ANALYSIS OF AND RESPONSES TO PUBLIC COMMENTS
Off-The-Shelf (OTS) Orthotics List
(August 2013)

INTRODUCTION

Section 1847(a)(2) of the Social Security Act defines Off-The-Shelf (OTS) orthotics as those orthoses described in section 1861(s)(9) of the Act for which payment would otherwise be made under section 1834(h) of the Act, which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Orthoses are described in section 1861(s)(9) of the Act as leg, arm, back, and neck braces.

The Medicare Benefit Policy Manual (Publication 100-02), Chapter 15, Section 130 provides the longstanding Medicare definition of "braces" as "rigid or semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body." The Centers for Medicare & Medicaid Services (CMS) regulations at 42 CFR 414.402 also define the term "minimal self-adjustment" to mean an adjustment that the beneficiary, caregiver for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification (ABC) in Orthotics and Prosthetics, Inc, or by the Board of Certification (BOC) for Orthotist/Prosthetist) or an individual who has specialized training.

The CMS issued guidance that initially identified specific Healthcare Common Procedure Coding System (HCPCS) codes that were considered OTS orthoses. CMS solicited public comments on the list of OTS HCPCS codes. We received approximately 185 comments pertaining to the proposed OTS orthotics list. There was no general consistency between the

various commenters on which specific HCPCS codes the commenters believed were appropriately deemed OTS.

CMS received comments from various experts in the field of orthotics, including but not limited to certified prosthetic/orthotic (CPOs) practitioners, physical therapists (PTs), occupational therapists (OTs), general medical doctors, physiatrists, registered nurses, the Veterans Administration (VA), and industry representatives. Input from each of these entities has been included into the final OTS list.

We received electronic and hard copy letters from orthotics and prosthetic practitioners and providers; durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, providers and manufacturers; national trade associations, advisory committees, and State certification, credentialing, and licensure boards. All public comments were reviewed and grouped by the same or related topics. Many commenters expressed their support for the proposed list while others made numerous useful recommendations to improve the OTS list. All of these suggestions and comments have been carefully examined and considered when finalizing the OTS list. The comments and our responses are summarized below.

A. GENERAL COMMENTS

Comment: Several commenters voiced concerns that the proposed OTS list contained HCPCS codes that reflected orthoses that require intimate adjustments that should be performed only by qualified practitioners, certified orthotists (COs), or CPOs who have specialized training and skills to trim, bend, cut, or build an orthosis from components. Several commenters stated that certain HCPCS codes come as a kit that requires trimming of excess foam and contouring of metal uprights. In addition, devices are routinely remolded and shaped to accommodate unique and complex issues much more than a minimal amount. Frequent issues such as abnormal tone

from neurological conditions such as stroke, Parkinson's disease, Multiple Sclerosis, and traumatic brain injuries require specialized devices within a code category.

Response: After considering all comments received on the initial OTS list, we have identified HCPCS codes that describe items that are never furnished OTS, HCPCS codes that describe items that are always furnished OTS, and HCPCS codes that describe items that may or may not be furnished OTS, depending on whether more than minimal fitting and adjustment of the device by experts is necessary for the individual patient. We are therefore exploding the HCPCS codes for items that may or may not be custom fitted, depending on each individual patient's needs, into separate codes that describe the item when it has been furnished OTS and when it has been custom fitted (i.e., when more than minimal fitting and adjustment of the device by experts is necessary) for the individual patient.

Comment: One commenter stated that we should consider adding to the OTS list tennis elbow braces, wrist braces, neck braces, knee braces, and ankle braces all commonly sold by standard size.

Response: We have thoroughly reviewed the HCPCS code set and believe we have identified all of the orthoses that may be provided OTS.

Comment: Several commenters suggested that certain HCPCS codes on the OTS list are used postoperatively and need to be adjusted to hold the pertinent body part in proper anatomical alignment to have the optimum outcome from the surgery. In addition, some of the items have rigid panels that must be customized by heating and/or trimming to properly contour the orthosis to the patient's anatomy.

Response: The creation of an OTS list does not preclude a CO or CPO from providing these items. These items may be provided in any setting that is deemed appropriate. For those

devices we have found may be modified, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

Comment: One commenter stated that the "fitting and adjustment" code descriptor pre-supposes that the patient will have follow-up and the brace adjusted as the patient wears it and their shape or condition changes. A supplier without specialized training would not be able to follow-up with the patient and check for possible complications from an improperly fit or adjusted brace and this can result in harm to the patient. Several commenters stated as long as "fitting and adjustment" are a requirement for the L code, a qualified practitioner must be the provider. One commenter stated the CMS website states that OTS orthoses does not require expertise to fit the beneficiary. Therefore, the statement "includes fitting and adjustment" should be deleted from the description of the OTS orthoses.

Response: The term “includes fitting and adjustment” indicates that any fitting and adjustment that is provided when furnishing the item is included in the procedure code and corresponding allowed payment amount. Items being billed under HCPCS codes with this term, such as HCPCS code L0631, may only require minimal self-adjustment or may not be fitted or adjusted at all. For example, as part of a report issued in December 2012, titled Medicare Supplier Acquisition Costs for L0631 Back Braces (OEI-03-11-0600), the Office of Inspector General in the Department of Health and Human Services found that for one-third of Medicare claims for HCPCS code L0631 that they sampled, suppliers did not report providing fitting and adjustment services. As indicated above, to resolve this matter, we are exploding codes such as L0631 into two codes so that the items furnished OTS and for which custom fitting is not necessary can be billed under one code while items for which custom fitting by individuals with

appropriate expertise is medically necessary and is furnished can be billed under a second, separate code.

Comment: One commenter stated that the term OTS refers to products that can be purchased at a pharmacy or any retail outlet. The term OTS refers to items that require no experience at all in their fitting or their use. These items should consist of products that cannot align or control a joint or the functionality of any body part.

Response: The site of service for an orthotic has no bearing on whether the orthotic that is furnished and covered by Medicare requires minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The category of OTS orthotics is not limited to those items that are sold in drug stores and other retail outlets and may be furnished by certified orthotists or other DMEPOS suppliers.

Comment: One commenter stated that many of the codes in the OTS list are reserved for licensed dispensation in certain states. Another commenter stated many of the codes that CMS plans to designate as OTS are reserved for licensed dispensation in Ohio. One commenter stated many of the codes that CMS plans to designate as OTS are conflicting with dispensation in Texas. Another commenter stated in the state of Florida, and in many others, these items cannot even be sold OTS since the licensing laws do not permit it specifically because the authorities realized that it would compromise patient safety and well being by having untrained, ill qualified individuals handing these out. At a minimum, in the state of Florida, an individual must be a certified orthotic fitter to dispense most of the items included on the proposed OTS list.

Response: We have reviewed all comments from individual states and their licensed dispensation requirements. There was no consistent agreement among the states regarding which

HCPCS codes should be deemed OTS. However, we took into consideration their differing perspectives. Individual states have the authority to exercise regulatory authority over their respective professional licenses. These standards in no way preclude CMS from establishing Medicare policy.

Comment: Two commenters stated that if you allow on-line vendors to send orthopedic goods to patient's homes, the patient will not have a qualified professional fitting these items properly, adjusting, instructing, or any follow-up care. In addition, orthotists can recognize if the prescription is appropriate for the diagnosis or if there is a better option that could be recommended. Physicians rely heavily on orthotists for their expertise.

Response: The Medicare definition of orthotic does not indicate that the item must be custom fitted. Medicare covers orthotics that do not require custom fitting and the statute mandates that competitive bidding programs be phased in for these items. Physicians often prescribe specific products that do not require custom fitting and are appropriate for the patient. It is the physician's responsibility to evaluate the beneficiary and provide a written prescription ordering the orthosis they determine to be medically necessary.

Comment: One commenter stated that products that directly affect the biomechanical alignment, structural support, and ambulation of patients should be applied by trained, certified, and credentialed providers. Another commenter stated that range of motion is important to understand when bracing a patient. Placement of braces is important and without proper training, the brace could cause further strain or damage, or be ineffective in treating the condition.

Response: OTS orthotics require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the

individual. The definition specifically states "does not require expertise." The orthoses deemed OTS must meet this definition.

Comment: One commenter stated they have concerns that a majority of the codes have criteria that must be met is based on anatomical landmarks and these codes would now be fit by an individual without any medical training. There are codes on the list that have metal bars and joints that need to be contoured to a patient to match their anatomical shape while still maintaining the joints in square alignment.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

Comment: Several commenters stated fitting services provided by orthotic fitters are important to provide proper orientation with various braces including providing the service and addressing any questions. This would put complicated medical devices into the hands of patients/suppliers who have little to no training on how to properly apply or modify the equipment and eliminate the face to face assessment of the device's appropriateness. Other commenters stated a certified orthotic fitter and trained fitter should be fitting many of the braces considered OTS. Back braces need to be molded to a kyphotic/lordotic curve. Range of motion is important to understand when bracing a patient. Placement of the braces is important and

without proper training, the brace could cause further strain or damage or be ineffective in treating the condition. Several commenters stated products that directly affect the biomechanical alignment, structural support, and ambulation of patients should be applied by trained, certified, and credentialed providers.

Response: OTS orthotics by definition are orthoses which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The definition specifically states "does not require expertise." The orthoses deemed OTS must meet this definition. However, for those devices we have determined can be modified and require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

Comment: One commenter stated they believe there are a significant number of HCPCS on this list that should not be classified as OTS, there is a potential lack of appropriate HCPCS coding for the orthoses, and requests CMS release the HCPCS codes for the prefabricated and custom orthoses product categories, and hold a public meeting to discuss the HCPCS codes that are most appropriate for the OTS category with orthotic and prosthetic professionals.

Response: OTS orthotics by the definition are orthoses which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The definition specifically states "does not require expertise." The orthoses deemed OTS must meet this definition. However, for those devices we have determined can be modified and require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

Comment: Several commenters stated devices that are classified as having rigid or semi rigid components should always be adjusted and fit by COP or certified fitters. Items with components such as a semi rigid wire frame (e.g.: L0160), rigid or semi rigid plastic shells or panels (e.g.: L0460, 0625, 0626, 0637, 0639), or rigid metal frames (e.g.: L0466, 0668, 0633, 0637) can cause adverse pressures on spinal segments, and cause serious injury if not properly modified by trained personnel. Devices used to limit range of motion in extremities (eg: L1600, 1832, 1845, 4396, 4398), especially those with rigid or semi rigid frames or metal joints (L3710, 1850) if improperly fit can cause over rotation or over-correction of joints that can lead to serious re-injury of affected areas. Another commenter stated devices described by codes L0174, L0456, L0627, L0631, L0637, L1620, L1810, L1832, L1843, L1845, L1902, L1906, L3670, L3675, L3807, L3908, L3923, L4350, L4360, and L4386 often, if not always, require more than minimal adjustment to obtain a proper anatomical fit. Another commenter stated L3923, L3807, L0631, and L4396 are typically modified through use of a heat gun to fit individual patients and should not be on the OTS list. Another commenter stated L1832, L1843, L1845, L1847, L0639-L0627 and L0468-L0460 should not be on the OTS list. Another commenter stated L0639, L1832, L1843, L1845, L3807, and L4360 should not be on the OTS list. Two commenters stated L1843, L1845, L0637, L0631, L0456, L0172 should not be on the OTS list. Another commenter stated L0627 to L0454 - All those braces, LSOs and TLSOs - needs straps adjustments and heating and remolding of plastic parts to fit the patient better.

Response: We received many inconsistent opinions regarding what codes should not be considered OTS orthoses. We have evaluated each HCPCS code thoroughly and identified each of the codes which appropriately fit the OTS definition. However, we acknowledge that there are a variety of products in each HCPCS code and that some of these products allow for

modification. Therefore, for those devices we have found may be modified, we are creating new HCPCS codes that will available for use in those instances when these items require custom fitting for a specific individual. If the device does not require modifications and requires "minimal self-adjustment" performed by the beneficiary, caregiver for the beneficiary, or supplier the appropriate OTS code should be utilized.

Comment: One commenter stated they believe only L0120, L0172, L0980, L0982, L0984, L1820 and L3170 meet the definition of OTS orthoses. Another commenter stated only L0120, L1810, L1902, L3170, L3650-L3670, L3807 and L3809 should be on OTS list. One commenter stated they believe only L0120, L0980, L0982, L1830, L3100, L3170, L3650, L3908, L3917, L3923, L4370, and L4380 should be on the OTS list. One commenter stated they believe only L0120, L0621, L0625, L0984, L1810, L1820, L1830, L1836, L1902, L1906, L3100, L3170, L3807, L4350, L4370, L4380, and L4396 should be on the OTS list. Another commenter stated they believe only L0172, L0621, L0984, L1600, L1810, L1902, L1906, L3710, L3762, L3908, L4350, L4398 should be included on the OTS list. They believe that if an unqualified person fits the other devices there will be a poor health outcome.

Response: We received many inconsistent opinions regarding what codes should be exclusively OTS orthoses. We have evaluated each HCPCS code thoroughly and have identified each of the codes which appropriately fit the OTS definition. However, we acknowledge that there are a variety of products in each HCPCS code and that some of these products allow for modification. Therefore, for those devices we have found may be modified, we are creating new HCPCS codes that will available for use in those instances when these items require custom fitting for a specific individual. If the device does not require modifications and requires "minimal self-adjustment" performed by the beneficiary, caregiver for the beneficiary, or

supplier the appropriate OTS code should be utilized.

Comment: Two commenters stated they agree that the items on the list should be classified in the category of OTS. The access to these items has been severely limited.

Response: We have thoroughly reviewed each HCPCS code and have provided clarity on which HCPCS codes may be provided as OTS without expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

Comment: Two commenters stated physicians often depend on working with a trained orthotist as a team member, to make sure that the bracing that is ordered is appropriate and effective and fits correctly to achieve the physician's treatment goals. Physicians often don't have the training to know exactly what type of "knee brace" (there are many) is appropriate and best for a particular patient and depend on the expertise of the orthotist to help determine this. Medicare should not be paying for OTS devices that are fit by the supplier, and that the supplier does not have the ability or facility to make proper adjustments when the standard fit does not conform to the actual needs of the beneficiary.

Response: The relationship between the orthotist and the medical team should not change merely because certain HCPCS codes meet the statutory definition of OTS. The OTS list does not preclude a physician from seeking the orthotist's input to determine the most appropriate orthosis for an individual patient. It is the physician's responsibility to ensure the patient receives the most appropriate orthosis.

Comment: Two commenters stated knee braces L1845, L1843, and L1832 do require adjustments while fitting the patient. One commenter stated clinicians (i.e. orthotist or orthotic fitter) must have knowledge and training specifically in the biomechanics of the knee to insure proper placement. More specifically if a clinician put an "unloading" knee brace (L1843 and

L1845) on a patient that has degenerative joint disease (DJD) and the correction is placed on the wrong side of the knee then more damage will be caused and possibly will require surgery, or cause the patient to become disabled. Lumbar, thoracic, cervical orthosis L0631, LO637, L0456 and L0172 also require the proper training in biomechanics of the spine. When a clinician is dealing with a patient that has a compression fracture, stenosis, etc. if a brace is put on incorrectly then there could be more damage by the orthosis requiring additional surgery and again could cause the patient to be disabled. This commenter has dispensed over a 1000 braces and states 78% of these patients have had to be adjusted and or modified in one way or another.

Response: We have evaluated each HCPCS code thoroughly and identified each of the codes which appropriately fit the OTS definition. For those devices we have found can be modified we are creating new HCPCS codes that will available for use in those instances when these items require custom fitting for a specific individual.

Comment: One commenter stated releasing a list of OTS is very helpful in keeping providers in the loop of compliance and experience.

Response: We believe this code clarification will provide guidance regarding what items should be provided with the appropriate service per the OTS definition.

Comment: One commenter stated they have significant concerns about the potential for deleterious impacts on the future of patient safety, patient compliance, and quality outcomes if the following HCPCS codes are permanently included within the definition of OTS: L1902, L1906, L3100, L3170, L4360, L4370, L4380, L4386, L4396, and L4398. From the start, all of the codes listed are currently dispensed only with a prescription from a physician qualified to determine that such devices are necessary for the patient, and are usually utilized following post-traumatic surgeries, wound care – especially in diabetic patients where the outcome is preventing

lower extremity amputations resulting from diabetic wound complications, lower extremity bone fractures, etc. Based on the physician's prescription and the determination of the supplier providing the device, a range of product options exist that can meet the treatment goals for the patient. However, it takes the knowledge of the supplier, with the support of the prescribing physician, to determine the best device for each condition presented, and make the necessary adjustments and modifications specific to that patient and their condition. It would be irresponsible and detrimental to the well-being of the patient, and the desire of a positive outcome, to allow the patient to be able to walk into a CVS/pharmacy, a Walgreen's or a Walmart, and simply pick a device from a small selection and walk out of the store without the ability to consult with an on-site professional for proper fitting, modification, or instruction for use.

Response: We have evaluated each HCPCS code thoroughly and identified each of the codes which appropriately fit the OTS definition. For those devices we have found can be modified we are creating new HCPCS codes that will available for use in those instances when these items require custom fitting for a specific individual.

Comment: One commenter stated L0450 through L0460 and L0625 through L0639 - these codes are for TLSOs or LSOs that support or position the spinal column. Spinal devices must be fitted by a properly trained practitioner who understands the anatomy of the spine and how to position the patient to control the unwanted motion otherwise there is the potential for serious debilitating and irreversible damage to the patient (such as disc or nerve damage and subsequent pain or paralysis). L3915 and L3929- These are wrist/hand orthoses (WHO) and finger orthoses (FO) that are applying complicated corrective forces via elastic and/or turnbuckle sections. The direction and amount of force being applied is determined by the skill of the

practitioner who is fitting the orthosis. This can be done only with a properly trained practitioner with a complete knowledge of hand anatomy and positioning techniques.

Response: We have evaluated each HCPCS code thoroughly and identified each of the codes which appropriately fit the OTS definition. For those devices we have found can be modified, we are creating new HCPCS codes that will available for use in those instances when these items require custom fitting for a specific individual.

Comment: One commenter stated although some of these codes such as L0172 and L0174 do not require much in the way of adjustment or modification, they do require an expertise in fitting and sizing. In most cases, at our hospital based facility, we are dealing with a fracture of the spine, very often an unstable fracture, requiring delicate movements, and placement or the results can be disastrous in terms of the patients well being. Without proper spinal precautions carried out, the results could mean paralysis.

Response: We have determined that these devices meet the definition of OTS. However, this definition in no way precludes the device being provided by a skilled individual in a hospital environment.

Comment: Several commenters stated please place the prefabricated items (L3908, L4396, L0120, and L4350) in the Medicare DMEPOS supplier category of OR03 (Off-The-Shelf). The commenters stated they are a family owned business and need to be able to make a living.

Response: We have evaluated each HCPCS code thoroughly and identified each of the codes which appropriately fit the OTS definition. For those devices we have found can be modified, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual. The payment amounts for all

HCPCS L-codes include payment for necessary fitting and adjustment.

Comment: One commenter stated they strongly encourage CMS to meet with the O&P Alliance and in particular with AOPA (the American Orthotic and Prosthetic Association). The commenter had conversations with Joe McTernan (Director of Coding and Reimbursement) and Tom Fise (Executive Director) that they have offered/requested and are more than willing to meet with CMS to establish what level of expertise is required in order to properly and safely fit, adjust, and follow-up any orthosis.

Response: We met with the O&P Alliance and considered their suggestions before finalizing the OTS list.

Comment: One commenter stated we object to the following codes being considered as OTS as they include "fitting and adjustment" in the code language: L0450, L0454, L0456, L0460, L0466, L0468, L0621, L0623, L0625, L0626, L0627, L0628, L0630, L0631, L0633, L0637, and L0639. In addition, we do not believe that products assigned L0172 or L0174 codes should be classified as OTS products. We sell products with a warranty that guarantees the products, but that warranty is based on the requirement that a "licensed healthcare practitioner" apply the product. A decision to characterize a L0631 as an OTS orthotic would, therefore, void the warranty, and any subsequent improper sizing or fitting by untrained individuals can be expected to compromise patient care.

Response: The term "includes fitting and adjustment" indicates that any fitting and adjustment that is provided when furnishing the item is included in the procedure code and corresponding allowed payment amount. Items being billed under HCPCS codes with this term, such as HCPCS code L0631, may only require minimal self-adjustment or may not be fitted or adjusted at all. For example, as part of a report issued in December 2012, titled Medicare

Supplier Acquisition Costs for L0631 Back Braces (OEI-03-11-0600), the Office of Inspector General in the Department of Health and Human Services found that for one-third of Medicare claims for HCPCS code L0631 that they sampled, suppliers did not report providing fitting and adjustment services. As indicated above, to resolve this matter, we are exploding codes such as L0631 into two codes so that the items furnished OTS and for which custom fitting is not necessary can be billed under one code while items for which custom fitting by individuals with appropriate expertise is medically necessary and is furnished can be billed under a second, separate code.

B. CERVICAL ORTHOTIC (L0120 – L0174)

L0120: CERVICAL, FLEXIBLE, NON-ADJUSTABLE (FOAM COLLAR)

Comment: The majority of the commenters agreed this HCPCS code is an OTS orthosis. One commenter stated there are a variety of styles (with or without chin contours) and heights available, besides neck circumference and they believe a beneficiary wouldn't know what size was appropriate.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods, fabric based, preassembled, requiring minimal self-adjustment that conforms to the patient's anatomy by simple means of a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0160: CERVICAL, SEMI-RIGID, WIRE FRAME OCCIPITAL/MANDIBULAR SUPPORT

Comment: One commenter stated these devices are used for increased cervical immobilization over foam cervical collar providing increased immobilization over that of a simple foam collar and requires that the metal wire frame be contoured to the anatomy of the patient. Clinical application would determine whether or not advanced training is necessary to

fit this device. Provision for any application to cervical area should take into consideration appropriate fitting skills. Another commenter stated the device comes in multiple sizes and the patient must be measured and the correct size provided and fit. Once selected the device must be contoured to fit the patient, avoiding excessive pressure on the bony anatomy, especially the clavicle. It may also be necessary to adjust the collar to provide the desired flexion/extension position of the cervical spine. Several commenters stated improper fitting may cause mal-alignment resulting in nerve impingement; movement of skeletal fragments and puts the patient at further risk of spinal cord injury, ineffectiveness of the brace with the potential for increased pain, muscle spasm, and improper healing of the cervical injury/surgical procedure.

Response: We have included this HCPCS code on the final OTS list. The collar is an open-air design held in place with pre-molded occipital support. This cervical device is applied in the same or similar fashion as soft foam collars with a simple Velcro closure that can be applied by the individual. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these cervical devices fit within the scope of minimal self-adjustment. This cervical orthosis does not require custom fitting to the beneficiary by an individual with expertise.

L0172: CERVICAL, COLLAR, SEMI-RIGID THERMOPLASTIC FOAM, TWO PIECE

Comment: Several commenters stated these devices describe collars that stabilize the cervical spine, decreasing motion. This class of device requires a choice between 4 to 15 sizes to provide appropriately size and fit. This device is typically provided for stabilization of the cervical spine where moderate stabilization is required. The stabilization applied by the device needs to be evaluated by a professional to ensure proper clearance over bony prominences in order to prevent skin breakdown and adequate control of motion. Improper fitting may cause

mal-alignment resulting in nerve impingement or movement of skeletal fragments. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device. Another commenter stated the collar is often cut and trimmed to relieve pressure and make adjustments for hospital lines and tubes. All "flextabs" need to be bent to provide pressure dispersion and a customized fit. Several commenters stated that this device requires expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. In addition, other commenters stated do not include these devices on the OTS list as they require a certified fitters experience to fit and follow-up, device is used postoperatively and must hold the head in the optimum anatomical position for safety and healing of the surgery optimally.

Response: We have included this HCPCS code on the final OTS list. This plastizote cervical collar provides neutral alignment of the cervical spine when applied. The collar has contoured shoulder supports for stability, ventilation openings to reduce heat and moisture, and a maneuverable chin support for airway management. It is applied with adjustable bilateral Velcro hook and loop fasteners by the individual and is form fitting. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these cervical devices fit within the scope of minimal self-adjustment. This cervical orthosis does not require custom fitting to the beneficiary by an individual with expertise.

L0174: CERVICAL, COLLAR, SEMI-RIGID, THERMOPLASTIC FOAM, TWO PIECE WITH THORACIC EXTENSION

Comment: One commenter stated this device is available in separate component parts requiring appropriate size, selection, and fitting. When necessary the fronts and backs can be mixed to optimize fit for nonstandard heights, circumferences, or to achieve non neutral flexion angles. Once applied the anterior mandibular and posterior occipital sections are adjusted to

balance forces on the skeletal structures and provide well-distributed support of the spine. This device offers increased stabilization over other cervical orthoses as an anterior extension reduces flexion, due to its longer stabilization on the sternum. Improper fitting may cause mal-alignment resulting in poor healing, nerve impingement, and movement of skeletal fragments or spinal column damage. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device. Another commenter stated the collar is often cut and trimmed to relieve pressure and make adjustments for hospital lines and tubes. All "flextabs" need to be bent to provide pressure dispersion and a customized fit. Another commenter stated this device requires expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Sizing is a crucial step in fitting the product. The Vista TX cervical collar has a unique universal adjustment system. The Vista TX orthosis requires height, circumference adjustments to control specific motion. All "flextabs" need to be bent to provide pressure dispersion and a custom fit. Several commenters stated do not include this device on the OTS list as it requires intimate adjustments that should be performed only by qualified practitioners, CO or CPOs. It requires follow-up care be available.

Response: We have included this HCPCS code on the final OTS list. This plastizote cervical collar with thoracic extension provides neutral alignment of the cervical spine when applied. The collar has contoured shoulder supports for stability, ventilation openings to reduce heat and moisture, and a maneuverable chin support for airway management. Individuals can apply this device and secure it by Velcro hook and loop fasteners. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these cervical devices fit within the scope of minimal self-adjustment. This cervical orthosis does not require custom fitting to the beneficiary by an individual with expertise.

C. THORACIC ORTHOTIC (L0450 – L0639)

L0450: TLSO, FLEXIBLE, PROVIDES TRUNK SUPPORT, UPPER THORACIC REGION, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS WITH RIGID STAYS OR PANEL(S), INCLUDES SHOULDER STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated these devices are used for clinical scenarios emphasizing issues in thoracic spine from T12-T3. This is a fabric type spinal orthosis utilizing metal stays or moldable plastic inserts requiring special equipment (hydrocollator, etc) to sufficiently warm the panels and allow bending and/or trimming to accommodate varying patient anatomy. These devices come in multiple sizes and require proper sizing and contouring of stays/panels, which must be removed for modification and re-inserted in corset to ensure optimum fit and function. These devices are non-elastic in nature, emphasizing proper choice in size. Additionally they would need instruction, often repetitively, to ensure application of the device for appropriate function. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow-up care is essential following fitting of these types of devices. Another commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods, fabric based, preassembled, requiring minimal self-adjustment that conforms to the patient's anatomy by simple means of a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0454: TLSO FLEXIBLE, PROVIDES TRUNK SUPPORT, EXTENDS FROM SACROCOCCYGEAL JUNCTION TO ABOVE T-9 VERTEBRA, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS WITH RIGID STAYS OR PANEL(S), INCLUDES SHOULDER STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated the devices coded under L0454 provide stability over a surface area greater than those coded as L0450. Fitting will require increased expertise given the complexity of some of the devices included in this code category. Heating and trimming are methods of modifying such units requiring special equipment (hydrocollator, etc) to sufficiently warm the panels and allow bending and/or trimming to accommodate varying patient anatomy. Another commenter stated this TLSO is determined by multiple measurements, providing stabilization to the thoracic and lumbar spine. Sizing allows fitting of both neutral and pendulous patients, requiring the fitter to have more than a passing knowledge of anatomy for application. The devices come in 6 circumferences. Height of the devices must be properly selected to allow for standing and sitting without compromising overall fit and function of the device. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow-up care is essential following fitting of these types of devices. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device. Another commenter stated do not include these devices on the OTS list as they require a certified fitters experience to fit and follow-up.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items

require custom fitting for a specific individual.

L0456: TLSO, FLEXIBLE, PROVIDES TRUNK SUPPORT, THORACIC REGION, RIGID POSTERIOR PANEL AND SOFT ANTERIOR APRON, EXTENDS FROM THE SACROCOCCYGEAL JUNCTION AND TERMINATES JUST INFERIOR TO THE SCAPULAR SPINE, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISKS, INCLUDES STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated the same parameters apply as L0454 with increased complexity relative to fitting and clinical application. Some models come with separate anterior extension bars as shown above to provide additional stabilization to the torso, requiring drilling, heating, and shaping to achieve an appropriate fit requiring special equipment (hydrocollator, etc) to sufficiently warm the panels. This goes far beyond a simple OTS type of application. Another commenter stated this TLSO consist of a full-length posterior section that is secured with straps that attached to a rigid anterior apron front. The device requires measurements to select the appropriate size, bending of the posterior stabilizing portion of the device and trimming of the straps to achieve an optimal fit. The fitting of this device cannot be done without assistance and requires the fitter applies adjustment after the device to the patient. Once applied, the straps typically need to be further tuned to allow for standing and sitting without compromising the device function. As this patient typically has limited mobility often techniques need to be developed to permit device application. Follow-up instructions are commonly required. It would not be possible for this device to be fit by someone with an understanding of basic skeletal anatomy to appropriately position the device, to assure stabilization and to accommodate the variation in sitting and standing postural changes without causing irritation. Another commenter stated the Summit 456 needs to be accurately sized and the many components must be properly adjusted which takes training and a level of decision

making that results from clinical experience. The Summit 456 requires an increase or reduction of the lordosis to properly fit the specific Cobb angle and may require cutting to insure an optimal fit for some patients. The Summit 456 also requires a crucial height adjustment. If a specific height is not achieved, the product creates downward forces instead of a posterior pull. A downward force renders the product in effective. Several commenters stated do not include these devices on the OTS list as they need to be fitted by Prosthetist/Orthotist, Orthotist, or orthotic fitter and have follow-up care available. These devices are used postoperatively and should be adjusted to hold the torso in proper anatomical alignment to have the optimum outcome from the surgery.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0460: TLSO, TRIPLANAR CONTROL, MODULAR SEGMENTED SPINAL SYSTEM, TWO RIGID PLASTIC SHELLS, POSTERIOR EXTENDS FROM THE SACROCOCCYGEAL JUNCTION AND TERMINATES JUST INFERIOR TO THE SCAPULAR SPINE, ANTERIOR EXTENDS FROM THE SYMPHYSIS PUBIS TO THE STERNAL NOTCH, SOFT LINER, RESTRICTS GROSS TRUNK MOTION IN THE SAGITTAL, CORONAL, AND TRANSVERSE PLANES, LATERAL STRENGTH IS PROVIDED BY OVERLAPPING PLASTIC AND STABILIZING CLOSURES, INCLUDES STRAPS AND CLOSURES, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: Two commenters stated these devices are representative of two shelled TLSO that overlaps to interlock on the torso. Multiple measurements are required to ensure an

appropriately sized module. Sizing chart demonstrates both neutral and pendulous design, requiring the fitter to have more than a passing knowledge of anatomy for application. Modules are designed to be modified by the use of heat to compensate for potential areas of pressure. Plastic can be cut by scissors or machinery. Cut edges must be properly smoothed which cannot be done without some type of power tool. Trim lines must be properly configured to allow for standing and sitting without compromising overall fit and function of the device. Improper fitting may lead to exacerbation of orthopedic condition and issues with skin that can lead to breakdown. Follow-up care is essential following fitting of these types of devices. Application involves appropriate knowledge of patient positioning from supine to standing positions without causing injury to compromising fit of the device. Another commenter stated fitting the brace requires a clinical understanding of the appropriate positioning. Patient is then instructed on proper fitting via anatomical landmarks and instructed on proper application, removal, and care for brace per prescribed plan of care. An improper fit can lead to ineffectiveness of the brace with the potential for increased pain, muscle spasm, increased risk of re-injury, and improper healing of the spine injury/surgical procedure. Patient will follow-up at first post-op visit for evaluation and brace re-check. Several commenters stated the "fitting and adjustment" code descriptor presupposes that the patient will be followed up and the brace adjusted as the patient wears it and their shape or condition changes. A supplier without specialized training would not be able to follow-up the patient and check for possible complications from an improperly fit or adjusted brace and can do harm to the patient. Another commenter stated these braces can dig into the pubic region and rigid panel needs to be trimmed, a beneficiary who has a short waist may need proximal anterior shell trimmed down.

Response: We have removed this HCPCS code from the OTS list as these orthoses

require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.

L0466: TLSO, SAGITTAL CONTROL, RIGID POSTERIOR FRAME AND FLEXIBLE SOFT ANTERIOR APRON WITH STRAPS, CLOSURES AND PADDING, RESTRICTS GROSS TRUNK MOTION IN SAGITTAL PLANE, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISKS, INCLUDES FITTING AND SHAPING THE FRAME, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: Two commenters stated these devices are a rigid posterior paneled TLSO made of either metal (Freeman) or plastic (US Orthotics) with an apron front with multiple sized options. Posterior section must be appropriately shaped to ensure contact with torso. Depending on the design selected, modifications to ensure an appropriate fit must be performed via heat and cutting for the plastic model or bending irons or other orthotic specific tools for the metal model. Shaping and contouring require anatomical knowledge and clinical skills as well as familiarity in working with different materials. Improper application can result in less than proper function, adverse pressure applied to the spine and surrounding tissue, which could lead to skin breakdown and exacerbation of existing clinical issues. Application of such an orthosis will require follow-up care to ensure proper functioning. Several commenters stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up, device is used postoperatively and should be adjusted to hold the torso in proper anatomical alignment to have the optimum outcome from the surgery.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or

fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0468: TLSO, SAGITTAL-CORONAL CONTROL, RIGID POSTERIOR FRAME AND FLEXIBLE SOFT ANTERIOR APRON WITH STRAPS, CLOSURES AND PADDING, EXTENDS FROM SACROCOCCYGEAL JUNCTION OVER SCAPULAE, LATERAL STRENGTH PROVIDED BY PELVIC, THORACIC, AND LATERAL FRAME PIECES, RESTRICTS GROSS TRUNK MOTION IN SAGITTAL, AND CORONAL PLANES, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISKS, INCLUDES FITTING AND SHAPING THE FRAME, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated these devices are similar to L0466 but with the addition of rigid lateral frames to increase the functional stability, this rigid posterior paneled TLSO is made of either metal (Becker) or plastic (Freeman) with an apron front with multiple sized options. Posterior section must be appropriately shaped to ensure contact with torso. Depending on the design selected, modifications to ensure an appropriate fit must be done via heat and cutting for the plastic model or bending irons or other orthotic specific tools for the metal model. Shaping and contouring require anatomical knowledge and clinical skills as well as familiarity in working with different materials. Improper application can result in less than proper function, adverse pressure applied to the spine and surrounding tissue, which could lead to skin breakdown and exacerbation of existing clinical issues. Application of such an orthosis may require follow-up care to ensure proper functioning. Several commenters stated do not include on the OTS list as these devices are not minimal fit.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that

include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0621: SACROILIAC ORTHOSIS, FLEXIBLE, PROVIDES PELVIC-SACRAL SUPPORT, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: Several commenters stated this item should be included as an OTS item. One commenter stated fitting the brace requires a clinical understanding of the appropriate positioning and alignment of the brace to anatomical landmarks. The patient is instructed on proper fitting via anatomical landmarks and instructed on proper application (including appropriate lacer compression tension), removal, and care for brace per prescribed plan of care. An improper fit can lead to ineffectiveness of the brace with the potential for increased pain, muscle spasm, increased risk of re-injury, and improper healing of the sacroiliac injury/surgical procedure. Another commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up. One commenter stated specific instructions on orthotic wear are important.

Response: We have included this HCPCS code on the final OTS list. These devices are flexible pelvic-sacral supports which are primarily soft goods, fabric based, preassembled, requiring minimal self-adjustment that conforms to the patient's anatomy by simple means of a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0623: SACROILIAC ORTHOSIS, PROVIDES PELVIC-SACRAL SUPPORT, WITH RIGID OR SEMI-RIGID PANELS OVER THE SACRUM AND ABDOMEN, REDUCES MOTION ABOUT THE SACROILIAC JOINT, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated orthoses in this category provide support and compression for the sacroiliac joint (SI) as in SI joint syndrome (common during pregnancy). It stabilizes and relieves pressure on the pelvis and symphysis and, with its two-part visco-elastic cushion (pad), massages the sacroiliac joints. This stimulates circulation, thus helping the healing process. Another commenter stated there are a range of sizes. It includes anterior and posterior panels, which must be positioned properly and would prove more restrictive in motion. This device must be worn properly in order for it to function. Proper sizing is important and the patient must be educated on this proper positioning and warning signs. Several commenters stated do not include these devices on the OTS list as they require a certified fitters experience to fit and follow-up, when used for control of pelvic instability or fractures, it needs to be adjusted by a qualified practitioner to avoid negative outcomes. Another commenter stated specific instructions on wear are important. An overweight beneficiary may need panels adjusted.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods, fabric based, preassembled, requiring minimal self-adjustment that conforms to the patient's anatomy by simple means of a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0625: LUMBAR ORTHOSIS, FLEXIBLE, PROVIDES LUMBAR SUPPORT, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PENDULOUS ABDOMEN DESIGN, SHOULDER STRAPS, STAYS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated there is a large surface area of contact, and with that greater area is a broader range of sizing that must be properly evaluated. Items in this code category must also be provided based upon a patient's shape which will vary by length, circumference and contours of the abdomen and spine. As the items in this category are essentially non-elastic, there is less "forgiveness" of material, hence the importance of an appropriate fit. Also present may be stainless steel stays, which must be properly shaped, not only for comfort but for appropriate control of the lumbar portion of the spine. Often these items will be provided in a post surgical situation, requiring appropriate clinical understanding of mechanics in the application both standing and supine to ensure no injury during the fitting. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods, fabric based, preassembled, requiring minimal self-adjustment that conforms to the patient's anatomy by simple means of a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0626: LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID POSTERIOR PANEL(S), POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated spinal orthosis, usually one piece in nature, made of fabric that utilizes posterior panels to increase the rigidity of the base material. Strapping usually is of Velcro closures. On occasion, additional straps may extend to and include the shoulder for purposes of positioning and shoulder motion restriction. Another commenter stated this style orthoses may require heating and contouring of the rigid material in the posterior panel. This

technique is specialized to the trained orthotist. If not, edges may be left sharp without proper cutting and sanding equipment. Two commenters stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up, device used postoperatively and should be adjusted to hold the torso in proper anatomical alignment to have the optimum outcome from the surgery.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0627: LUMBAR ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM L-1 TO BELOW L-5 PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES,VERTEBRA, PRODUCES INTRACAVITARY MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated orthoses in this category are usually fabric in nature, designed with anterior and posterior rigid panels to provide additional stabilization to the lower spine. The posterior panel is usually heat molded, requiring special equipment (hydrocollator, etc) to sufficiently warm the panels, based on the contours of the specific patient, while the anterior panel provides additional abdominal compression for load reduction on the discs. On occasion, additional straps may extend to and include the shoulder for purposes of positioning and shoulder motion restriction. One commenter stated the forces implemented by the brace to

control sagittal control with this bi-valve rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical location to prevent unwanted motion direction then the patient puts themselves at a higher risk of injury. The trim lines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure skin integrity and prevent skin breakdown. The amount of intracavitary pressures provided by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be reviewed with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces. Another commenter stated this device is not soft goods and not minimal fit. Another commenter stated needs to be accurately sized and the components must be properly adjusted and properly locked in place and a level of decision making that comes from clinical experience. The QuikDraw RAP also may require heating and bending to increase or reduction of the lordosis to properly fit the specific Cobb angle. The anterior panel must be adjusted to fall in the center of the abdomen. The patient must be educated as to how to properly utilize the independent top and bottom compression mechanism to ensure proper use and fit. Several commenters stated do not include these devices on the OTS list as they require a certified fitters experience to fit and follow-up, these devices are used postoperatively and should be adjusted to hold the torso in proper anatomical alignment to have the optimum outcome from the surgery.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or

fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0628: LUMBAR-SACRAL ORTHOSIS, FLEXIBLE, PROVIDES LUMBO-SACRAL SUPPORT, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this orthoses requires exact sizing and measurements. When fit incorrectly, the orthoses will be extremely difficult to tolerate and would cause discomfort to the lumbar spine as well as cause skin irritation. Heat molding and bending of the posterior panel requires specific training and special equipment (hydrocollator, etc). Two commenters stated these devices need to be fitted by CPO, CO, or orthotic fitter and have follow-up care available.

Response: We have included this HCPCS code on the final OTS list. These orthoses are spinal orthoses that are easy to adjust using preformed panels with a Velcro closure system. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0630: LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID POSTERIOR PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated these devices provide compression and stabilization to lumbar, sacral, and abdominal regions. Rigid posterior insert offers increased support. These are spinal orthosis, usually one piece in nature, made of fabric that utilizes posterior panels to increase the rigidity of the base material. Strapping is usually made of Velcro closures. On occasion, additional straps may extend to and include the shoulder for purposes of positioning and shoulder motion restriction. Similar to L0626 but extends to a higher spinal level of control. Another commenter stated the forces implemented by the brace to control sagittal control with this rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate anatomical location to prevent unwanted motion direction then the patient puts themselves at a higher risk of injury. The trim lines of posterior and anterior rigid panel and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provide by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The strapping configuration and appropriate tightness of the straps needs to be review with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces. Several commenters stated do not include on the OTS list as these devices need to be fitted by a CPO, CO, or orthotic fitter and have follow-up care available.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals

with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0631: LUMBAR-SACRAL ORTHOSIS, SAGITTAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated orthoses in this category are usually fabric in nature, designed with anterior and posterior rigid panels to provide additional stabilization to the lower spine. The posterior panel is usually heat molded, requiring special equipment (hydrocollator, etc) based on the contours of the specific patient, while the anterior panel provide additional abdominal compression for load reduction on the discs. On occasion, additional straps may extend to and include the shoulder for purposes of positioning and shoulder motion restriction. These devices are similar to L0627 but extend to a higher spinal level of control. Another commenter stated the forces implemented by the brace to control sagittal control with this rigid device need to be evaluated by a professional to ensure or maintain skin integrity and prevent skin breakdown. If the forces are not directed in the appropriate anatomical locations to prevent unwanted motion direction then the patient puts themselves at a higher risk of injury. The amount of intracavitary pressures provided by the brace needs to be assessed to ensure an appropriate pressure. The strapping configuration and appropriate tightness of the straps needs to be reviewed with the patient. Poorly adjusted straps decrease the overall effectiveness of the brace and increase the risk of injury with poorly directed strap forces. Several commenters stated do not include on the OTS list as this device requires a certified fitters experience to fit

and follow-up, the device is used postoperatively and should be adjusted to hold the torso in proper anatomical alignment to have the optimum outcome from the surgery.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0633: LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, WITH RIGID POSTERIOR FRAME/PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, LATERAL STRENGTH PROVIDED BY RIGID LATERAL FRAME/PANELS, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, STAYS, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated an LSO that is framed with either plastic or metal that extends from the posterior aspect of the spine to lateral mid-points on the torso. It has an anterior component usually made of fabric, but can be plastic, used to position the posterior section onto the torso and to provide anterior compression on the abdomen for spinal disc unloading. Shoulder straps may be optional in order to assist with device positioning and restriction motion for additional spinal stabilization. Devices that have rigid frames provide increased stabilization relative to the fabric design but also require additional expertise when it comes to fitting and follow-up. Clinical applications are similar to other spinal devices. The inherent frame designs increase the stabilization factor many times. Several commenters stated

this orthoses requires specific sizing, heating, and bending during the initial fitting requiring special equipment (hydrocollator, etc). Another commenter stated fitting the brace requires a clinical understanding of the appropriate positioning and alignment of the brace to anatomical landmarks. Patients are instructed on proper fitting via anatomical landmarks and instructed on proper application, removal, and care for brace per prescribed plan of care. An improper fit can lead to ineffectiveness of the brace with the potential for increased pain, muscle spasm, increased risk of re-injury, and improper healing of the lumbar injury/surgical procedure. Several commenters stated do not include on the OTS list as these devices need to be fitted by CPO, CO, or orthotic fitter and have follow-up care available.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0637: LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, WITH RIGID ANTERIOR AND POSTERIOR FRAME/PANELS, POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, LATERAL STRENGTH PROVIDED BY RIGID LATERAL FRAME/PANELS, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON INTERVERTEBRAL DISCS, INCLUDES STRAPS, CLOSURES, MAY INCLUDE PADDING, SHOULDER STRAPS, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated an LSO that is framed with either plastic or metal that extends from the posterior aspect of the spine to lateral mid-points on the torso. It is similar to

L0633 but utilizes an anterior and posterior frame and/or panel design. The anterior component is usually rigid in nature, often plastic, as opposed to that of L0633 where it is commonly fabric. It is used to position the posterior section onto the torso and to provide anterior compression on the abdomen for spinal disc unloading. Shoulder straps may be optional in order to assist with device positioning and restriction motion for additional spinal stabilization. Devices that have rigid frames provide increased stabilization relative to the fabric design but also require additional expertise when it comes to fitting and follow-up. Another commenter stated the forces implemented by the brace to control sagittal and coronal control with this bi-valve rigid device need to be evaluated by a professional. If the forces are not directed in the appropriate direction to prevent unwanted motion direction then the patient puts themselves at a higher risk of injury. The trimlines of posterior, anterior, and lateral rigid panels and pressures over bony prominences encompassed by the brace needs to be evaluated by a professional to ensure maintain skin integrity and prevent skin breakdown. The amount of intracavitary pressures provided by the brace needs to be assessed to ensure an appropriate amount of force is being applied and abdominal structures and internal organs are not being constricted due to excessive pressures. The Vista LSO also requires an increase or reduction of the lordosis to properly fit the specific Cobb angle and may require cutting to insure an optimal fit for some patients. The Vista LSO also requires a circumferential adjustment of over 40 inches. The system is purchased fully assembled however, 85% of patients will require removal and adjustment of a minimal of one of the many components comprising the Vista LSO. Several commenters stated needs to be fitted by CPO, CO, or orthotic fitter and have follow-up care. In addition, the "fitting and adjustment" code descriptor presupposes that the patient will be followed up and the brace adjusted as the patient wears it and their shape or condition changes. A supplier without specialized training

would not be able to follow-up the patient and check for possible complications from an improperly fit or adjusted brace and can do harm to the patient.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L0639: LUMBAR-SACRAL ORTHOSIS, SAGITTAL-CORONAL CONTROL, RIGID SHELL(S)/PANEL(S), POSTERIOR EXTENDS FROM SACROCOCCYGEAL JUNCTION TO T-9 VERTEBRA, ANTERIOR EXTENDS FROM SYMPHYSIS PUBIS TO XYPHOID, PRODUCES INTRACAVITARY PRESSURE TO REDUCE LOAD ON THE INTERVERTEBRAL DISCS, OVERALL STRENGTH IS PROVIDED BY OVERLAPPING RIGID MATERIAL AND STABILIZING CLOSURES, INCLUDES STRAPS, CLOSURES, MAY INCLUDE SOFT INTERFACE, PENDULOUS ABDOMEN DESIGN, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated devices in this category are usually plastic in nature, though some may have a frame design. The plastic is usually total contact, either a single circumferential shell, or a two piece (bi-valved) design. It may have a soft lining that is used to reduce pressure off of the skin secondary to the total contact nature. The orthosis usually has multiple straps for adjustability. This design provides the maximum amount of functional support in the classification of spinal orthoses. It is commonplace for the plastic to be modified with heat requiring special equipment (hydrocollator, etc) to sufficiently warm the panels and trimming to obtain the best fit, as the exacting nature of the design must accommodate each patient's unique anatomy, especially bony prominences. Another commenter stated the lumbar-

sacral orthosis is a rigid device which limits motion. This device provides circumferential support and total contact which requires the following: accurate measurement, proper device assessment, and skilled fitting and delivery. The critical areas of fit involve angle of lordosis, assessment of existing deformity, and proper height. In the event of poor assessment and fit, the result could be pain, open wounds, or additional negative outcomes. Several commenters stated requires specialized training, skill to trim, bend, cut, or build from components, etc. to assure they are properly fit within the anatomical landmarks described in the code. Patients without specialized training would not be able to assure these landmarks are met.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

D. ADDITIONS TO SPINAL ORTHOTIC (L0980 – L0984)

L0980: PERONEAL STRAPS, PAIR

Comment: One commenter stated these devices are appropriately classified as OTS. Another commenter stated these straps are most commonly used as an addition to a spinal orthosis, whether the orthosis is custom-fabricated or custom-fitted. Their primary use is to keep the orthosis from migrating proximally ("riding up") on the patient. They are important in maintaining the proper relationship of the orthosis to the body. If the orthosis migrates out of its

proper orientation, the control of the orthosis and its stabilizing effect will be negated. The straps are available prefabricated but also may require custom fabrication for patients who are obese or of unusual anatomical shape. The proper adjustment of these straps is required to maintain the orthosis in its intended position. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods; fabric based, preassembled, and requires minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0982: STOCKING SUPPORTER GRIPS, SET OF FOUR (4)

Comment: One commenter stated appropriately classified as OTS. Another commenter stated these grips are typically used in conjunction with a custom-fabricated or custom-fitted spinal orthosis. As an addition to a spinal orthosis, they have two potential functions. They may be used to support thigh-high stockings or compression hose to prevent them from migrating distally. Alternately, these may be attached to thigh-high hose to keep the spinal orthosis they are attached to from migrating proximally. In either case, they need to be appropriately adjusted to maintain the correct positioning of either the stockings or the spinal orthosis.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods; fabric based, preassembled, and requires minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L0984: PROTECTIVE BODY SOCK, EACH

Comment: One commenter stated appropriately classified as OTS. Another commenter stated a protective body sock is typically used as an addition to a custom fabricated or custom-fitted spinal orthosis. Its purpose is to provide a protective interface between the orthosis and the

patient's skin. The sock must be appropriately sized by taking measurements of the patient to ensure an intimate fit. A correct fit of the protective body sock is imperative because the spinal orthosis will be securely tightened over the sock. A poorly sized or fitted sock could result in wrinkling or bunching under the orthosis resulting in excessive pressure, discomfort or skin break-down. The sizing and fitting of this sock is best done by a trained professional who can also give appropriate application and use instructions to the patient at the time of fitting.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods; fabric based, preassembled, and requires minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

E. HIP ORTHOTIC – FLEXIBLE (L1600 – L1620)

L1600: HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, FREJKA TYPE WITH COVER, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this code describes a particular hip abduction orthosis which is used in the treatment of infants with congenital hip dysplasia or congenitally dislocating or subluxing hips. The function of the orthosis is to position the hips in flexion and abduction to maintain the proper positioning of the femoral heads in the acetabulum. Over the typical wearing period of approximately one to two months, the position maintained by the orthosis allows the ligamentous structures above the hip to tighten while the femoral head and acetabulum model together for the optimal conformity and congruency of the two structures. The appropriate sizing of the orthosis and subsequent fitting of the orthosis on the child requires specialized training. If this orthosis is not properly fitted, there can be profound consequences for the infant including pain, a functional leg length discrepancy, early on-set hip arthritis or the possible need for surgical reduction of the hip. Another commenter stated the Frejka pillow is a thick, layered or padded material with adjustable shoulder straps. It is designed to reduce

stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Inappropriate fit can result in inability to ambulate, painful ambulation, required surgical intervention or multiple poor outcomes. Several commenters stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up, device used postoperatively and for dislocations of femur from acetabulum. Another commenter stated the code could be redefined as not requiring "fitting and adjustment" in the descriptor. One commenter stated these are used on infants to correct a certain type of congenital hip defect. The period of time in which this defect can be corrected successfully is extremely short and therefore requires precise positioning immediately. This can be done only with a properly trained practitioner with the knowledge of hip anatomy and positioning techniques.

Response: We have removed this HCPCS code from the OTS list as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.

L1610: HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, (FREJKA COVER ONLY), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this code represents a replacement cover for the Frejka hip reduction orthosis. A replacement cover such as this would typically be provided by the professional who custom-fitted and adjusted the Frejka hip abduction orthosis, as this practitioner would know the appropriate size of the cover to be replaced. Another commenter

stated the Frejka pillow is a thick, layered or padded material with adjustable shoulder straps. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Inappropriate fit can result in inability to ambulate, painful ambulation, required surgical intervention or multiple poor outcomes. In the event of cover change, the same fitting criteria are required. The replacement of the cover requires reapplication and same fitting criteria as with the original device. Several commenters stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up, device used postoperatively and for dislocations of femur from acetabulum. Another commenter stated code could be redefined as not requiring "fitting and adjustment" in the descriptor. Another commenter stated do not include - devices in this category are routinely remolded and shaped to accommodate unique and complex issues much more than a minimal amount. Frequent issues such as abnormal tone from neurological conditions such stroke, Parkinson's disease, Multiple Sclerosis, and traumatic brain injuries require specialized devices within a code category.

Response: We have removed this HCPCS code from the OTS list as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.

L1620: HIP ORTHOSIS, ABDUCTION CONTROL OF HIP JOINTS, FLEXIBLE, (PAVLIK HARNESS), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this code describes a particular hip abduction orthosis which is used in the treatment of infants with congenital hip dysplasia or congenitally dislocating or subluxing hips. The function of the orthosis is to position the hips in flexion and abduction to maintain the proper positioning of the femoral heads in the acetabulum. Over the typical wearing period of approximately one to two months, the position maintained by the orthosis allows the ligamentous structures above the hip to tighten while the femoral head and acetabulum model together for the optimal conformity and congruency of the two structures. The appropriate sizing of the orthosis and subsequent fitting of the orthosis on the child requires specialized training. If this orthosis is not properly fitted, there can be profound consequences for the infant including pain, a functional leg length discrepancy, early on-set hip arthritis or the possible need for surgical reduction of the hip. Another commenter stated the Pavlik harness is made of webbing, straps, foam, and Velcro. It is designed to reduce stresses across the affected hip joint or joints of newborns and infants. It is designed to maintain the femoral head to be contained within the acetabulum, while the hip joint is stabilized bilaterally at the end desired degrees of abduction as well as the desired degrees of internal rotation. Professional fit is essential for the proper degrees and limited range of motion. Biomechanically correct strap position is required for maximum effectiveness in treating hip dysplasia. If straps are applied incorrectly it will prevent the hip from forming in the correct alignment which can result in dislocation, inability to ambulate, painful ambulation, or required surgical intervention. Another commenter stated it is a harness made of canvas straps, Velcro, and buckles. It serves to keep the legs apart and at the correct angle. Each week or two in the beginning of treatment, the position of the harness will be checked by the doctor or nurse practitioner and probably adjusted. This will allow for natural growth, keeping the hip joint in the best position. Several

commenters stated do not include on the OTS list - as the infant must be fitted and adjusted by a qualified practitioner and this will require follow-up care. Another commenter stated code could be redefined as not requiring "fitting and adjustment" in the descriptor. One commenter stated this device is used to treat infants born with a dislocated hip(s), it is also used to treat infants with femur fractures. If applied improperly it may disrupt the blood supply to the femur and cause the bone to die. These problems are well documented in orthopedic literature. Also, if the infant is not scheduled for frequent follow-up visits to accommodate for growth, this complication may also occur. Orthotists and only some physicians have the training to apply these devices properly.

Response: We have removed this HCPCS code from the OTS list as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.

F. KNEE ORTHOTIC (L1810-1850)

L1810: KNEE ORTHOSIS, ELASTIC WITH JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated there are literally hundreds of orthoses that fit the L1810 classification. The vast majorities of these orthoses are utilized and require little if any adjustment to the orthosis or knee joints. They are primarily used for knee sprains, strains, partial tears of the medial collateral ligament (MCL) and lateral collateral ligament (LCL), and occasionally for arthritic patients and patients with mild valgus or varus instability. Because of code consolidation however, this classification is very broad and contains some orthoses that include joints that are adjustable for range of motion and that are contoured to the patient’s limb

anatomy. Because of these outliers, this HCPCS code should not be classified as OTS despite their wide availability over the internet and at retail locations. In the alternative, devices under this code that require adjustments due to range of motion or limb anatomy should be segregated and recoded under the HCPCS coding system as a non-OTS code. Another commenter stated the knee orthosis is made of elastic, neoprene, or like materials with hinged joints medially and laterally positioned over the knee joint. This device provides mild medio-lateral stabilization, circumferential support, and resists hyperextension. The metal knee joints require proper adjustments to accommodate anatomical angles. Inappropriate fit puts the patient at risk of tourniquet injury and wounds resulting from inappropriate pressure on bony prominences and other negative outcomes. Two commenters stated needs to be fitted by Prosthetist/Orthotist, Orthotist, or orthotic fitter and have follow up care available.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L1830: KNEE ORTHOSIS, IMMOBILIZER, CANVAS LONGITUDINAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated they agree this device should be an OTS item. Another commenter stated knee immobilizers are made of foam, nylon straps, and Velcro to secure the brace in place. It serves to keep the leg in a position to allow proper healing after

surgery or injury. The aluminum stays posterior and medial/lateral on the leg need to be contoured in the correct position for optimal healing. The clinician placing the knee immobilizer must follow the contour of the leg from mid thigh to the ankle to ensure the leg is in proper position and fully restricts the knee range of motion. Clinician adjustments will also occur during usage as the patient often has thigh and calf atrophy. Another commenter stated fitting the brace requires a clinical understanding of the appropriate positioning and alignment of the brace to anatomical landmarks. The patient is then instructed on proper fitting via anatomical landmarks and instructed on proper application, removal, and care for brace per prescribed plan of care. An improper fit can lead to ineffectiveness of the brace with the potential for increased pain, increased risk of re-injury and improper healing of the knee injury/surgical procedure.

Response: We have included this HCPCS code on the final OTS list. Knee immobilizers are made from a variety of materials utilizing Velcro closures to secure the orthosis in place. These orthoses are easy to adjust using preformed stay(s) with a Velcro closure system. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L1832: KNEE ORTHOSIS, ADJUSTABLE KNEE JOINTS (UNICENTRIC OR POLYCENTRIC), POSITIONAL ORTHOSIS, RIGID SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this class of orthoses almost always includes knee joints with adjustable range of motion (ROM), selective locking mechanisms and sometimes telescoping joints. The range of diagnoses includes simple knee and leg injuries to complex post-operative use in knee ligament repairs and total knee replacements to name a few. Because of the complexity of the clinical applications this code should not be considered for OTS.

Another commenter stated this device is indicated for locked or limited motion control of knee during rehabilitation after operative procedures or injury to knee ligaments, cartilage, or stable or internally fixed fractures of tibial plateau, condyles, or proximal tibia and distal femur. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align and apply this device may lead to further injury of the knee. Another commenter stated this knee orthosis has straps, rigid uprights, and range of motion stops in order for the brace to be properly fit and secured on the leg. The uprights need to be aligned and contoured to the leg to ensure the knee is in proper healing position, thereby allowing the proper range of motion required post injury or surgery. The uprights are bent to properly contour to the leg, but this can only be accomplished by the medical professional to ensure the correct knee alignment. The range of motion must only be adjusted by a physician or medical professional to ensure the post injury or post surgery protocol is followed correctly. The straps can be modified to create the best fit for the patient's leg. The fitting and adjusting should only be done by a physician or medical professional to confirm accurate brace placement and fit for patient safety and proper healing.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items

require custom fitting for a specific individual.

L1836: KNEE ORTHOSIS, RIGID, WITHOUT JOINT(S), INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device can be classified as OTS. Another commenter stated these orthoses represent a narrow spectrum of simple positional orthoses most often utilized in the extended care environment. They are not complex and do not pose any adjustment prospects for the patient. Another commenter stated this device allows for functional ROM by maintaining knee position. Two commenters stated do not include on the OTS list as these devices are not minimal fit. This orthosis is constructed with a rigid posterior bar that often requires tools to contour to patient's leg.

Response: We have included this HCPCS code on the final OTS list. These orthoses are a simple soft positional orthoses with preset degrees of extension. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L1843: KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this style of orthosis is used exclusively for patients with osteoarthritis (OA), mild to moderate varum and valgum disorders of the knee. Commonly referred to as “Unloader Orthoses” these are single upright orthoses that provide graduated correction of angular deformities to produce reduction in compartment pressures and compression. The sizing charts and application process are often complex as is the selection criteria for each orthosis. This code should not be considered for OTS based on the complexity

of clinical application. Another commenter stated this orthosis is designed to unload and/or stabilize the knee joint. A proper understanding of the diagnosis, knowledge of the anatomy of the knee joint and proper understanding of the knee orthosis and how to fit this and adjust the settings is crucial to proper functioning of the orthosis. Without this knowledge the orthosis would not be fit properly and the proper unloading effects would not be experienced. Knowledge and experience with these orthoses would allow the professional to know whether this orthosis will fit properly and control the excessive knee motion. Several commenters stated do not include on the OTS list as these devices need to be fitted by Prosthetist/Orthotist, Orthotist, or orthotic fitter and have follow-up care available.

Response: We have removed this HCPCS code from the OTS list as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.

L1845: KNEE ORTHOSIS, DOUBLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated the orthoses described by this code literally number in the thousands and are used for moderate to severe OA and severe ligamentous instability and injuries. Once again, code consolidation has created a classification with broad variety and broad clinical application. One group of orthoses in this classification are double upright "Unloader Orthoses" that provide graduated correction of angular deformities to produce reduction in compartment pressures and compression. Another group is used for immobilization of ligament injuries and post-surgical stabilization. All orthoses in this classification require

considerable knowledge and effort to select the appropriate orthosis for the individual patient's anatomical presentation and offer multiple adjustment options for knee valgum/varum adjustments, corrective force adjustments and/or knee joint range of motion. The complexity of these orthoses and the complexity of the clinical applications remove this code from OTS consideration.

Response: We have removed this HCPCS code from the OTS list as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.

L1847: KNEE ORTHOSIS, DOUBLE UPRIGHT WITH ADJUSTABLE JOINT, WITH INFLATABLE AIR SUPPORT CHAMBER(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated the knee orthoses described by this code offer two adjustable components that are too complex for patient self-adjustment and would require the presence of a qualified individual to properly determine both the appropriate range of motion settings and the amount of air to inject in the corrective force pad to apply the corrective forces. Another commenter stated this orthosis is used to provide stability to an injured knee and requires knowledge of the anatomy of the knee as well as the knowledge of the injury type to understand how the knee joint should be adjusted as well as how much air pressure should be added to the orthosis. Improper fitting of this orthosis could cause further damage to the knee. A trained person should fit this and also provide follow-up as needed. Several commenters stated do not include on the OTS list as these devices need to be fitted by Prosthetist/Orthotist, Orthotist, or orthotic fitter and have follow-up care available.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L1850: KNEE ORTHOSIS, SWEDISH TYPE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated these orthoses are commonly used for hyperextension disorders of the knee and ligamentous laxity and injuries. They require significant adjustment to the posterior knee cuffs to create the corrective force and restore balance and stability to the gait of the patient. Significant knowledge is required to adjust these orthoses correctly and it is not self-adjustable by the patient. One commenter stated this orthosis is prescribed to provide posterior control of the knee joint which could be caused by a variety of injuries. Improper alignment of the knee joints could allow further damage to the knee or injuries to the soft tissue if the uprights are not contoured correctly. If the orthosis is adjusted improperly, and keeps the knee to extended, injury could result if the patient fell from lack of knee stability. Proper fitting in adjusting of this orthosis is crucial to proper function. Several commenters stated do not include on the OTS list as this orthosis is specifically for genu recurvatum or significant hyperextension of the knee joint and needs to be fit by a qualified practitioner, CO or CPO.

Response: We have included this HCPCS code on the final OTS list. These orthoses are aluminum, bilaterally interchangeable, adjustable knee orthoses to prevent hyperextension of the

knee. They are applied with soft closure materials that can be easily contoured. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

G. ANKLE-FOOT ORTHOTIC (L1902 – L1906)

L1902: ANKLE FOOT ORTHOSIS, ANKLE GAUNTLET, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated they agree this device should be an OTS item. There were no objections to including this code on the final OTS list.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L1906: ANKLE FOOT ORTHOSIS, MULTILIGAMENTUS ANKLE SUPPORT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated they agree this device should be an OTS item. Another commenter stated this device is not soft goods and not a minimal fit. These devices require advanced understanding of foot anatomy, with an understanding of the dynamics and indicators for dorsi-flexion. These device may require repeated adjustment during patient rehabilitation.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

H. ARCH SUPPORT, NONREMOVABLE, ATTACHED TO SHOE (L3100 - L3170)

L3100: HALLUS-VAGUS NIGHT DYNAMIC SPLINT

Comment: All commenters agreed this HCPCS code should be included on the OTS list.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L3170: FOOT, PLASTIC, SILICONE OR EQUAL, HEEL STABILIZER, EACH

Comment: All commenters agreed this HCPCS code should be included on the OTS list.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

I. SHOULDER ORTHOTIC (L3650 – L3677)

L3650: SHOULDER ORTHOSIS, FIGURE OF EIGHT DESIGN ABDUCTION RESTRAINER, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: Several commenters stated this device can be classified as OTS. It is a simple abduction orthosis. It requires appropriate application and fitting with little or no follow-up. Another commenter stated adjustable straps and buckles ensure correct fit and to help prevent slippage. These braces can functionally stabilize, assist, or restrict movement according to the specific needs. Various straps may be adjusted and trimmed for proper fit and function as determined by clinician. Clinician should check for desired level of mobility and stability post-application. One commenter stated fitting the brace requires a clinical understanding of the appropriate positioning and alignment of the brace to anatomical landmarks. The patient is

assessed and measured by a qualified healthcare professional for correct size. The patient is then instructed on proper and instructed on proper application, removal, and care for brace per prescribed plan of care. Careful guidance on appropriate tension of posterior straps is paramount in the effective use of the brace to reduce pain and aid in the proper clavicle positioning. An improper fit can lead to ineffectiveness of the brace with the potential for increased pain, muscle spasm, increased risk of re-injury, and improper healing of the clavicle injury. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L3660: SHOULDER ORTHOSIS, FIGURE OF EIGHT DESIGN, ABDUCTION RESTRAINER, CANVAS AND WEBBING, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device can be classified as OTS. It is an abduction restraining orthosis. It requires appropriate application and fitting with little or no follow-up. Another commenter stated proper application of this device involves appropriate knowledge of a qualified practitioner on patient positioning of the elbow and shoulder to protect the patient from compromising the post surgical healing process. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the shoulder. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L3670: SHOULDER ORTHOSIS, ACROMIO/CLAVICULAR (CANVAS AND WEBBING TYPE), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device can be classified as OTS. It is an orthosis to pull together acromioclavicular joint. It requires appropriate application and fitting with little or no follow-up. Another commenter stated this brace is intended to stabilize the acromioclavicular joint to reduce pain and joint motion. Proper fit and adjustment of straps is required for stabilization. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for stabilization needed to facilitate healing. Failure to properly align/apply this device may lead to further injury of the shoulder and increased pain potentially leading to surgery. Proper application of this device involves appropriate knowledge of a qualified practitioner on patient positioning of the elbow and shoulder to protect the patient from compromising the post surgical healing process or from further damaged to the rotator cuff that could lead to further surgical intervention. Another commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L3675: SHOULDER ORTHOSIS, VEST TYPE ABDUCTION RESTRAINER, CANVAS WEBBING TYPE OR EQUAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device can be classified as OTS. It is a vest style orthosis which limits shoulder abduction. It requires appropriate application and fitting with little or no follow-up. Another commenter stated the device is designed to protect and stabilize the shoulder post-injury and post-operatively. The clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for immobilization needed to facilitate healing. Casual application by an inexperienced individual could place the involved shoulder at risk. Another commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L3677: SHOULDER ORTHOSIS, SHOULDER JOINT DESIGN, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device is a vest style orthosis which limits shoulder abduction. Requires appropriate application and fitting and trimming of plastic material to customize fit and achieve desired level of motion restriction. Some follow-up may be required. Another commenter stated the clinician applying the device must clearly understand the proper application techniques and range of motion limitations and adjustments required for immobilization needed to facilitate healing. Casual application by an inexperienced individual could place the involved shoulder at risk. Requires appropriate application and fitting and

trimming of plastic material to customize fit and achieve desired level of motion restriction. Another commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

J. ELBOW ORTHOTIC (L3710 –L3762)

L3710: ELBOW ORTHOSIS, ELASTIC WITH METAL JOINTS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated designed to provide mild medial-lateral support of the elbow with elastic compression and rigid metal joints, with or without range of motion adjustments. This device requires appropriate application and fitting with minimal follow-up. Do not recommend OTS because joints have to be conformed to the patient. Another commenter stated the elbow orthosis described by this code offers adjustable elbow joint components that are too complex for patient self-adjustment and would require the presence of a qualified individual to properly determine both the appropriate range of motion settings and the amount of contouring required to apply corrective forces or stabilization of the elbow. There is a dramatic range of orthopedic diagnoses of patients who would be candidates for this orthosis. Because of the complexity of the orthosis and the vast array of clinical applications this should not be

considered for OTS. The elbow orthosis is made of a combination of elastic, neoprene or similar materials with associated metal stays or hinges that are located medially and laterally and positioned over the elbow joint to control motion or to stabilize the soft tissue and boney anatomy that surround the elbow. This device provides medial and lateral stabilization and restricts unwanted motion through circumferential support and compression and immobilization. The metal joints require contouring and bending that is specific to the anatomy and must accommodate anatomical angles. Another commenter stated these devices need to be fitted by Prosthetist/Orthotist, Orthotist, or orthotic fitter and have follow-up care available.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods, preassembled, with contourable metal supports requiring minimal self-adjustment to conform to the patient's anatomy. These types of elbow orthoses use a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver without the use of any specialized equipment.

L3762: ELBOW ORTHOSIS RIGID, WITHOUT JOINTS, INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITITNG AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. This is an orthosis to restrict elbow motion. Requires appropriate application and fitting with minimal follow-up. Another commenter stated a rigid elbow orthosis without joints is indicated for postsurgical immobilization or immobilization to prevent injury to oneself in some cases. A static elbow brace is used to properly align or position the elbow joint and associated bones after surgery. This ensures proper healing of a fracture or surgical site. Without proper fitting and adjustments by a credentialed professional, the joint could heal in malalignment, which may indicate a surgical revision or deformity that the patient must live with.

Response: We have included this HCPCS code on the final OTS list. These devices are

primarily soft goods, preassembled, with contourable metal supports requiring minimal self-adjustment to conform to the patient's anatomy. These types of elbow orthoses use a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver without the use of any specialized equipment.

K. WRIST-HAND-FINGER ORTHOTIC (L3807)

L3807: WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated a wrist hand and finger orthosis (WHFO) designed to position the wrist, hand and fingers in a more functional position. This device requires appropriate application and fitting. Code consolidation has created a classification that that includes literally hundreds of orthoses that are used for a broad range of diagnoses from simple orthopedic injuries to complex rehabilitation and positioning of neurologically involved patients. Significant numbers of patients in the Medicare beneficiary category require orthoses for diagnoses that require medical knowledge and skill to apply, shape, modify, and maintain this type of orthosis for contracture prevention, functional rehabilitation, and functional positioning. Despite this, types of these orthoses are readily available on the internet and in retail outlets. Classifying this orthosis as OTS would have a significant negative impact on care. Another commenter stated a WHFO without joints is indicated for a person who does not have optimum neuromuscular skeletal function of the wrist, hand, or fingers. This type of brace is used for static positioning of the wrist, hand, and fingers. The brace provides corrective forces or tension to the flexors and extensors to prevent shortening of the ligaments and/or muscles to prevent or correct contractures. Some users of this brace have no sensation in their hand or fingers and must use this brace to prevent damage to their skin or joints. These braces provide sagittal and frontal plane stability for the flail wrist and hand. Proper evaluation and fitting is required to

ensure an optimal fit to prevent skin break down, ligament damage, or joint contracture. The length of this orthosis and the fit of the straps are critical to the success of the brace in protecting the patient. Due to the nature of the typical user of this orthosis, self-adjustment may be impossible as well as dangerous for the patient. Another commenter stated boxer's fracture brace (BFB) is molded just like a cast by a clinician with training in the casting or bracing of fractures. Positioning of the hand, wrist, and fingers is crucial to a good outcome. The device may be trimmed to adjust for best fit and function by a clinician. Proper molding and fit avoids skin pressure issues which can lead to skin breakdown. Another commenter stated this device is a combo device, not just a wrist splint or a finger splint. This device is designed to maintain the wrist in an extended position. There is generally a rigid stay that can be removed from the device and requires contouring to the patient's anatomy. Knowledge of forearm, wrist, and hand anatomy and internal structures are required to prevent unnecessary pressure and offloading. Several commenters stated these devices need to be fitted by Prosthetist/Orthotist, Orthotist, or orthotic fitter and have follow-up care available, not minimal fit.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L3908: WRIST HAND ORTHOSIS, WRIST EXTENSION CONTROL COCK-UP, NON MOLDED, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: All commenters agreed this HCPCS code should be included in the OTS list.

Response: We have included this HCPCS code on the final OTS list.

L. OTHER UPPER EXTREMITY ORTHOTICS (L3908-L3929)

L3912: HAND FINGER ORTHOSIS, FLEXION GLOVE WITH ELASTIC FINGER CONTROL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. Another commenter stated do not include on the OTS list as these devices should be fit by an OT, CO, CPO for patient safety due to diagnosis related to trauma.

Response: We have included this HCPCS code on the final OTS list. These devices are primarily soft goods requiring minimal self-adjustment to conform to the patient's anatomy. These types of hand finger orthoses can be donned by a supplier, the beneficiary, or caregiver.

L3915: WRIST HAND ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), ELASTIC BANDS, TURNBUCKLES, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated these devices are used for very different reasons. The OTS wrist is used primarily as a preventative device for high activity sports. The Comfy hand orthosis is used to support and stabilize the wrist/hand secondary to neurological injury. Positioning within the device is very important for purposes of stabilization. Proper fitting an absolute necessity when clinical application involves orthopedic/neurological deficits. Another commenter stated the complex strapping and Velcro adjustments require a trained clinician in order to achieve proper stabilization. The product has a number of extension stops, the use of which is determined by the clinician/doctor. Proper setting is crucial to maintaining function while preventing re-injury. The device also has radio-ulnar stops that require similar expertise to

evaluate and set. Two commenters stated do not include on the OTS list as these devices should be fit by an OT, CO, or CPO for patient safety due to diagnosis related to trauma.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L3917: HAND ORTHOSIS, METACARPAL FRACTURE ORTHOSIS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated these devices are used to treat acute and post-acute fractures. Proper fitting is an absolute necessity to assure alignment of fracture is maintained. Device commonly needs modifications to accommodate post-acute fluctuating edema, with follow-up and adjustments likely. Need for customization and clinical complexity required qualified providers. Another commenter stated a hand orthosis, which is used to heal metacarpal fractures, immobilizes the bones of the hand to prevent met movement and allow healing. A hand orthosis is the primary treatment method of a metacarpal fracture. Without professional fitting and evaluation by a credentialed individual, the fracture site may close in mal-alignment and cause deformity of the bone. Two commenters stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that

include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L3923: HAND FINGER ORTHOSIS, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated there are a great variety of devices on the Pricing, Data Analysis and Coding (PDAC) approved list for this code. Some orthoses are simple thumb supports, such as the RCAI malleable thumb splint. Some devices are significantly more complex to fit and pose a much greater risk to patients, such as the Benik Hand Based Cerebral Vascular Accident (CVA)/ Traumatic Brain Injury (TBI) Splint. This device is used with patients who have complex neurologic conditions and there is the presence of increased muscle tone. In this type of clinical situation, it would require a great amount of expertise by the provider to assure an appropriate fit and function. This item should not be considered for OTS designation based in part on clinical application. Another commenter stated a rigid hand finger orthosis is molded just like a cast by a clinician with training in the casting or bracing of fractures or other injuries of the hand. Positioning of the hand and thumb is crucial to a good outcome. The device may be trimmed to adjust for best fit and thumb function by a clinician. Proper molding and fit avoids skin pressure issues which can lead to skin breakdown. Another commenter stated a hand finger orthosis without joints is used to protect and immobilize the bones and ligaments of the hand and fingers. It places the hand in a safe position to prevent injury while wearing. The brace places the thumb and hand in a position for 3-point prehension

for ADL's. Without proper fitting and evaluation by a credentialed individual, the orthosis could cause shortening of ligaments, which would decrease range of motion and function of the fingers. It could also cause ligamentous laxity or weakness in the hand or fingers and may allow unwanted motions of the fingers or hand, which would prolong the healing process. Another commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L3925: FINGER ORTHOSIS, PROXIMAL INTERPHALANGEAL (PIP)/DISTAL INTERPHALANGEAL (DIP), NON TORSION JOINT/SPRING, EXTENSION/FLEXION, MAY INCLUDE SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. These devices are used for applications where joint tightness or soft contracture is present. This device requires minimal adjustment. However, clinical application would determine whether or not expertise is necessary to fit this device. Another commenter stated this finger orthosis is used to protect and immobilize the Distal Interphalangeal (DIP) and/or Proximal Interphalangeal (PIP) joints of the finger after injury or surgery. It provides minimal compression and prevents motion of the PIP and DIP joints, which aids in the healing process. A finger splint that is improperly fitted could

be too restrictive and decrease circulation to the finger. If the patient fit this device loosely, it would allow motion at the DIP and PIP, which would decrease the healing processes, it was intended to assist. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These finger wire devices require minimal self-adjustment to conform to the patient's anatomy. These types of finger orthoses can be donned by a supplier, the beneficiary, or caregiver.

L3927: FINGER ORTHOSIS, PROXIMAL INTERPHALANGEAL (PIP)/DISTAL INTERPHALANGEAL (DIP), WITHOUT JOINT/SPRING, EXTENSION/FLEXION (E.G. STATIC OR RING TYPE), MAY INCLUDE SOFT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. These devices are used for applications where joint tightness or soft contracture is present. This device requires minimal adjustment. However, clinical application would determine whether or not expertise is necessary to fit this device. Another commenter stated a qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These assorted size finger splints require minimal self-adjustment to conform to the patient's anatomy. These types of finger orthoses can be donned by a supplier, the beneficiary, or caregiver.

L3929: HAND FINGER ORTHOSIS, INCLUDES ONE OR MORE NONTORSION JOINT(S), TURNBUCKLES, ELASTIC BANDS/SPRINGS, MAY INCLUDE SOFT

INTERFACE MATERIAL, STRAPS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated there is no PDAC approved devices listed for this code. In 2008, 7 previous codes were consolidated into this code. Those were "knuckle bender" and wire spring type devices. Some of those codes could have possibly been listed as OTS, some of them (the wire spring and dynamic tension orthoses) should not be in OTS. Many of the dynamic assist types of orthoses would require expertise in fitting and setting the appropriate tension in the tension bands. These orthoses should not be designated as OTS due to the need to correctly set the length and tension of the bands. Another commenter stated a qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional. Two commenters stated do not include on the OTS list as these devices should be fit by an OT, CO, or CPO for patient safety due to diagnosis related to trauma.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

M. MISCELLANEOUS LOWER LIMB SUPPORTS (L4350-L4398)

L4350: ANKLE CONTROL ORTHOSIS, STIRRUP STYLE, RIGID, INCLUDES ANY TYPE INTERFACE (E.G., PNEUMATIC, GEL), PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. There were no comments disputing this code being included as an OTS orthoses.

Response: We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L4360: WALKING BOOT, PNEUMATIC AND/OR VACUUM, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device is used for multiple diagnoses, including plantar fasciitis, severe ankle sprains, metatarsal fractures, post-acute tibial fractures, and Charcot joints. Code consolidation of the versions with and without joints has created significant numbers of clinical outliers that require a qualified provider fit these devices to insure appropriate care and functional outcomes without adverse effects. The need for expertise in fitting and instructing the patient would depend on the diagnosis present and whether the version being fitted had adjustable joints and/or metal lateral struts that require contouring to the individual patient. Although we recognize that large numbers of these devices are used in the orthopedic arena with little need for adjustments, significant numbers are utilized on Medicare beneficiaries with complex diagnoses. Another commenter stated a qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular

head to avoid peroneal nerve pressure, proper foot plate length/adjustments, proper vacuum/pneumatic adjustments, contour changes for anatomical shape). When the pneumatic device is properly inflated, it decreases pain and swelling around the surgical or injury site. An improperly inflated device can cause excessive swelling and pain around the site being protected, prolonging the healing process and possibly require further intervention. Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional. Another commenter stated the pneumatic walking boot has aircells that require professional adjusting for a proper and secure fit. A walking race with a shell can be trimmed with a cast saw for proper fit; a walking brace with malleable uprights can be adjusted to accommodate a variety of patients for a better fit and more support. Range of motion walking braces have various settings on the "hinge" to allow for different degrees of plantar and dorsiflexion. All of these "modifiable" features should be handled in the physician office to ensure adjustments are made safely and appropriately.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L4370: PNEUMATIC FULL LEG SPLINT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. The majority of

the commenters did not provide comments disputing this code being included as an OTS orthotic. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up. Another commenter stated requires the skill of balancing the other leg as well as shaping uprights and padding placement in order to fit appropriately.

Response: We have included this HCPCS code on the final OTS list. We have included this HCPCS code on the final OTS list. These devices are provided in a variety of standard sizes which do not require the skills of an expert to measure and fit. We find these devices fit within the scope of minimal self-adjustment. Sizing and application may be performed by a supplier, the beneficiary, or caregiver.

L4380: PNEUMATIC KNEE SPLINT, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this item can be classified as OTS. The majority of the commenters did not provide comments disputing this code being included as an OTS orthotic. Two commenters stated do not include - requires a certified fitters experience to fit and follow-up.

Response: This code was deleted and cross-walked to L4370.

L4386: WALKING BOOT, NON-PNEUMATIC, WITH OR WITHOUT JOINTS, WITH OR WITHOUT INTERFACE MATERIAL, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated this device is similar to L4360 except for the absence of pneumatic control and it too is used for multiple diagnoses, including plantar fasciitis, severe ankle sprains, metatarsal fractures, post-acute tibial fractures and Charcot joints. Code consolidation of the versions with and without joints has created significant numbers of clinical outliers that require a qualified provider fit these devices to insure appropriate care and

functional outcomes without adverse effects. The need for expertise in fitting and instructing the patient would depend on the diagnosis present and whether the version being fitted had adjustable joints and/or metal lateral struts that require contouring to the individual patient. Although we recognize that large numbers of these devices are used in the orthopedic arena with little need for adjustments, significant numbers are utilized on Medicare beneficiaries with complex diagnoses. Another commenter stated a qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper foot plate length/adjustments, contour changes for anatomical shape). Adjustments to the orthosis which could be detrimental to the fit and function should only be performed by a qualified professional. Another commenter stated that a walking brace with a shell can be trimmed with a cast saw; a walking brace with malleable uprights can be bent to accommodate a variety of patients for a better fit and more support. ROM walking braces have various settings to allow for different degrees of plantar and dorsiflexion. All of these modifications should be done in the physician's office by a skilled individual to ensure accurate adjustments and proper fit.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined can be modified and are modified for specific individuals who require expertise in fitting, we are

creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L4396: STATIC OR DYNAMIC ANKLE FOOT ORTHOSIS, INCLUDING SOFT INTERFACE MATERIAL, ADJUSTABLE FOR FIT, FOR POSITIONING, MAY BE USED FOR MINIMAL AMBULATION, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: One commenter stated a wide variety of devices are on the PDAC approved list for L4396 and subsequently they address a broad range of clinical complexities. Some of the devices are more simple and straightforward; however some devices are much more complex and would require expertise in setting up and fitting to ensure appropriate function. With the great differences in types of devices approved for L4396, and the requirements for bending, molding and customizing, it should not be designated as OTS. Another commenter stated a qualified medical professional has the knowledge necessary to fit the device to the proper anatomical joint as prescribed. If donned incorrectly the inappropriate forces could lead to joint contracture, abrasions and possible skin breakdown. Other issues include proper height (distal to the fibular head to avoid peroneal nerve pressure, proper footplate length/adjustments, contour changes for anatomical shape. An improper fitting Pressure Relief Ankle Foot Orthosis (PRAFO) can decrease healing time or even prevent healing which can, in some cases, lead to amputation. A qualified professional should only perform adjustments to the orthosis, which could be detrimental to the fit and function.

Response: In reviewing the products and items classified under the codes on the initial OTS list and the comments received on the initial list, we have identified several codes that include a variety of items, some of which are dispensed to patients with no modifications or fitting necessary, and some for which custom fitting by certified orthotists or other individuals with specialized training may be necessary. Therefore, for those devices we have determined

can be modified and are modified for specific individuals who require expertise in fitting, we are creating new HCPCS codes that will be available for use in those instances when these items require custom fitting for a specific individual.

L4398: FOOT DROP SPLINT, RECUMBENT POSITIONING DEVICE, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

Comment: Several commenters stated this item can be classified as OTS. The majority of the commenters did not provide comments disputing this code being included as an OTS orthosis. One commenter stated do not include on the OTS list as these devices require a certified fitters experience to fit and follow-up.

Response: We have included this HCPCS code on the final OTS list. These foot drop splint devices are preassembled softly padded ankle foot splints, with a contourable metal support requiring minimal self-adjustment to conform to the patient's anatomy. These types of orthoses use a variety of closures and materials. Sizing and application may be performed by a supplier, the beneficiary, or caregiver without the use of any specialized equipment.

N. CONCLUSION

After reviewing all of the comments and thoroughly examining each HCPCS code that is included on the final OTS list we are revising the original list. We believe the final OTS list contains orthoses that meet the OTS definition as outlined in 1861(s)(9) of the Act requiring minimal self-adjustment for the appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The HCPCS codes finalized on this list will be considered OTS effective January 1, 2014.