar supports are better than no intervention or any other intervention.<sup>50</sup>
  - Another systematic review demonstrated no evidence to support the use of lumbar supports or education in the primary prevention of low back pain in the workplace.<sup>51</sup>



### ❖ Hard Shell Back Braces (Thoracolumbar Spinal Orthosis–TLSO/ Lumbosacral Orthosis–LSO)

- **Indications:** Hard shell back braces are most appropriate for patients with compression or stable fractures, excluding spondylolisthesis. TLSOs/LSOs can facilitate healing post-operatively in the acute healing phase for spinal surgeries such as laminectomy or fusion. TLSOs/LSOs are not typically indicated for long-term use; however, they may be effective at supporting weak spinal/core muscles in patients with neuromuscular conditions (i.e., spinal cord injury, amyotrophic lateral sclerosis).<sup>11</sup>
- **Clinical Guidance:** Hard shell braces can facilitate healing in patients with spinal fractures or post-operatively. They can support weak spinal muscles in patients with neuromuscular disease.
- **Evidence:**
  - Spinal orthoses are oftentimes prescribed for immobilization following surgery or aid in alleviation of low back pain. Scientific literature does not provide adequate data to support or oppose the use of orthoses for either of these functions. The ability of orthoses to restrict individual intervertebral motions is questionable, and the postoperative outcomes of treatments with and without bracing are conflicting. Therefore, the decision about the use of orthoses is often based on a surgeon's opinion or experience.<sup>17,38</sup>
  - TLSOs restricted 39% of motion in the lumbar region and 45% of motion in the thoracic region in three similar braces.<sup>13</sup>



## KNEE BRACES

### ❖ General Knee Braces (Sleeves and Hinged)

- **Indications:** A neoprene knee sleeve is supported for use in patients with osteoarthritis and pre-operative internal derangements. A neoprene sleeve likely improves a patient's joint-position sense.
- **Clinical Guidance:** Both neoprene sleeves and offloader braces (see below) have demonstrated improvements in function and pain in patients with osteoarthritis.
- **Evidence:**
  - There is strong evidence to suggest that people with knee osteoarthritis can walk further when wearing a neoprene brace after one year of wear.<sup>8</sup>
  - Wearing a neoprene knee sleeve may help to prevent falls in those with knee osteoarthritis.<sup>14</sup>
  - There is low-quality evidence to support that people with knee osteoarthritis experience a reduction in pain from wearing a neoprene brace.<sup>8</sup>
  - Neoprene sleeves and patellofemoral braces have not been found to reduce pain or improve function in those with patellofemoral pain.<sup>1,38</sup>



### ❖ Metal Hinged Knee Braces (Sports Brace or Functional Brace)

- **Indications:** Use in cases of knee instability, as determined by physical examination and/or imaging. They may be used post-operatively to enhance knee stability through increased skin contact, resulting in improved neuromuscular control.
- **Caution:** May pose a security threat.
- **Clinical Guidance:** May aid in enhancing functionality in someone with ligamentous instability pre-operatively.
- **Evidence:**
  - There is moderate evidence to suggest that a “sports brace” may enhance functionality in someone with ligamentous instability.<sup>4,37</sup>
  - A systematic review of brace wear after ACL reconstruction surgery did not show differences in outcomes between brace use and non-use.<sup>37</sup>
  - A randomized multicenter clinical trial with a minimum of a two-year follow-up demonstrated that individuals who were braced after ACL reconstruction demonstrated no statistical changes in functional testing, Lysholm scores, knee range of motion, or isokinetic strength testing.<sup>40</sup>



### ❖ Osteoarthritis (Offloader) Knee Brace

- **Indications:** Osteoarthritis braces are oftentimes called “offloader” or “unloader” braces. They are designed to decrease loading and mechanical stress on the knee. They are more cost-effective and more effective in treating painful knee osteoarthritis than a standard hinged brace (see above). Osteoarthritis braces are most effective in enhancing mobility while reducing pain in those patients with unicompartmental knee osteoarthritis. The brace is customized by size and the particular compartment (medial or lateral) it is designed to offload. Improvement may result from enhanced proprioception and neuromuscular control.



- **Clinical Guidance:** Both neoprene sleeves and offloader braces have demonstrated improvements in function and pain reduction in patients with osteoarthritis. An offloader brace can serve to offload the medial or lateral tibiofemoral compartment, which is most beneficial when a patient demonstrates unicompartmental osteoarthritis (for example, medial offloader brace for patient with medial tibiofemoral compartment narrowing).
- **Cautions:** May pose a security threat. Ordering this type of brace is specific to offloading the appropriate tibiofemoral compartment.
- **Evidence:**
  - In a Cochrane review, knee braces that were specifically designed for use with osteoarthritis were found to be effective for management of symptoms.<sup>8</sup>
  - Offloader braces were shown to have greater benefit than simple hinged knee braces during walking; they are also more cost-effective.<sup>8</sup>
  - High-quality evidence has demonstrated that a valgus-producing brace in patients with varus gonarthrosis (arthritic bow-legged knees) significantly reduces pain during functional activities after six months of use.<sup>32</sup> In a Cochrane review, people were able to walk 1.8 km longer after wearing this kind of knee brace for one year.<sup>8</sup>

## NECK SUPPORTS (SOFT COLLAR)

- **Indications:** No specific indications.
- **Evidence:** Treatment with a soft collar was found to have no obvious benefit in terms of functional recovery after neck injury and was associated with a prolonged time period off work.<sup>16</sup>



## ORTHOTICS

- **Indications:** Research is mixed regarding the issuance of insoles. It is noted that in the general population, over-the-counter insoles are comparable to custom orthotics. Therefore, initial fitting with over-the-counter insoles is appropriate for the general population. Full-length insoles are recommended over those that are ½ or ¾ length.

Patients with diabetes and accompanying sensory loss, deformity, and a history of ulceration will benefit from a custom molded orthotic with a medical shoe. It is recommended that diabetic custom insoles are constructed by a qualified specialist.



- **Clinical Guidance:** It is important to recognize that foot orthoses cannot be considered independent of a rehabilitation protocol that includes stretching and strengthening therapies. In addition, it is important to consider an individual's athletic regime, training surface, and current footwear. For diabetic individuals who have protective sensation loss, consider an extra depth shoe with compression molding inserts.
- **Evidence:**
  - A recent Cochrane review demonstrated only limited evidence for the effectiveness of foot orthoses in treating knee osteoarthritis.<sup>8</sup> However, the scientific basis for applying wedged insoles to offload an arthritic tibiofemoral compartment is well-documented.<sup>39</sup>
  - In-shoe orthotics are a beneficial intervention for preventing diabetic foot ulcerations, due to their cushioning and pressure re-distribution effects.<sup>46</sup>

- Evidence exists to support orthoses for the treatment of plantar fasciitis.<sup>2,47</sup> Customized semi-rigid insoles appear to have greater benefit than over-the-counter orthotics.<sup>28</sup>
- The use of foot orthotics to treat patellofemoral pain demonstrates small to moderate benefits, at best. Treatments are variable, and the research in this area is not definitive.<sup>5,18,27,28</sup>
- The evidence supports the use of foot orthoses to prevent a first occurrence of lower limb overuse. However, there is no definitive difference between custom and pre-fabricated orthoses. The evidence was insufficient to recommend foot orthoses of any type for the treatment of lower limb overuse conditions.<sup>15</sup>
- Custom-made orthoses are effective for painful pes cavus (rigid, high-arched) individuals.<sup>9,26</sup>
- Evidence demonstrates that custom-designed and semi-rigid orthoses and special shoes are likely to be beneficial in patients with rheumatoid arthritis. However, further research is necessary.<sup>22</sup>

## WALKING AIDS

### ❖ Canes

- **Indications:** Used in individuals with minimal to moderate balance deficits or those who have an antalgic gait.
- **Clinical Guidance:** Can offload the opposite lower extremity by 40-60%.



### ❖ Crutches

- **Indications:** Used for those individuals with minimal balance deficits after an injury or surgery.
- **Clinical Guidance:** Aluminum crutches are easier to adjust; however, wooden crutches are more durable.



### ❖ Walkers

- **Indications:** Used for individuals who can ambulate, but require assistance due to weakness or balance deficits.
- **Clinical Guidance:** Front-wheeled walkers are the most stable. They are available in many different frames and options, including standard folding, bariatric use, and fold-down seats. Four-wheeled walkers with a seat offer moderate support and are best for those who may need intermittent rest while walking. Four-wheeled walkers do require more frequent maintenance and should not be propelled with weight on the seat.



## WHEELCHAIRS

- **Indications:** Used for individuals with a reduced ability to walk due to neuromuscular or orthopedic pathology.
- **Clinical Guidance:** Wheelchairs are not appropriate for patients with back or radicular pain. In most instances, wheelchairs should be used on a short-term basis, and ambulation should be encouraged. Patients with spinal cord injuries require a lightweight or ultralight wheelchair and should be professionally fitted for the appropriate wheelchair and cushion.



## WRIST SUPPORTS

- **Indications:** May be used in patients with carpal tunnel syndrome or rheumatoid arthritis.
- **Evidence:**
  - Patients with rheumatoid arthritis tend to prefer working wrist splints, but there is not strong evidence to demonstrate the effectiveness of wrist supports in pain reduction, decreased swelling, or improved grip strength.<sup>20</sup>
  - A Cochrane review demonstrated improved symptoms after four weeks in patients with carpal tunnel syndrome. Symptom duration of less than three months and absence of sensory impairment at presentation are predictive of a lasting response to conservative management.<sup>24</sup> No systematically sound studies to demonstrate benefit in patients with tendinitis or De Quervain's tenosynovitis. There is no evidence to support use in individuals with a "trigger finger."<sup>42</sup>
  - Nonsurgical management of De Quervain's tenosynovitis, consisting of corticosteroid injections and supportive thumb spica splinting, is usually successful.<sup>29</sup>



## WOUND CARE

- Includes mattresses, shower cushions, medical footwear, wound healing shoes, and compression.
- Please refer to the BOP Clinical Practice Guidelines on *Prevention and Management of Acute and Chronic Wounds, Appendix 3: Durable Medical Equipment (DME) Resources*. Available at: [http://www.bop.gov/resources/health\\_care\\_mngmt.jsp](http://www.bop.gov/resources/health_care_mngmt.jsp)

## TENS UNITS

- **Indications:** Most appropriate for patients with chronic pain, such as: diabetic neuropathy, postherpetic neuralgia, phantom pain after amputation, and complex regional pain syndrome.
- **Caution:** TENS is contraindicated in those with a pacemaker or implantable cardioverter defibrillator.
- **Clinical Guidance:** TENS is a battery-operated device that uses electrodes placed on the skin to deliver low-voltage transcutaneous electrical stimulation for pain control. Although TENS is widely used in the treatment of chronic pain, definitive use remains unclear due to poor study methodology. There is no definitive evidence for the use of TENS as an isolated treatment for individuals with acute pain.<sup>23</sup>
- **Evidence:**
  - A TENS trial is considered an important nonpharmacological component in the management of chronic neuropathic pain.<sup>12</sup> One study showed that TENS applied weekly, and then once every month, reduced the pain and discomfort of peripheral neuropathy in 83% of diabetic patients.<sup>34</sup>
  - In a Cochrane Systematic Review, it was unclear whether TENS units are beneficial in reducing back pain intensity or have any role in reducing chronic low back pain.<sup>31</sup>
  - In another review, pain relief for knee osteoarthritis could not be ascertained.<sup>44</sup>
  - Systematic reviews have demonstrated conflicting evidence for patients with rheumatoid arthritis.<sup>7</sup>
  - There is some evidence to suggest that TENS units may aid in reducing pain in patients with peripheral neuropathy.<sup>30</sup>
  - No conclusive benefit was demonstrated in a Cochrane Systematic Review for patients with neck pain.<sup>33</sup>
  - There is insufficient evidence demonstrating relief of pain in cancer patients (Cochrane database).<sup>43</sup>
  - Evidence for use in patients with chronic pain is inconclusive.<sup>41</sup>
  - Overall study quality is poor, and research is evolving for further use of TENS.



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