Agenda
Multi-Disciplinary Task Force
Defining OTS vs. Custom-Fitted Orthotics
Documentation and Continuity of Care
April 15, 2014

1. Call to Order & Introductions — Dr. Fisk
2. Purpose and Objectives — Dr. Fisk & Mr. Fise
    a. Prospective Look and Usage of End Product
    b. Medical Necessity/Physician Documentation & Claims
3. Background — Mr. Fise
    a. OTS, Competitive Bidding & Alternatives
    b. Examples of RAC/Prepayment Audits in Prosthetics, Physician Documentation and CMS Physician Template
4. Review of Rough Draft Preliminary Framework — Dr. Fisk and Mr. DiBello
5. Consideration of Content and Compilation — Dr. Fisk, et al.
6. Next Steps — Dr. Fisk
    a. Needed Information
    b. Assignments
    c. Follow-up – Meeting/Conference Call/Draft
7. New Business — Dr. Fisk
8. Adjourn — Dr. Fisk

CMS Attempts to Change/Expand Congress' Rules Defining The Off-the Shelf" Devices That Can be Eligible for Competitive Bidding Would Shortchange Quality of Care, and Harm Patients Whose Mobility Is Already Compromised!

The American Orthotic and Prosthetic Association (AOPA) believes that the recently released second iteration of a correct coding bulletin by each of the four the DME MACs entitled, "Definitions Used for Off–the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces)" represents an **inappropriate interpretation of the statutory definition of off-the shelf orthoses and the term "minimal self adjustment"**. Enforcement of this revised policy may result in irreparable damage to Medicare beneficiaries and unnecessary expenditures by the Medicare program. AOPA's concerns rest in three areas:

(1) the bulletin continues to ignore the clear meaning of the federal statute, 42 U.S.C. section 1395w-3(a)(2)(C) which defines with impeccable clarity the clear line of demarcation between off-the-shelf orthotics and custom fitted orthotics; namely**, <u>if and only</u> if the device can be used by the patient with minimal self-adjustment can the device be treated by CMS and its contractors as off-the-shelf without violating the federal law**;

(2) the resulting **introduction of the new term "substantial", which has absolutely no foundation in the statute**, as well as the resulting and distinct publications/statement purporting to define language documentation criteria in respect to the Local Coverage Determination for AFOs/KAFOs, Knee orthoses, and Spinal orthoses effective for claims with a date of service on or after January 1, 2014 (more than three months prior to the publication of the bulletin and revised policy) risks further injury and reduced mobility for these Medicare beneficiaries; and

(3) the continued **failure** of CMS and its contractors to appropriately **recognize the requirements of Section 427 of BIPA 2000**, in this case by the **failure to recognize and establish orthotic fitter criteria as qualified providers** that meet the statutory requirement of certification/accreditation.

The following "real life" case examples from an AOPA member practice in the eastern United States clearly illustrate scenarios where the absence of access to the clinical expertise by a certified orthotist may have resulted in either an ill fitting orthosis or an inappropriate treatment modality, resulting in the potential for harm to the patient as well as unnecessary costs to the Medicare program.

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Case 1: Blind Patient with Hemiparesis Resulting in Compromised Small Motor Skills

Female patient with a diagnosis of cerebral palsy. Patient referred for a pre-fabricated lumbar orthosis to address chronic back pain. Patient is blind, hemi-paretic with significant hand dysfunction and had never used a spinal orthosis before. Attempted to fit her and worked on the donning with the occupational therapist. She was not able to don the orthosis so, we called the physician and she was prescribed an alternate treatment for the back pain which worked fine. If she had simply been handed a box with a spinal orthosis, she would have not been managed properly. This required a certified orthotist.

Case 2: Patient with Unusual Anatomical Proportions and a Need for Additional Sacral Control

Female patient that travels regularly for work. The patient travels domestically and internationally as part of her job. Patient referred to us for a pre-fabricated lumbar orthosis to address chronic and persistent lower back pain. We attempted to fit this orthosis and realized that her problem required a lumbo-sacral orthosis to provide support for the proper area of the spine (lumbar and sacral spine) and, the orthosis needed to be fitted to provide compression and her body shape was atypical (large hips, narrow waist). She is a professional and the orthosis that has been fitted works to manage her pain and she can wear it under most clothing during professional work. If she would have been handed a box with a spinal orthosis, she would not have been managed properly. This required a certified orthotist.

Case 3: Patient with Acute Knee and Ankle Injury and History of Brain Injury and Hemiparesis

Female patient with a history of brain injury. Patient referred to us for a knee brace and ankle brace due to an acute injury. She had a history of a brain injury with hemi-paresis, already was wearing a custom Ankle-Foot-Orthosis (AFO) and had hand dysfunction. We worked with her therapists to develop a plan to manage the orthoses for the short term of the injury. If she had been simply handed two boxes with two pre-fabricated orthoses (one for the knee and one for the ankle) she would not have known how to don them or how to use them in conjunction with her current AFO and she would not have been managed properly. With proper fitting of the orthoses, the patient has been able to attend school and manage her activities of daily living independently. This required a certified orthotist

Case 4: Patient with Complicated Medical History Involving Management of the Spinal Column

Female Patient with chronic spinal issues: Patient was referred to us for a prefabricated cervical orthosis. Patient had a very complicated medical history. Patient had been provided with a cervical orthosis decades earlier. Upon clinical evaluation by a certified orthotist, the determination was made that the patient could potentially benefit from a TLSO style orthosis to reduce kyphosis and pain. We worked with the physician to develop a plan of care and ultimately addressed her cervical pain and instability and reduce her kyphosis through the provision of a properly fit TLSO. If she had been provided with an OTS cervical collar without thorough evaluation by a certified orthotist her medical needs would not have been managed appropriately.

August 11, 2011

Dear Physician – Documentation of Artificial Limbs

Dear Physician,

The Durable Medical Equipment Medical Administrative Contractors (DME MAC) have jurisdiction for processing claims from prosthetists for artificial limbs. In the event of an audit, the Medicare contractor may request medical records to demonstrate that the prosthetic arm or leg was reasonable and necessary. Since the prosthetist is a supplier, the prosthetist's records must be corroborated by the information in your patient's medical record. It is the treating physician's records, not the prosthetist's, which are used to justify payment.

The patient's functional capabilities are crucial to establishing the medical necessity for a prosthetic device. Many prosthetic components are restricted to specific functional levels; therefore, it is critical that physicians thoroughly document the functional capabilities of their patients, both before and after amputation. Clinical assessments of a patient's rehabilitation potential must be based on the following classification levels:

> **Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
>
> **Level 1:** Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
>
> **Level 2:** Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
>
> **Level 3:** Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
>
> **Level 4:** Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

The records must document the patient's current functional capabilities and his/her expected functional potential, including an explanation for the difference. Note that it is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

The physician's assessment of a patient's physical and cognitive capabilities typically includes:

- History of the present condition(s) and past medical history that is relevant to functional deficits
- Symptoms limiting ambulation or dexterity
- Diagnoses causing these symptoms
- Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis
- What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)
- Description of activities of daily living and how impacted by deficit(s)
- Physical examination that is relevant to functional deficits

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- Weight and height, including any recent weight loss/gain
- Cardiopulmonary examination
- Musculoskeletal examination
    - Arm and leg strength and range of motion
- Neurological examination
    - Gait
    - Balance and coordination

The assessment points above are not all-inclusive and physicians should tailor their history and examination to the individual patient's condition, clearly describing the pre and post-amputation capabilities of the patient. The history should paint a picture of your patient's functional abilities and limitations on a typical day. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for the patient's ambulatory or upper extremity difficulties or impact on the patient's functional ability.

Note that when physicians are unable to provide the requested documentation to the supplier, the suppliers receive denials for the items billed which could result in your patient being financially responsible for all or part of the charges for the items/service received. If a supplier contacts your office to request additional clinical documentation, please partner with the supplier to establish what clinical records are needed to support that the service/item you ordered is medically necessary.

Section 1842(p)(4) of the Social Security Act mandates that:

> [i]n case of an item or service…ordered by a physician or a practitioner…but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time that the item or service is ordered by the physician or practitioner.

Providing medical records to the supplier is not a violation of the HIPAA Privacy Rule. Thank you for your cooperation in future documentation requests.

Sincerely,

Paul J. Hughes, MD
Medical Director, DME MAC Jurisdiction A
NHIC, Corp.

Stacey V. Brennan, MD, FAAFP
Medical Director, DME MAC Jurisdiction B
National Government Services

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC Jurisdiction C
CGS

Richard W. Whitten, MD, MBA, FACP
Medical Director, DME MAC Jurisdiction D
Noridian Administrative Services

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American Orthotic & Prosthetic Association

Facts about Orthotics and Prosthetics and Competitive Bidding

Background

Some have suggested that Medicare savings could be achieved by including orthotics and prosthetics in competitive bidding. AOPA believes that current law, which includes only orthotics that need "minimal **self** adjustment" (emphasis added) to be used by an individual, provides the appropriate balance and inclusion of products that are similar enough to be included in competitive bidding. AOPA and the Amputee Coalition, the largest advocacy group for amputees believe, and have communicated to all Congressional offices that any misdirected effort to expand competitive bidding beyond off-the-shelf orthotics to include other O&P devices would be extraordinarily detrimental to patient care because it would deny Medicare beneficiaries with limb loss and limb impairment access to the clinical care, the cost of which is now included in the fee Medicare pays for most O&P devices. A great deal has happened in the past six months: (1) CMS has published a list of OTS devices, including 23 devices (so-called exploded codes) which can either be Off-the-Shelf or custom fitted depending on the patient and physician prescription; (2) established codes for these OTS devices; (3) remarkably for these 23 exploded codes, CMS determined to pay the identical reimbursement for the OTS version with NO orthotic services, and the same reimbursement for the same device as custom fitted with clinical support of bending, molding fitting, trimming and training from the certified/licensed orthotist, and; (4) sought comments on its direction for competitive bidding (AOPA responded on March 28, 2014).

1. When Competitive Bidding was authorized, "off the shelf" orthoses were designated as appropriate for possible inclusion in competitive bidding. The statutory definition, contained in section 1847(a) (2) (C) of the Social Security Act, defines off the shelf orthoses as those: 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.
2. CMS has not yet included in competitive bidding these 'off-the-shelf "orthoses, those for which minimal self adjustment by the individual patient (and this is, and should remain the only contingent of O&P devices eligible for possible competitive bidding).
3. Prosthetics and more complex orthotics were not included in competitive bidding because these items are customized to fit an individual and need more specialized tailoring to the individual's body and needs.
4. Prosthetics and orthotics are not part of Durable Medical Equipment and have a separate Medicare fee schedule.

(Over)

5. Unlike many products in competitive bidding, a prescription is needed for prosthetics and more complex orthotics. The IRS found that most prosthetics and their component parts are exempt from the Affordable Care Act's 2.3% medical device excise tax because they fit the retail sales exemption as do eye glasses and hearing aids which were specifically exempted by statute and because like prosthetics/orthotics, they are sold at retail for individual use and require a prescription.
6. Competitive Bidding works best when applied to products and services that cost very little and require little if any expertise on the part of the provider. Most prosthetics and orthotics are made to fit a specific individual and therefore are not comparable or produced on a scale needed to make competitive bidding work.
7. CMS expanded the definition of the term "minimal self adjustment" in C.F.R. 414.402 as follows: minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board of Certification/Accreditation) or an individual who has specialized training.
8. As noted above, CMS created a new subset of prefabricated items/services/procedures, 55 in total, which they deemed to be off-the-shelf (OTS) orthoses. They also created a series of 23 "split codes" or orthoses that can be provided either off the shelf or customized to fit a specific patient by an individual with expertise. The introduction of 23 "split codes" that represent items that are sometimes delivered OTS and sometimes delivered with proper fitting and training by a certified/ trained individual has only created more questions, considering CMS has not issued any clear guidance on the proper use of the new "split codes".

Recommendation

Congress was very specific in specifying that only those off-the-shelf orthoses that can be used by the patient with "minimal self adjustment" by the individual user could be considered for the competitive bidding program. AOPA believes that the expanded regulatory definition of minimal self adjustment goes beyond the intent of the statute, and the use of this expanded definition has resulted in the classification of many orthotic items and services as off the shelf; which in reality requires a level of professional care to avoid potential harm to Medicare beneficiaries.

We ask for your support as we seek regulatory refinements to ensure that the term "off-the shelf orthoses" is appropriately defined, and that only those items which meet the statutory definition of off-the-shelf are considered eligible to be included in future rounds of the competitive bidding program.

For more information contact the American Orthotic & Prosthetic Association (AOPA) at (571) 431-0876 or www.AOPAnet.org.

3/21/14

American Orthotic & Prosthetic Association

Overview of O&P RAC Audit/Pre-payment Audit Problem

Background

Actions of the Medicare Contractors Is So Severely Constricting Cash Flow in Small O&P Businesses (Annual Total Sales Roughly $1 Million) As Major Force Prompting Closings of These Businesses and Trigger Fewer Choices/Providers to Patients and a Significant Consolidation in Field

1. HHS OIG generated a report which was premised on very significant misunderstanding of the patient care delivery model, and recommended inaccurate and unrealistic actions.
2. CMS accepted most of the major findings of the OIG report without correction or rebuttal.
3. That said, CMS' Office of Program Integrity has determined that whatever is going on with O&P care and documentation, there is generally an absence of indicators of fraud (contrary to the premise of the OIG report)
4. Medicare contractors exacerbated the problem by 'announcing' new standards without reference to the APA and without the benefit of any rulemaking
5. Audit contractors have applied the newly announced standards retrospectively as to claims where the provider could have no knowledge of the standard at the time services rendered.
6. OIG's gross misunderstandings of the care model, faulty conclusions drawn from those inaccuracies, and contractor false assumptions of fraud have triggered a second wave of massive pre-payment audits designed to stimulate diminution in the applicable standard of amputee care. These pre-payment audits (in Jurisdiction B approaching 100% of prosthetic claims) have made the cash-flow problems for small O&P businesses dramatically worse.
7. O&P practitioners and patients have become Medicare's surrogates and collateral damage because neither has the leverage to compel physicians to provide the greater documentation that CMS demands and physicians are unwilling to give.
8. CMS contractors appear to operate without rules, supervision or coordination.
9. When CMS contractors do secure substantial caches of additional physician documentation it is misused as rationale for detached audit personnel who have never seen the amputee patient, generally without either credentials or experience in orthotics or prosthetics, to countermand the prescription and care orders of the physician who has the responsibility for the overall clinical care of the patient.

(Over Please)

10. In April, 2013, 35 House Members signed on to a Joint Letter to Secretary Sebelius, seeking fixes to the RAC problem. When the Secretary replied over three months later, in July, she offered no substantive changes or actions to resolve the problem, and those actions she promised have not been implemented yet, another nine months later.
11. In April 2013, CMS Administrator Tavenner promised to issue before 12/31/13 proposed regulations to implement Section 427 of BIPA 2000 so as to define qualified providers, and thus clarify the legitimacy of the prosthetist's notes/records. No such proposed regulations have been released by CMS, a full 12 months later.

Recommendation

Communicate your concerns as a Member of Congress: (1) by signing onto the joint, bipartisan Congressional letter to Secretary Sebelius and CMS Administrator Tavenner relating to excessive delays to reach ALJ hearings (2) join in support of Part B – RAC Audit legislation; and/or (3) by communicating directly in a letter to CMS Administrator Tavenner and follow-up discussions with top CMS staff, that patients with limb loss or limb impairment may be getting shortchanged in the type of device they receive or experience delayed treatment when overzealous CMS contract auditors cite misunderstood documentation errors as basis for claim denials. The audits are designed to uncover fraud and abuse and not to foster "gotcha" denials adversely affecting patient care.

For more information contact the American Orthotic & Prosthetic

Association (AOPA) at (571) 431-0876 or www.AOPAnet.org

3/21/14

DANKMEYER

PROSTHETICS & ORTHOTICS

March 13, 2014

Senator Barbara Mikulski
United State Senate
Hart Senate office Building #503
Washington, DC 20510

Dear Senator Mikulski:

A prior commitment is precluding me from being present in person for the meeting in your office this afternoon relating to orthotic devices. I am a lifetime Maryland resident and the second generation to continue the tradition of Dankmeyer, Inc., an orthotics and prosthetics patient care facility enterprise which employs 35 persons. Dankmeyer proudly serves Maryland's amputee and mobility-impaired citizens. All of us at Dankmeyer are in support of the positions and needs being presented by both AOPA and the BOC. I am the President-Elect of AOPA, and in December, will be assuming the duties of AOPA's Presidency.

Let me say that we are cognizant of the financial pressures on the Medicare system, and we are opposed to all fraud which may adversely impact our patients. Neither are we opposed to competitive bidding as it has been implemented, nor as it may ultimately legitimately impact off-the-shelf orthotics. We are however, committed to assuring that CMS operates this program within the specific authority, definitions and guidance that Congress wisely established for this program. Unfortunately, the problem about which we are approaching you, and have also approached Senator Grassley, relates to CMS going well beyond the statutory definition with a much more expansive view than Congress envisioned in its recent actions relating to off-the-shelf orthotics. I am very hopeful that you may be willing to join with Senator Grassley in reminding CMS that the wisdom and thoughtfulness which characterized Congress' action when you clearly defined the OTS devices appropriate for competitive bidding. The definition of OTS devices developed by Congress rings all the more true and essential today, despite CMS' apparent wish that it could strike the word "self" from the statutory text for "minimal self-adjustment."

Thank you for your consideration of this important question on the OTS definition, and for all that you do for the citizens of Maryland and the Nation. Please do not hesitate to contact me if I can provide any further insights or answer any questions on this issue.

Very truly yours,
DANKMEYER, INC.

C. H. Dankmeyer

Charles Dankmeyer, CPO

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Congress of the United States
Washington, DC 20515

April 15, 2013

The Honorable Kathleen Sebelius
Secretary, US Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

CC: Marilyn Tavenner, Acting Administrator, Centers for Medicare and Medicaid Services

Dear Secretary Sebelius,

We are writing because of our concern that efforts to reduce fraud and abuse in Medicare claims for prosthetics may be harming access to care for the most vulnerable Medicare beneficiaries.

We strongly support efforts to combat fraudulent payments. According the GAO, for Fiscal Year 2011, the estimated improper payments within Medicare cost approximately $65 billion. Finding and stopping these fraudulent payments is a critical task, however, we are seriously concerned about the unintended consequences of current efforts that may reduce patient access to care and harm upstanding small businesses. It has been brought to our attention that audits conducted by the Centers for Medicare and Medicaid Services (CMS) contractors concerning claims for prosthetics are jeopardizing the economic viability of these critical health care providers.

As we see it there are two issues. The first is challenges to physician documentation for prosthetics. Auditors are now using a standard that CMS contractors, without the benefit of any rulemaking processes, generated in an August 2011 "Dear Physician" letter that is based on a flawed 2011 Office of Inspector General Report. Second, according to the industry, the number and scope of audits are continuing to increase dramatically. Furthermore, these claims are being appealed, with some adverse decisions by CMS contractor auditors being overturned at the administrative law judge (ALJ) level.

Consequently, CMS's current policies are resulting in contractor audits challenging legitimate payments for prosthetic care to the degree that these critical health providers are facing terminal cash flow deficiencies. In addition to jeopardizing the jobs and economic growth added by providers of orthotic and prosthetic devices and services, many of which are small businesses, the inability of these providers to serve patients, including vulnerable Medicare beneficiaries, creates an unnecessary barrier to access.

The American Orthotic and Prosthetic Association (AOPA), representing facilities that provide orthotic and prosthetic services, recently completed a survey of its members' encounters with such audits. The survey found that 77 percent of AOPA's facilities have been subject to one or more recovery audit contractor (RAC) audits relating to physician documentation, with many facilities having been subjected to more than 20 such audits in the 11 months preceding the survey. At the facility level, these and other similar audits have led to many small businesses being stretched to their breaking points financially, hindering economic growth and costing

precious jobs. Taken collectively, the strain on the industry undermines critical patient access to orthotic and prosthetic services.

It is imperative that we find a way to develop policies that allow CMS to eliminate true fraud and abuse, while not slowing payment to providers so significantly that they cannot function. We believe it is possible to strike a reasonable balance that would ensure effective scrutiny and protection of taxpayer dollars while still preserving the viability of crucial orthotic and prosthetic specialists.

We understand it is not CMS' intent to harm these facilities. CMS leadership has also acknowledged significant deficiencies with the physician documentation standard (from the "Dear Physician" letter) that CMS contractors apply, frequently retroactively, to claims from before that standard was articulated. However, given that this has been the effect of anti-fraud activities, we respectfully request clarification on a few areas of concern for orthotic and prosthetic suppliers. Please respond to the following questions in writing.

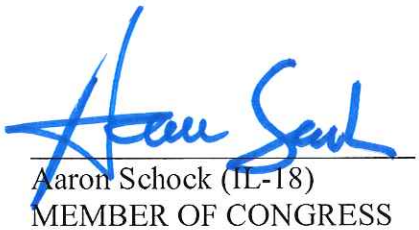
- What specifically is CMS' policy to ensure that anti-fraud activities, while necessarily rigorous, do not place undue and/or counterproductive burdens on providers?
- Does CMS believe that implementing regulations pursuant to the Benefits Improvement Protection Act of 2000 (BIPA), Transmittal 656, or other measures, including legislation, could aid in ensuring that only licensed and/or accredited providers be eligible for Medicare reimbursement, thereby reducing instances of fraud and the need for overly burdensome "pay and chase" activities?
- Given the growing number and scope of audits, and the confusion over standards that providers are subject to, are there interim steps CMS could take to maintain program integrity while not restricting provider cash flow so severely?
- In some instances, after delivery of an orthotic or prosthetic device, auditors may disagree with a single line-item amongst an otherwise wholly appropriate course of treatment, resulting in a provider's payment being entirely withheld. Would it be possible for CMS to withhold reimbursement for the specific codes or components of an artificial limb that CMS' auditors believe is inappropriate, instead of denying payment for the entire limb or service?
- Can you provide information documenting the rate at which ALJ decisions ultimately result in auditor payment denials being reversed, both in number and as a percentage of total appeals, also noting at what stage of appeal the final decision was made?

If you have any questions, please do not hesitate to contact Kalina Bakalov in the office Representative Tammy Duckworth at 202-225-3711, or Megan Spindel in the office of Representative Brett Guthrie at 202-225-3501.

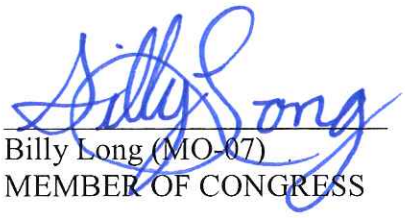
Sincerely,

Tammy Duckworth (IL-08)
MEMBER OF CONGRESS

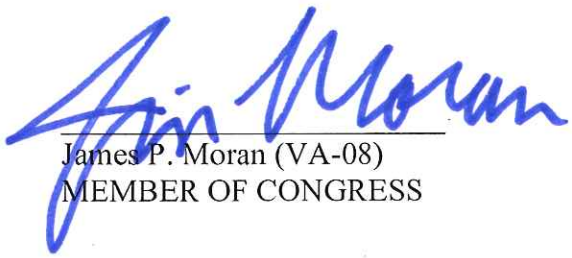
Brett Guthrie (KY-02)
MEMBER OF CONGRESS



Aaron Schock (IL-18)
MEMBER OF CONGRESS



Billy Long (MO-07)
MEMBER OF CONGRESS



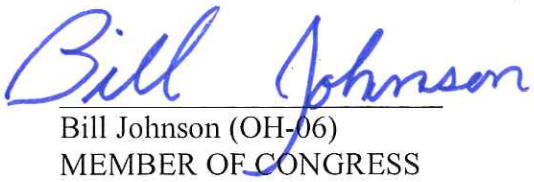
James P. Moran (VA-08)
MEMBER OF CONGRESS

David Phillip "Phil" Roe (TN-01)
MEMBER OF CONGRESS

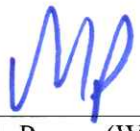
Robert E. Latta (OH-05)
MEMBER OF CONGRESS

Danny K. Davis (IL-07)
MEMBER OF CONGRESS

Todd Rokita (IN-04)
MEMBER OF CONGRESS

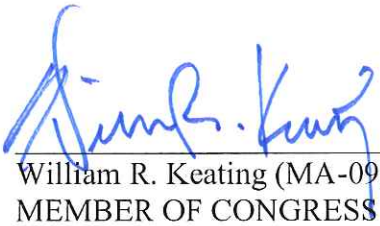


Bill Johnson (OH-06)
MEMBER OF CONGRESS

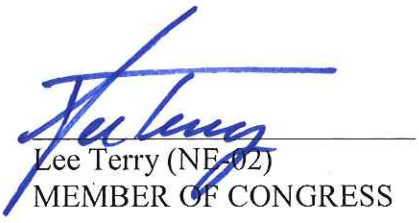


Mark Pocan (WI-02)
MEMBER OF CONGRESS

Daniel B. Maffei (NY-24)
MEMBER OF CONGRESS



William R. Keating (MA-09)
MEMBER OF CONGRESS



Lee Terry (NE-02)
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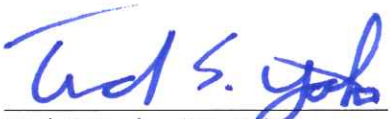
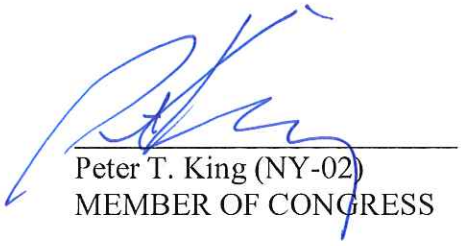
Eric Swalwell (CA-15)
MEMBER OF CONGRESS

Carol Shea-Porter (NH-01)
MEMBER OF CONGRESS

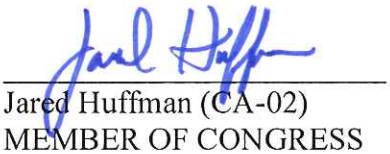


Ted S. Yoho (FL-03)
MEMBER OF CONGRESS



Peter T. King (NY-02)
MEMBER OF CONGRESS

Mike Quigley (IL-05)
MEMBER OF CONGRESS



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Chellie Pingree (ME-01)
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Sam Graves (MO-06)
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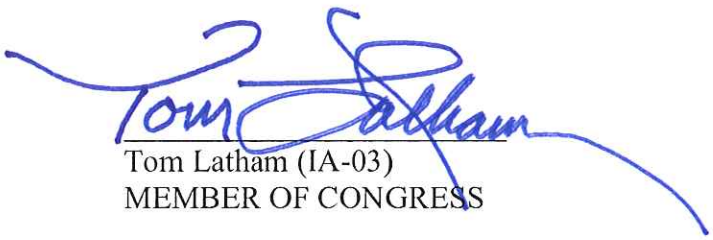

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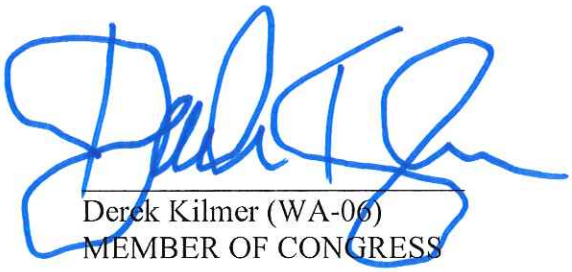

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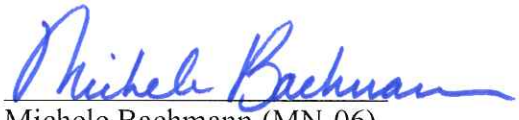

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André Carson (IN-07)
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Steve Chabot (OH-01)
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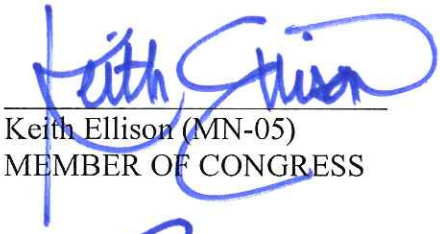
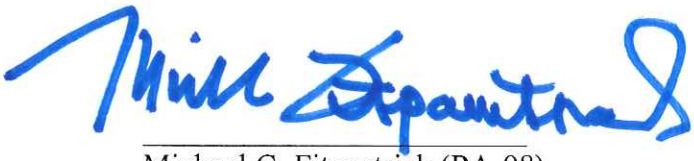


Keith Ellison (MN-05)
MEMBER OF CONGRESS



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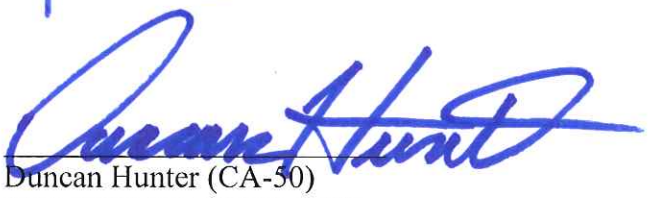
MEMBER OF CONGRESS



Duncan Hunter (CA-50)
MEMBER OF CONGRESS

C.A. Dutch Ruppersberger (MD-02)
MEMBER OF CONGRESS

American Orthotic &
Prosthetic Association

April 2, 2014

Laurence Wilson, Director Chronic Care Policy Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Wilson,

The American Orthotic and Prosthetic Association (AOPA) would like to express its concern regarding the recently released second iteration of a correct coding bulletin by each of the four the DME MACs entitled, "Definitions Used for Off–the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces)." AOPA's concerns rest in three areas: (1) the bulletin continues to ignore the clear meaning of the federal statute, 42 U.S.C. section 1395w-3(a)(2)(C) which defines with impeccable clarity the clear line of demarcation between off-the-shelf orthotics and custom fitted orthotics; namely, if and only if the device can be used by the patient with minimal self-adjustment can the device be treated by CMS and its contractors as off-the-shelf without violating the federal law; (2) the resulting introduction of the new term "substantial modification", which has absolutely no foundation in the statute, as well as the resulting and distinct publications/statement purporting to define language documentation criteria in respect to the Local Coverage Determination for AFOs/KAFOs, Knee orthoses, and Spinal orthoses effective for claims with a date of service on or after January 1, 2014 (more than three months prior to the publication of the bulletin and revised policy); and (3) the continued failure of CMS and its contractors to appropriately recognize the requirements of Section 427 of BIPA 2000, in this case by the failure to recognize orthotic fitters as qualified providers that meet the statutory requirement of certification/accreditation.

Last week, AOPA took the opportunity to address some of these issues in our response to CMS' ANPRM relating to the future of competitive bidding. At the time we prepared those comments the second iteration of the policy bulletin had not been published by the DME MACs; however, we had noted the same flaws in the initial DME MAC statements on this matter, announced on February 28, 2014 and quickly withdrawn on March 7, 2014. Because the second iteration of the policy bulletin simply re-states and perpetuates the errors first stated in the February 28th statement, our comments challenging those positions that AOPA stated in its ANPRM comments remain accurate, timely and germane to this second iteration.

It is noteworthy and important that the DME MAC bulletins completely avoids any recitation of the applicable law--42 U.S.C. section 1395w-3(a)(2)(C) is nowhere cited by CMS' contractors. The statement references 42 CFR section 414.402 as

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if that were the statute! Of course, there would be no authority for CMS or its contractors to make any statements about off-the-shelf orthotics had authority to do so not first been granted to the agency in 42 U.S.C. section 1395w-3(a)(2)(C) and related sections in that same statute. The first question which needs to be asked by CMS and its contractors as they consider an action should be: ***where, if at all, is CMS given statutory authority to undertake this activity, and in what way does the statutory authority define and constrain the agency's actions?***

Here are the most pertinent sentences which AOPA has previously presented in its comments on the very serious shortcomings of the DME MAC policy bulletins.

II. AOPA Remains Concerned About the Expanded Definition of the term "Minimal Self Adjustment" Used to Define Off the Shelf Orthoses

AOPA, once again, would like to express its continued concern regarding the use of the expanded regulatory definition of the term "minimal self adjustment" as the basis for the inclusion of a total of 55 HCPCS codes in the category of off the shelf orthoses. The statutory definition of an off the shelf orthosis contained in section 1847(a)(2)(C) of the Social Security Act defines off the shelf orthoses as those:

> ***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.***

CMS expanded the definition of the term "minimal self adjustment" in C.F.R. 414.402 as follows:

> ***Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.***

AOPA has repeatedly voiced its concern regarding the expanded regulatory definition of the term "minimal self adjustment" and the subsequent use of the regulatory definition to classify 55 HCPCS codes as OTS, 23 of which represent HCPCS codes that were "exploded" into custom fitted and OTS codes used to describe the same device, differentiated by the process used in ensuring a proper fit for the patient. Efforts to date have included multiple pieces of correspondence with CMS officials, the CMS Administrator, as well as the Secretary of Health and Human Services.

AOPA believes that the expanded regulatory definition of minimal self adjustment goes beyond the intent of the statute in defining OTS orthoses subject to competitive bidding. The use of this expanded definition has resulted in the classification of many orthotic HCPCS codes as off the shelf items that in reality require some level of professional care to avoid potential harm to Medicare beneficiaries. The subsequent explosion of 23 HCPCS codes that represent items that are sometimes delivered OTS and sometimes delivered with proper fitting and training by a certified or trained individual has only

created more questions and confusion regarding documentation requirements for claim payment.

This confusion has been further escalated by the February 28, 2014 joint release and subsequent March 7, 2014 retraction of a policy bulletin on OTS orthoses by the four DME MAC contractors. While only published for a short time before its retraction, several statements in the policy bulletin reinforced AOPA's concern regarding the correct use of both off the shelf orthosis and custom fitted orthosis codes when submitting claims to Medicare contractors. An example of this ambiguity is contained in the discussion regarding the definition of custom fitted orthoses. The policy bulletin included a statement that custom fitted orthoses require ***substantial modification*** *for fitting at the time of delivery. The bulletin further defines substantial modification as "changes made to achieve an individualized fit of the item that requires the expertise of a qualified practitioner i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self adjustment." While the bulletin attempts to clearly define the term substantial modification, it actually creates confusion among the supplier community when trying to decide if modifications they have made to assure a proper fit of the orthosis will meet the threshold of "substantial" modification. This will lead to increased exposure to audit activity and may contribute to unnecessary claim denials due to different interpretations of the term substantial. The policy bulletin also indicates that providers must provide the product that is specified by the ordering physician, i.e. type of orthosis and method of fitting and/or fabrication (OTS, custom fitted or custom fabricated). AOPA believes that in most cases, the ordering physician is relying on the specific expertise of the orthotist to determine, through direct evaluation, if the patient requires an OTS or custom fitted orthosis and therefore cannot pre-determine the exact method of fabrication and fitting that will be required. While the policy bulletin was retracted on March 7, 2014, AOPA expects a revised version of the bulletin to be published in the near future and remains concerned that DME MAC attempts at clarification may actually lead to additional confusion among suppliers.*

AOPA strongly believes that competitive bidding authority, as designated by the statute, should be limited to only those OTS orthoses that may be provided with the need for minimal self adjustment, specifically provided by the patient.

It should be noted that the DME MAC narrative limiting the decision on the type of device to the physician *only* would create access to care and delay of care problems for Medicare beneficiaries.

CMS needs to instruct its contractors that the word "substantial modification" used as a requirement for coding a device under the HCPCS codes that are now defined as custom fitted is completely without authority, is in error, and must be withdrawn. 'Custom fitted' devices are the next level up the chain of orthotic device complexity after 'off-the-shelf.' The statute makes a clear definition of "off-the-shelf" as noted above stating that this term applies only to orthotics that can be used by the patient "with minimal self-adjustment." This text not only defines 'off-the-shelf,' but it also defines custom fitted—a custom fitted device, by simple reading of the statute is a device which requires the smallest increment of clinical services by the licensed/certified orthotist (or other party specifically deemed as qualified by the statute) greater than "minimal self-adjustment." By interspersing the term

'substantial modification' which is completely alien to, and without any foundation whatsoever in the statute, CMS, via its contractors compounds the violation of the statute. The term 'substantial modification' would necessarily infer that there is some ground between "minimal self-adjustment" and "substantial modification." But, of course there is none—any device which cannot be used by the patient with 'minimal self-adjustment," falls inexorably, at least, into the next adjacent level of complexity, i.e. custom fitted—there is no place in between, and so the term "substantial modification" must be removed from any consideration as contrary to the statute, confusing and unreasonable and inappropriate.

The DME MACs have gone even further in their error as they have sought to make the inappropriate, unsupported and illegal definitions this statement postulates for "minimal self-adjustment" the basis for guidance on documentation and other coding requirements relating to distinguishing OTS from custom AFOs/KAFOs. AOPA has stated previously in a 2012 communication to the DME MAC medical directors that we believe that the addition of language of this type represents a substantive change to existing medical policy and is therefore subject to appropriate notice and rulemaking provisions of the Administrative Procedure Act. The simple addition of this language as part of an LCD revision did not provide stakeholders, including AOPA members as well as physicians, the opportunity to provide comments on the potential impact this statement represents to both Medicare beneficiaries and providers.

AOPA contends that the publication of this policy change as part of a unilateral revision to the local coverage determination did not provide the public or physician community with adequate notification or opportunity to provide comment regarding this substantive policy change. This, in turn, has contributed to the unusually high claim denial rate for AFOs that was reported by the Jurisdiction D DME MAC. In addition to the publication of the revised policy bulletin on the proper coding of OTS versus custom fitted orthoses, the DME MACs simultaneously published revisions to the LCDs and Policy Articles for AFOs/KAFOs, Knee orthoses, and Spinal orthoses that incorporated the provisions of the policy bulletin into the actual medical policies. These policies are being applied retroactively for claims with a date of service on or after January 1, 2014. AOPA believes that the DME MACs do not have the authority to make claim decisions using policies that were not published at the time the service was delivered.

Congress has set the standard that, "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing . . . the eligibility of individuals, entities, or organizations to furnish . . . services or benefits . . . shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)." There has been no such regulation promulgated to support this change.

Further, the statute says that orthoses for a Medicare patient must be "reasonable and necessary." CMS might maintain that concrete standards for determining

whether an orthosis is "reasonable and necessary" are set forth in the MPIM and LCDs—none of which was promulgated by regulation. In taking such action the government faces an unpleasant choice—either it set or it changed the standard without going through the required rulemaking. In either case, the absence of appropriate procedure under the Administrative Procedure and Medicare Acts renders the July 2012 (if not the entire LCD) void and in violation of the Congressional statute.

Finally, the DME MAC policy bulletins seem to take cognizance of the certification/accreditation requirements of Section 427 of BIPA 2000 when it states:

> "...requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

We do not agree with the context in which this reference appears because it comes up in the context of "substantial modification," and further because it misreads another statute both by ignoring the possibility that an individual could be certified by another entity which meets the statute's requirements by evaluating certification/accreditation candidates to a standard substantially equivalent to that applied by either ABC or BOC, and by omitting the adjective 'qualified' which appears before the terms physical therapist and occupational therapist in the statute, but has been dropped entirely in this publication..

But much more importantly, the DME MAC policy bulletins and subsequent LCD revisions further miss the mark by failing to indicate that an orthotic fitter is also subject to these same requirements, and must demonstrate certification/accreditation in accordance with section 427 of BIPA 2000, on precisely the same terms as the licensed/certified orthotist.

One closing note is that a second two-part action of CMS and its contractors, such as the DME MACs, is both the failure to recognize that changes to the standard by which provider submissions of requests for payment via coding MUST be established via an Administrative Procedure Act validated notice and comment rulemaking which allows the opportunity for participation and input from all stakeholders—including providers and patients. Further, policy criteria, such as those for whether a device falls within the descriptor of a HCPCS code, and whether a therapeutic intervention is deemed effective and/or appropriate for payment MUST be supported by scientific basis. AOPA has already provided previously, in our comments on the CMS draft OTS list extensive comments on errors by CMS, and in other communications, the errors of its contractors in not providing even the minimal scintilla of scientific rational, or references to support what are undeniably scientific/medical/clinical decisions about efficacy and appropriateness of specific treatments for specific orthotic patients. The policy in

the DME/MAC policy bulletins join these others, like the publication on the OTS list itself, in falling well short under both of these standards. There is nothing in the Medicare statute which authorizes either CMS or its contractors to establish payment polices ab initio and without sound scientific basis and procedural integrity under APA. Moreover, Congress delegated decisions on 'coverage' of devices to CMS, and it delegated findings of the efficacy of devices to FDA. When PDAC (perhaps with input from the DME MACs) assigns a code to a device in conjunction with the HCPCS process, they have properly addressed coverage; it goes beyond the authority of CMS or its contractors when either venture beyond coverage to attempt to abrogate authority which Congress never granted to CMS as to efficacy determinations

In conclusion, AOPA believes that CMS has no choice but to withdraw this DME MAC policy bulletin and the resulting and counterpart LCD revisions, and maintain them with no effect, pending initiating a full rulemaking which complies with the 3 statutory failings of this one—namely a rulemaking under the APA notice and comment process that complies BOTH with 42 U.S.C. section 1395w-3(a)(2)(C) AND with Section 427 of BIPA 2000.

If I can be of any assistance, please feel free to contact me at tfise@aopanet.org or via telephone at (571)431-0802.

Respectfully submitted,

Thomas F. Fise
Executive Director

cc: Marilyn Tavenner, CMS Administrator
AOPA Board of Directors

Suggested Electronic Clinical Template Elements for
Medical Documentation Submitted to CMS in Support of Claims for Lower Limb Prostheses
Proposed Draft[MHO edit]

Patient History

Name:_____ DOB:_____ Gender:_____

Date of Amputation: ____/____/____ **Side of Amputation**: ☐ L ☐ R ☐ Bilateral

Diagnosis/ Cause of Amputation: ☐ Diabetes ☐ Vascular disease ☐ Trauma
☒ Infection ☐ Cancer/Tumor ☐ Other:_____

Level of Amputation: ☐ Partial foot ☐ Symes ☐ Below knee ☐ Knee disarticulation
☐Above knee ☐ Hip disarticulation/Hemipelvectomy

Physical Exam

Physical Exam Height:____ft ____in **Weight**:_____lbs

Weight changes since last prosthetic fitting (> 10lbs, if applicable): ☐ No ☐ Yes

Residual Limb			
Strength		Range of Motion	
☐	Normal	☐	Normal
☐	Other:_____	☐	Other:_____

Unaffected Limb			
Strength		Range of Motion	
☐	Normal	☐	Normal
☐	Other:_____	☐	Other:_____

Current Residual Limb Condition

Shape:
☐ Ready for prosthesis (Ex. Conical, Cylindrical)
☐ Needs shrinking and shaping (ex. Excessively bulbous)
☐ Requires prosthetic accommodations for (ex. Bony prominence, ulceration)

Residual Limb Color: ☐ Normal ☐ Other:_____

Temperature of Residual Limb: ☐ Normal / Warm ☐ Other:_____

Residual Limb Incision:
☐ Well healed ☐ Staples / Sutures ☐ Intact STSG (split thickness skin graft) ☐ Moist ☐ Necrotic ☐ Dry ☐ Other:_____

Residual Limb Drainage:
☐ None ☐ Purulent drainage ☐ Serosanginous ☐ Serous ☐ Other:_____

Suggested Electronic Clinical Template Elements for
Medical Documentation Submitted to CMS in Support of Claims for Lower Limb Prostheses
Proposed Draft[MHO edit]

Residual Limb Pain:

☐ On palpation – Location(s):_____

☐ Acute – Location(s):_____

☐ Chronic – Location(s):_____

☐ Phantom pain – Location(s):_____

Functional Assessment

Does patient currently have and utilize a prosthesis? ☐ No ☐ Yes

Has the patient expressed a desire to ambulate with a prosthesis? ☐ No ☐ Yes

Based upon a physical examination, do you feel the patient is a good candidate to be able to utilize a prosthesis for purposes of transfer and/or ambulation?
☐ No ☐ Yes

Balance and Coordination: ☐ Normal ☐ Other:_____

Capability to transfer or ambulate on level surfaces at a fixed cadence, commonly in an institutional or home setting, often with assistive devices:
☐Ability ☐Potential ☐No Potential

Capability to ambulate in an environment with low level barriers such as stairs, curbs, driveways, ramps, etc.:
☐ Ability ☐ Potential ☐ No Potential

Capability to ambulate at speeds of a variable cadence:
☐ Ability ☐ Potential ☐ No Potential

Capability to ambulate and performs activities that are representative of community ambulation, navigating all barriers at all speeds:
☐ Ability ☐ Potential ☐ No Potential

Capability to engage in high impact/high energy generating activities, often repetitive in nature, such as athletics and vocational actions:
☐Ability ☐ Potential ☐ No Potential

Additional Functional Outcome Information(PAVET score, AMPRO, NoPRO, TUG test etc.) :

_____

For the new amputee, what activities did he/she engage in prior to their amputation:

_____☐ N/A

For the experienced amputee, what activities does he/she engage in relative to their prosthetic use:

_____ ☐ N/A

Current Prosthetic Assessment (if applicable):

Describe the patient's current prosthesis type:
☐Immediate post-operative ☐Preparatory/Temporary ☐Definitive

What is the age of the patient's current prosthesis:_____

Wearing Time of Current Prosthesis (hrs per day): ☐ < 4 ☐ 4 to 8 ☐ 8+

Suggested Electronic Clinical Template Elements for
Medical Documentation Submitted to CMS in Support of Claims for Lower Limb Prostheses
Proposed Draft[MHO edit]

Does it currently meet the patient's prosthetic needs: ☐ Yes ☐ No (If no, please indicate why:
☐ Prosthesis is currently in disrepair.

The following needs replacement:
☐Socket ☐Hip ☐Knee ☐Ankle ☐Foot ☐Liner(s)
☐ Other:_____

☐ Patient has undergone a physical change which impacts the function of the prosthesis:

_____

☐ Weight gain/loss (amount_____) ☐ Revision surgery

☐ Patient's skin condition requires a modification to existing designs:

_____

☐ Patient's functional activity level capability has increased(describe):
_____

☐ Other (describe)
_____

_____

Recommendations

Medically Necessary Prosthetic Services (See Rx for specifics):
☐ New device ☐ Adjustment ☐ Repair ☐ Replacement ☐ None

What outcomes do you expect from the prescribed prosthetic services?:
☐ Increased balance ☐ More energy efficient gait ☐ Greater ambulatory distances
☐ Less dependence on ambulatory aids ☐ Other:_____

_____ _____
Prosthetist's Signature Date

_____
Prosthetist's Name (printed)

Lower Limb Prosthesis (LLP) Electronic Clinical Template

Lower Limb Prosthesis Electronic Clinical Template

CMS is exploring the development of a list of suggested clinical elements for an electronic clinical template that will assist providers with documenting the physician notes that substantiate the need for a Lower Limb Prostheses. This template may also facilitate the electronic submission of medical documentation. Visit the “Downloads” section and click on the “Lower Limb Prosthesis Suggested Electronic Clinical Template” link to view the document which describes the data elements that CMS believes would be useful in supporting the documentation requirements for coverage of Lower Limb Prosthesis.

CMS is planning to host a series of Special Open Door Forum (ODF) calls to provide an opportunity for suppliers and physicians to provide feedback on the development of Lower Limb Prosthesis Electronic Template for possible nationwide use. Please monitor this webpage for more details on the ODF schedule that will be provided soon. At the conclusion of the ODF calls, CMS plans to forward the resulting list of clinical elements to the electronic Determination of Coverage (eDoC) workgroup.

Downloads

- Lower Limb Prosthesis Suggested Electronic Clinical Template [PDF, 71KB]
- Page last Modified: 05/07/2013 11:55 AM

Lower Limb Prosthesis Electronic Clinical Template Background

CMS is working in collaboration with the DHHS Office of the National Coordinator for Health IT (ONC) to develop an electronic template that will assist providers with data collection and medical documentation to support selected items and services such as Lower Limb Prostheses. This template may also facilitate the electronic submission of medical documentation. The attached document describes the data elements that CMS believes would be useful in supporting the documentation requirements for coverage of Lower Limb Prostheses. Once finalized these proposed data elements will be delivered to ONC for consideration and/or inclusion in ONC’s development process. This list of data elements is NOT intended to be a final data entry form.

Medical documentation submitted to CMS in support of a claim for a Lower Limb Prosthetic should accurately reflect the beneficiary’s medical condition(s) that necessitate the use of the specifically ordered Lower Limb Prosthetic as well as beneficiary’s medical condition(s) that would impact the beneficiary’s ability to effectively utilize the specifically ordered Lower Limb Prosthetic in achieving a defined functional state. Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician’s office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). As such not all data elements will be applicable to all beneficiaries and answers to all data elements in any given record would not generally be expected. Only those data elements that pertain to the individual’s medical condition would be relevant.

Lower limb prostheses are covered under the Medicare Artificial Legs, Arms and Eyes benefit (Social Security Act §1861(s)(9)). In order for a beneficiary to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determinations (LCD: L11442, L27013, L11464, and L11453).

A lower limb prosthesis is covered when the beneficiary:

1. Will reach or maintain a defined functional state within a reasonable period of time; and
2. Is motivated to ambulate.

For Medicare payment purposes, lower limb prosthetic devices are categorized based on the following five K-Levels. A beneficiary is placed at one of the five potential functional levels based on the reasonable expectations of the supplier and the referring physician. It is important to note that the ordering physician's medical documentation must support the medical necessity, within the context of his or her overall medical problems, for the corresponding level of device that is selected and delivered to the beneficiary.

Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.

Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

****IMPORTANT NOTE TO PHYSICIANS AND SUPPLIERS****

Records from suppliers or healthcare professionals (specifically in this case, prosthetists) with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary

*** Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are insufficient, by themselves, to support medical necessity for Medicare payment purposes.**

*** Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.Suggested Electronic Clinical Template Elements for Lower Limb Prostheses**

Suggested Electronic Clinical Template Elements for
Medical Documentation Submitted to CMS in Support of Claims for Lower Limb Prostheses
DRAFT v3 (05/07/13)

The data elements listed below are designed to prompt the practitioner to include key aspects of documentation for lower limb prostheses in the medical record.

A. Chief Complaint

A1. State the beneficiary's need for an initial or replacement prosthesis.

B. History of Present Illness

B1. Describe the beneficiary's current medical conditions that effect ambulation, such as congestive heart failure, chronic lung disease, arthritis, etc.
B2. Describe the beneficiary's lower limb amputation leading to the need for a prosthetic and its etiology.
B2a. Describe any current problems or complications with the amputated limb.
B2b. Describe any past complications with the residual limb.
B3. If this is an evaluation for a replacement of an existing prosthesis
B3a. Describe how often and how long the beneficiary uses the current prosthesis (if applicable) each day.
B3b. Explain the reason for replacement and any change in prosthetic requirements.
B4. Describe the beneficiary's activity level transfers, ambulation, balance, endurance, and strength and any functional limitations relating to ambulation.
B4. Describe any impairments of the non-amputated limb(s).
B5. Describe the beneficiary's motivation to ambulate and general desired ambulation goals including vocational requirements and athletic goals beyond simple locomotion.

C. Past Medical and Surgical History

C1. List the beneficiary's medical conditions and previous surgeries.
C2. List the beneficiary's current medications.

D. Social History

D1. Describe any current or anticipated vocational, therapeutic, exercise or athletic activities that demand prosthetic utilization beyond short distances, not already noted.
D1a. Describe any environmental barriers (e.g. number of steps to enter the home, number of steps within the home, type of home (tri-level, 2-story, etc.), navigation of multiple flights of steps, farm fields, construction sites, etc.).
D1b. If the beneficiary requires assistance to don/doff his/her prosthesis independently or transfer/ ambulate independently (with or without mobility aids), describe the availability of caregiver assistance and if applicable, any reliance on caregivers for ADLs.

E. Review of Systems (ROS)

Describe any symptoms effecting ambulation.

E1. Constitutional

E1a. Describe any recent change in weight of greater than 10 pounds.
E1b. Describe any medical or surgical procedures planned that will affect the beneficiary's rehabilitation potential (including revision of the residual limb). If applicable, describe: type of procedure, expected recovery time.
E1c. Describe any significant change in the beneficiary's rehabilitation potential during the last 6 months.
E1d. Describe any current use of a Power Mobility Device, cane, walker, or wheelchair.

E2. Eyes

E.2.a Is the beneficiary's vision sufficient to ambulate safely?

E3. Respiratory

E3a. Describe the beneficiary's respiratory symptoms that restrict his/her rehabilitation potential.
E3b. Does the beneficiary require the use of supplemental oxygen? If yes, list the frequency, duration, delivery system, and flow rate.
E3c. Does beneficiary get SOB while performing MRADLs? If yes: **Suggested Electronic Clinical Template Elements for Lower Limb Prostheses** Draft V3 7MAY2013 Page 3 of 4

E3ci. Describe ADLs that make the beneficiary SOB in or outside the home (with supplemental oxygen if required);
E3cii. Describe interventions (other than the use of oxygen) that palliate SOB while performing MRADLs,

E4. Cardiovascular

E4a. Describe the beneficiary's cardiovascular symptoms that limit his/her rehabilitation potential.
E4b. Describe the beneficiary's complaints of increased heart rate, palpitation, ischemic pain, etc., that occur or worsen when the beneficiary attempts or performs ADLs or ambulate (with supplemental oxygen if required)?
E4c. Describe measures that have been taken in the past that have worked or failed to alleviate these symptoms.

E5. Musculoskeletal

E5a. Describe the beneficiary's musculoskeletal symptoms that effect rehabilitation potential.
E5b. If the beneficiary has a history of falls, detail where they occur; the reason the beneficiary believes that she/he falls; the frequency and timing of the falls. Note whether the beneficiary is able to arise to a seated/standing position without the help of another person after a fall.
E5c. If the beneficiary experiences joint/bone pain, describe the signs/symptoms (decreased range of motion, crepitus, laxity, etc.) that occur or worsen with MRADLs. Specifically, describe any arthritic impairments or disabilities with the non-amputated limb.
E5d. Describe management of the beneficiary's chronic pain symptoms, including use of analgesics, particularly Schedule II drugs.
E5e. Describe complaints of abnormalities in strength or coordination with MRADLs.

E6. Neurological

E.6.a Describe any neurological symptoms that restrict MRADLs such as balance disturbance, peripheral neuropathy, base line Parkinsonian gait abnormality, etc.

E7. Skin

E.7.a Describe any skin ulcer(s) or other loss of skin integrity, and the etiology.

E8. Cognitive/Behavioral/Psychiatric

E.8.a Describe any complaints of cognitive impairment that could limit rehabilitation.

F. Physical Exam

Provide quantifiable, objective measures/tests of the beneficiary's physical condition;

F1. Constitutional

F1a. List Height, Weight, Blood Pressure (BP), Pulse Rate (P), and Respiratory Rate (RR) at rest.

F2. Eyes

F2a. Document visual acuity.

F3. Respiratory

F3a. Document the respiratory exam at rest (auscultation, pulse, resp rate, and SaO2)
F3b. After walking the maximum distance possible on level ground (up to 50 ft) with current best mobility device and supplemental oxygen if required, document the distance ambulated, pulse , respiratory rate, and O_2Sat.
F3bi. Describe beneficiary's respiratory effort (e.g., use of accessory muscles, intercostal retractions).
F3bii. Was mobility aid used? If yes, describe. If supplemental O_2 is used, list the frequency, duration delivery system and flow rate.
F3biii. Conduct a 6 minute walk test and document the results.

F4. Cardiovascular

F4a. Document the cardiovascular exam including any jugular venous distention, lower and upper extremity edema, and orthostatic pressures if applicable.

F5. Musculoskeletal F5a. Document the upper extremity and lower extremity individual muscle groups tone and strength (from 0 – 5) and then discuss how as they pertain to mobility related activities of daily living (MRADLs).
F5b. Document any abnormalities of joint range of motion and architecture (e.g., swelling, erythema, subluxation contractures, heterotopic ossifcans).
0: no muscular contraction detected
1: a trace muscular contraction detected
2: active movement of the muscle accomplished with gravity eliminated
3: active movement of the muscle accomplished against gravity with no resistance applied

4: active movement of the muscle accomplished against gravity with less than full resistance applied
5: active movement of the muscle accomplished against gravity and against full resistance
F5c. Document the condition (length, shape, etc.) of the beneficiary's residual limb, if any.
F5d. Document the beneficiary's ability/inability to transfer (include the use of current mobility aides, mechanical lift, one or two person assistance, and transfer board) and/or change from sit to stand position.
F5e. Describe the beneficiary's gait with the use of any current mobility aides.

F6. Neurological

F6a. Record any neurologic abnormalities that limit rehabilitation potential.

F7. Skin

F7a. Describe current areas of open wounds, edema, scarring or venous stasis that would affect rehabilitation potential.

F8. Psychiatric

F8a. Document the beneficiary's mental status, judgment, insight, and memory.

G. **Beneficiary Assessment**

Medical documentation submitted to CMS in support of a claim must document the beneficiary's current functional capabilities and his/her expected rehabilitation potential. Based on this examination indicate the beneficiary's anticipated functional activity achievable with a properly fitted lower limb prosthesis, within the context of his or her overall medical problems. Please keep in mind that the activity level supported by this exam must be consistent with the level of device delivered to the beneficiary.

H. Plan

H1. Based on this assessment, indicate your plan for satisfying the beneficiary's prosthetic requirements.

Thanks for the Special Efforts of the Following Professionals Who Compiled This Documentation: Sally Kenworthy, MSOP, CO, LO; Jeffrey Schiller, BS, Orthotic Resident; Eric Harriman, MSOP, Orthotic Resident; Breyanna Gordon, MSOP, Orthotic Resident; and Micah Smith, MSOP, Orthotic Resident

2014 HCPCS Code	2014 Descriptor	2013 Descriptor	New or Descriptor Change	Documentation Needed to Distinguish Patients that Require Clinic Care vs. Those that Can Be Fit OTS	Factors that Require Clinical Care (Co-Morbidities, Manual Dexterity, Device Complexity)	Potential Risks to Patient Associated with OTS Delivery	Documentation Required Beyond Written Prescription	Documentation Required to Show Coordination of Care between Physician and Practitioner
L0120	Cervical, flexible, non-adjustable, prefabricated, off-the-shelf (foam collar)	Cervical, flexible, non-adjustable (foam collar)	Descriptor Change-Always OTS	Clinic care needed for: Patients with documented structural instabilities/ damage of the cervical spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Abnormal size or anatomy. Documented structural instabilities or damage of cervical spine. Post-OP patients. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability to care for self or maintain own well being.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0160	Cervical, semi-rigid, wire frame occipital/mandibular support, prefabricated, off-the-shelf	Cervical, semi-rigid, wire frame occipital/mandibular support	Descriptor Change-Always OTS	Clinic Care Needed for: Those with documented structural instabilities/ damage of the cervical spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Neck drop related to muscle weakness that interferes with respiratory funtions should have clinic care to guarantee appropriate fit and function of device. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Abnormal size or anatomy. Respiratory complications. Documented structural instabilities or damage of cervical spine. Post-OP patients. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability to care for self or maintain own well being.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation and patient education; rationale for prescribed device; measurements and/or test results relevant to the orthopedic status of the patient; and a statement outlining modifications made to device to meet prescribed goals. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0172	Cervical, collar, semi-rigid thermoplastic foam, two-piece, prefabricated, off-the-shelf	Cervical, collar, semi-rigid thermoplastic foam, two-piece	Descriptor Change-Always OTS	Clinic Care Needed for: for those with documented structural instabilities/ damage of the cervical spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Abnormal size or anatomy. Respiratory complications. Documented structural instabilities or damage of cervical spine. Post-OP patients. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability to care for self or maintain own well being.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0174	Cervical, collar, semi-rigid, thermoplastic foam, two piece with thoracic extension, prefabricated, off-the-shelf	Cervical, collar, semi-rigid, thermoplastic foam, two piece with thoracic extension	Descriptor Change--Always OTS	Clinic Care Needed for: for those with documented structural instabilities/ damage of the cervical spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Abnormal size or anatomy. Respiratory complications. Documented structural instabilities or damage of cervical or high thoracic spine. Post-OP patients. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability to care for self or maintain own well being.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0450	TIso, 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, off-the-shelf	TIso, 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	Descriptor Change-Always OTS	Clinic Care Needed for: Those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0455	Clinic Care Needed for: Those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0455	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, off-the-shelf		New-Split Pair with L0454	Clinic Care Needed for: Those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status. Those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, documented spinal stability, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0457	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: Those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0457	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, off-the-shelf		New-Split Pair with L0456	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, documented spinal stability, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change--Always Custom fit	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L0467	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0467	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, prefabricated, off-the-shelf		New-Split Pair with L0466	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, documented spinal stability, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L0469	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L0469	TIso, 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, prefabricated, off-the-shelf		New-Split Pair with L0468	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral, lumbar, or thoracic spine, post-OP status. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, documented spinal stability, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral, lumbar, or thoracic spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0621	Sacroiliac orthosis, flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf	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	Descriptor Change-Always OTS	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, documented spinal stability, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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, off-the-shelf	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	Descriptor Change-Always OTS	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, documented spinal stability, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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, off-the-shelf	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	Descriptor Change-Always OTS	Clinic Care Needed for: for those with documented structural instabilities/ damage of the lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of the lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0641	Clinic Care Needed for: for those with documented structural instabilities/ damage of the lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L0627	Lumbar orthosis, sagittal control, with rigid anterior and posterior panels, 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, shoulder straps, pendulous abdomen design, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Lumbar orthosis, sagittal control, with rigid anterior and posterior panels, 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, shoulder straps, pendulous abdomen design, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L0642	Clinic Care Needed for: for those with documented structural instabilities/ damage of the lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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, off-the-shelf	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	Descriptor Change-Always OTS	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due to mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0643	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0648	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0649	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0650	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L0651	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L0641	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, off-the-shelf		New-Split Pair with L0626	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0642	Lumbar orthosis, sagittal control, with rigid anterior and posterior panels, 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, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf		New-Split Pair with L0627	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0643	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, off-the-shelf		New-Split Pair with L0630	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0648	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, off-the-shelf		New-Split Pair with L0631	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0649	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, off-the-shelf		New-Split Pair with L0633	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L0650	Lumbar-sacral orthosis, sagittal-coronal control, with rigid anterior and posterior frame/panel(s), posterior extends from sacrococcygeal junction to t-9 vertebra, lateral strength provided by rigid lateral frame/panel(s), produces intracavitary pressure to reduce load on intervertebral discs, includes straps, closures, may include padding, shoulder straps, pendulous abdomen design, prefabricated, off-the-shelf		New-Split Pair with L0637	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0651	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, off-the-shelf		New-Split Pair with L0639	Clinic Care Needed for: for those with documented structural instabilities/ damage of the sacral or lumbar spine, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, spinal malalignment, or fixed spinal deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage of sacral or lumbar spine. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate spinal instability, damage, or radiculopathy. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0980	Peroneal straps, prefabricated, off-the-shelf, pair	Peroneal straps, pair	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor senstation in the pelvic or peroneal regions, and abnormal anatomy for education on how to adjust, use device. Clinical Care Not Required for: All other patients	Abnormal anatomy, skin or other conditions, lack of manual dexterity required to use device	Pain and discomfort, progression or reinjury due to inability to use device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0982	Stocking supporter grips, prefabricated, off-the-shelf, set of four (4)	Stocking supporter grips, prefabricated, set of four (4)	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor senstation in the thighs, and abnormal anatomy for education on how to adjust, use device. Clinical Care Not Required for: All other patients	Abnormal anatomy, skin or other conditions, lack of manual dexterity required to use device	Pain and discomfort, progression or reinjury due to inability to use device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L0984	Protective body sock, prefabricated, off-the-shelf, each	Protective body sock, prefabricated, each	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and senstation of the torso and proximal limbs. Abnormal anatomy and shape. Education on how to adjust, use device due to reasons stated above. Clinical Care Not Required for: All other patients	Abnormal anatomy, skin or other conditions, lack of manual dexterity required to use device	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L1600	Hip orthosis, abduction control of hip joints, flexible, frejka type with cover, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an inidividual with expertise	Hip orthosis, abduction control of hip joints, flexible, frejka type with cover, prefabricated, includes fitting and adjustment	Descriptor Change-Always Custom fit	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevention of injury; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the hip that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1610	Hip orthosis, abduction control of hip joints, flexible, (frejka cover only), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Hip orthosis, abduction control of hip joints, flexible, (frejka cover only), prefabricated includes fitiing and adjustment	Descriptor Change-Always Custom fit	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevention of injury; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration.*No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the hip that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1620	Hip orthosis, abduction control of hip joints, flexible, (pavlik harness), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Hip orthosis, abduction control of hip joints, flexible, (pavlik harness), prefabricated includes fitiing and adjustment	Descriptor Change-Always Custom fit	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevention of injury; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration*No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist	Abnormal size or anatomy. Documented structural instabilities or damage of the hip that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1810	Knee orthosis, elastic with joints, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Knee orthosis, elastic with joints, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L1812	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevention of injury; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1812	Knee orthosis, elastic with joints, prefabricated, off-the-shelf		New-Split Pair with L1810	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *OTS w/o clinic care: clincial notes defining minor structural instabilites; sprains/strains etc; clinical notes stating that the post operative healing is not soley dependent on proper orthotic fitting and alignment (post operative kinesthetic reminder); clinical documentation definiing comorbities that do not affect their ability to don and doff the device	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L1830	Knee orthosis, immobilizer, canvas longitudinal, prefabricated, off-the-shelf	Knee orthosis, immobilizer, canvas longitudinal, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical documentation defining comorbities that affect the patient's ability to don and doff the device without device alteration *OTS w/o clinic care: all other patients	Abnormal size or anatomy Indication for custom alteration of device for correct donning and doffing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1832	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L1833	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevent further injury to the knee joint; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf		New-Split Pair with L1832	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *OTS w/o clinic care: clincial notes defining minor structural instabilites; sprains/strains etc; clinical notes stating that the post operative healing is not soley dependent on proper orthotic fitting and alignment (post operative kinesthetic reminder); clinical documentation definiing comorbities that do not affect their ability to don and doff the device	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1836	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical documentation defining comorbities that affect the patient's ability to don and doff the device without device alteration *OTS w/o clinic care: all other patients	Abnormal size or anatomy Indication for custom alteration of device for correct donning and doffing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Always Custom fit	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevent further injury to the knee joint; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

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 item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Always Custom fit	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevent further injury to the knee joint; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1847	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L1848	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing or prevent further injury to the knee joint; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *No OTS option: Patients who are prescribed these devices need to been seen by a experienced orthotist.	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1848	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf		New-Split Pair with L1847	*Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes stating specific alignment requirements to facillitate post operative healing; MRI, Xray or other clinical testing results stating that the patient has moderate to severe structural instabilities; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. *OTS w/o clinic care: clincial notes defining minor structural instabilites; sprains/strains etc; clinical notes stating that the post operative healing is not soley dependent on proper orthotic fitting and alignment (post operative kinesthetic reminder); clinical documentation definiing comorbities that do not affect their ability to don and doff the device	Abnormal size or anatomy. Documented structural instabilities or damage of the knee that require an experience orthotist's fitting and device education. Patient's lacking protective sensation. Patient's lacking cognitive or physical ability don and doff the device Specific alignment requirements that need to be followed to facillitate post operative healing	Loss of intended device function due to inappropriate fit. Potential to exacerbate instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1850	Knee orthosis, swedish type, prefabricated, off-the-shelf	Knee orthosis, swedish type, prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinic care: documentation stating the patient has abnormal anatomy or irregular size and shape; clinical notes outlining other comorbidities that might inhibit the patient from properly donning the device without device alteration. OTS without clinical care: clinical documentation defining comorbities that do not affect their ability to don and doff the device	Documented structural instabilities or damage of knee joint. Patient's lacking protective sensation. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal.	Loss of intended device function due to inappropriate fit. Potential to exacerbate knee joint instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L1902	Ankle foot orthosis, ankle gauntlet, prefabricated, off-the-shelf	Ankle foot orthosis, ankle gauntlet, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and sensation, abnormal anatomy, and moderate/severe strains/sprains. Education on device function, how to adjust, clean, and donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly. Clinical Care Not Required for: Patients with minor strain/sprain in need of compression to reduce inflammation and/or give kinesthetic reminder.	Must trim and modify for bony anatomy, avoid excessive pressure on peroneal nerve, adjustment requires alignment with long bones of the leg and alignment with the ankle axis, manual dexterity and hand strength must be assesed to insure proper design of orthosis is chosen.	Loss of intended device function due to inappropriate fit. Potential to exacerbate ankle instability or damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potencial for additional injury due to inappropriate fit. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L1906	Ankle foot orthosis, multiligamentus ankle support, prefabricated, off-the-shelf	Ankle foot orthosis, multiligamentus ankle support, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and sensation, abnormal anatomy, and moderate/severe strains/sprains. Education on device function, how to adjust, clean, and donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly. Clinical Care Not Required for: Patients with minor strain/sprain in need of compression to reduce inflammation and/or give kinesthetic reminder.	Must trim and modify for bony anatomy, avoid excessive pressure on peroneal nerve, adjustment requires alignment with long bones of the leg and alignment with the ankle axis, manual dexterity and hand strength must be assesed to insure proper design of orthosis is chosen.	Skin breakdown at malleoli and/or midfoot, nerve pain, and/or additional strain on the ligaments leading to further damage or prolonged healing process	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3100	Hallus-valgus night dynamic splint, prefabricated, off-the-shelf	Hallus-valgus night dynamic splint	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and senstation of the foot/toes, abnormal anatomy, and wounds on heel for: Education on device function, how to adjust, clean, and donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly. Clinical Care Not Required for: All other patients	Education and training for users with poor circulation and sensation in the feet.	Skin breakdown/ulceration in webspace, metatarsals, and midfoot leading to infection of tissue/bone	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3170	Foot, plastic, silicone or equal, heel stabilizer, prefabricated, off-the-shelf, each	Foot, plastic, silicone or equal, heel stabilizer, each	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and senstation of the foot/toes, abnormal anatomy, and wounds on heel for: Education on device function, how to adjust, clean, and donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly. Clinical Care Not Required for: All other patients	Education and training for users with poor circulation and sensation in the feet. Modification of orthosis for patients with wounds on heel.	Skin breakdown/ulceration of heel leading to infection of tissue/bone	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3650	Shoulder orthosis, figure of eight design abduction restrainer, prefabricated, off-the-shelf	Shoulder orthosis, figure of eight design abduction restrainer, prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients using orthosis for proper ROM and positioning to facilitate healing of strain/sprain/break in shoulder complex. Clinical Care Not Required for: Patients requiring a kinesthetic reminder to avoid abduction of scapula/humerus for minor sprain/strain in shoulder complex.	Device complexity requires appropriate tensioning and positioning based on pts ROM and anatomy	Contracture of muscles in shoulder complex Improper healing and/or prolonged healing time Skin breakdown/ulceration leading to infection of tissue/bone	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3660	Shoulder orthosis, figure of eight design abduction restrainer, canvas and webbing, prefabricated, off-the-shelf	Shoulder orthosis, figure of eight design abduction restrainer, canvas and webbing, prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients using orthosis for proper ROM and positioning to facilitate healing of strain/sprain/break in shoulder complex. Clinical Care Not Required for: Patients requiring a kinesthetic reminder to avoid abduction of scapula/humerus for minor sprain/strain in shoulder complex.	Device complexity requires appropriate tensioning and positioning based on pts ROM and anatomy	Contracture of muscles in shoulder complex. Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to shoulder complex.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3670	Shoulder orthosis, acromio/clavicular (canvas and webbing type), prefabricated, off-the-shelf	Shoulder orthosis, acromio/clavicular (canvas and webbing type), prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients using orthosis for proper ROM and positioning to facilitate healing of strain/sprain/break in shoulder complex. Clinical Care Not Required for: Patients requiring a kinesthetic reminder to avoid abduction of scapula/humerus for minor sprain/strain in shoulder complex.	Device complexity requires appropriate tensioning and positioning based on pts ROM and anatomy Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	**Improper healing and/or prolonged healing time.** **Skin breakdown/ulceration leading to infection of tissue/bone.** **Reinjury to shoulder complex and/or elbow**	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L3675	Shoulder orthosis, vest type abduction restrainer, canvas webbing type or equal, prefabricated, off-the-shelf	Shoulder orthosis, vest type abduction restrainer, canvas webbing type or equal, prefabricated, includes fitiing and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients requiring a specific ROM restrictionto facilatate healing of moderate/severe strain/sprain Clinical Care Not Required for: Patients requiring a kinesthetic reminder to avoid abduction of scapula/humerus for minor sprain/strain in shoulder complex.	Device complexity requires appropriate tensioning and positioning based on pts ROM and anatomy Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.		Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3677	Shoulder orthosis, shoulder joint design, without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Shoulder orthosis, shoulder joint design, without joints, may include soft interface, straps, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L3678	Clinical Care Required for: Patients with a tear in rotator cuff complex and/or post operative needing complete restriction of flexion/extension/abduction/adduction and eliminating internal/external rotation with elbow flexion control. Clinical Care Not Required for: Not recommend this orthosis be fit by an individual without expertise.	Triplanar and rotational control necessary to insure proper healing of rotator cuff and reduction in possibility of reinjury.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to shoulder complex muscles/ligaments. Subluxation/dislocation of humeral head.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3678	Shoulder orthosis, shoulder joint design, without joints, may include soft interface, straps, prefabricated, off-the-shelf		New-Split Pair with L3677	Clinical Care Required for: Patients with a tear in rotator cuff complex and/or post operative needing complete restriction of flexion/extension/abduction/adduction and eliminating internal/external rotation with elbow flexion control. Clinical Care Not Required for: Not recommend this orthosis be fit by an individual without expertise.	Triplanar and rotational control necessary to insure proper healing of rotator cuff and reduction in possibility of reinjury.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to shoulder complex muscles/ligaments. Subluxation/dislocation of humeral head.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3710	Elbow orthosis, elastic with metal joints, prefabricated, off-the-shelf	Elbow orthosis, elastic with metal joints, prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and sensation of the arm, and abnormal anatomy for education on how to adjust, use device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to elbow muscles/ligaments. Aggravation of edema/inflammation	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3762	Elbow orthosis, rigid, without joints, includes soft interface material, prefabricated, off-the-shelf	Elbow orthosis, rigid, without joints, includes soft interface material, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and sensation of the arm, and abnormal anatomy for education on how to adjust, use device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to elbow muscles/ligaments. Aggravation of edema/inflammation	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3807	Wrist hand finger orthosis, without joint(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Wrist hand finger orthosis, without joint(s), prefabricated includes fitting and adjustment, any type	Descriptor Change-Split Pair with L3809	Clinical Care Required for: Patients with documented poor circulation, sensation of the arm, post-op, and/or abnormal anatomy for modification of device and additional care/education on how to use/adjust device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to wrist muscles/ligaments.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L3809	Wrist hand finger orthosis, without joint(s), prefabricated, off-the-shelf, any type		New-Split Pair with L3807	Clinical Care Required for: Patients with documented poor circulation, sensation of the arm, post-op, and/or abnormal anatomy for additional care/education on how to use/adjust device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to wrist muscles/ligaments.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3912	Hand finger orthosis (hfo), flexion glove with elastic finger control, prefabricated, off-the-shelf	Hand finger orthosis (hfo), flexion glove with elastic finger control, prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation, sensation of the arm, post-op, and/or abnormal anatomy for additional care/education on how to use/adjust device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to wrist muscles/ligaments.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3915	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L3916	Clinical Care Required for: Patients with documented poor circulation, sensation of the arm, post-op, and/or abnormal anatomy for modification additional care/education on how to use/adjust device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to wrist muscles/ligaments.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3916	Wrist hand orthosis, includes one or more nontorsion joint(s), elastic bands, turnbuckles, may include soft interface, straps, prefabricated, off-the-shelf		New-Split Pair with L3915	Clinical Care Required for: Patients with documented poor circulation, sensation of the arm, post-op, wrist spasticity, and/or abnormal anatomy for modification additional care/education on how to use/adjust device. Clinical Care Not Required for: All other patients	Abnormal anatomy Skin conditions or wounds Patient training/education on device function, how to adjust, clean, and how to donn/doff device. Additional education on what to expect from the device, who to contact when there are questions/concerns, and device not performing properly.	Improper healing and/or prolonged healing time. Skin breakdown/ulceration leading to infection of tissue/bone. Reinjury to wrist muscles/ligaments.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3917	Hand orthosis, metacarpal fracture orthosis, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Hand orthosis, metacarpal fracture orthosis, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L3918	*Clinic Care required for those with documented structural instabilities/ damage of the structures within the hand or fingers, or a post-OP status. *Clinic care required for patients with significant muscle tone, lack of ROM, or other conditions outside of the norm. *Clinical care for those with significant pain, need for optimal structural alignment, or fixed deformities. Clinic Care Not Needed for: those with minor muscle sprains, strains or injuries that do not appear tomographically, with documented stability, or for those where optimal device fit and function are less important due mild patient condition.	Moderate to severe documented structural instabilities or damage to the structures within the hand or fingers. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Loss of intended device function due to inappropriate fit. Potential to exacerbate already present instability and damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3918	Hand orthosis, metacarpal fracture orthosis, prefabricated, off-the-shelf		New-Split Pair with L3917	*Clinic Care required for those with documented structural instabilities/ damage of the structures within the hand or fingers, or a post-OP status. *Clinic care required for patients with significant muscle tone, lack of ROM, or other conditions outside of the norm. *Clinical care for those with significant pain, need for optimal structural alignment, or fixed deformities. Clinic Care Not Needed for: those with minor muscle sprains, strains or injuries that do not appear tomographically, with documented stability, or for those where optimal device fit and function are less important due mild patient condition.	Moderate to severe documented structural instabilities or damage to the structures within the hand or fingers. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Loss of intended device function due to inappropriate fit. Potential to exacerbate already present instability and damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L3923	Hand finger orthosis, without joints, may include soft interface, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Hand finger orthosis, without joints, may include soft interface, straps, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L3924	*Clinic Care required for those with documented structural instabilities/ damage of the structures within the wrist, hand, fingers, or post-OP status. *Clinic care required for patients with significant muscle tone, lack of ROM, or other conditions outside of the norm. *Clinical care for those with significant pain, need for optimal structural alignment, or fixed deformities. Clinic Care Not Needed for: those with minor muscle sprains and strains or injuries that do not appear tomographically, with documented stability, or for those where optimal device fit and function are less important due mild patient condition.	Documented structural instabilities or damage to the structures within the wrist, hand, or fingers. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Loss of intended device function due to inappropriate fit. Potential to exacerbate already present instability and damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3924	Hand finger orthosis, without joints, may include soft interface, straps, prefabricated, off-the-shelf		New-Split Pair with L3923	*Clinic Care required for those with documented structural instabilities/ damage of the structures within the wrist, hand, fingers, or post-OP status. *Clinic care required for patients with significant muscle tone, lack of ROM, or other conditions outside of the norm. *Clinical care for those with significant pain, need for optimal structural alignment, or fixed deformities. Clinic Care Not Needed for: those with minor muscle sprains and strains or injuries that do not appear tomographically, with documented stability, or for those where optimal device fit and function are less important due mild patient condition.	Documented structural instabilities or damage to the structures within the wrist, hand, or fingers. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Loss of intended device function due to inappropriate fit. Potential to exacerbate already present instability and damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3925	Finger orthosis, proximal interphalangeal (pip)/distal interphalangeal (dip), non torsion joint/spring, extension/flexion, may include soft interface material, prefabricated, off-the-shelf	Finger orthosis, proximal interphalangeal (pip)/distal interphalangeal (dip), non torsion joint/spring, extension/flexion, may include soft interface material, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	*Clinic Care required for those with documented structural instabilities/ damage of the structures within the fingers or a post-OP status. *Clinic care required for patients with significant muscle tone, lack of ROM, or other conditions outside of the norm. *Clinical care for those with significant pain, need for optimal structural alignment, or fixed deformities. Clinic Care Not Needed for: those with minor muscle sprains and strains or injuries that do not appear tomographically, with documented stability, or for those where optimal device fit and function are less important due mild patient condition.	Documented structural instabilities or damage to the structures within the fingers. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Loss of intended device function due to inappropriate fit. Potential to exacerbate already present instability and damage. Skin breakdown, discomfort, loss of patient acceptance and use of device. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
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, off-the-shelf	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 ajustment	Descriptor Change-Always OTS	Clinic care needed for those with documented structural instabilities/ damage of the structures within the fingers, or post-OP status. Clinic care required for patients with significant tone, lack of ROM, or other physical issues outside of the norm. OTS w/o clinic care for those with minor muscle sprains and strains or injuries that do not appear tomographically, with documented stability, or for those where optimal device fit and function are less important due mild patient condition. Clinical care for those with significant pain, need for optimal structural alignment, or fixed deformities.	Documented structural instabilities or damage to the structures within the fingers. Patient's lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Documented structural instabilities or damage to the structures within the fingers. Patient'slacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3929	Hand finger orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L3930	Clinic Care Needed for: for those with documented structural instabilities/ damage of the hand and fingers, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, malalignment, or fixed hand deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage to the structures within the hand or fingers. Patient lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Experienced clinical care required to accurately identify anatomical ladmarks for measurement and fitting. Inadequate support or pressure at incorrect locations could fail to address condition, or cause additional pain, discomfort, or injury. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L3930	Hand finger orthosis, includes one or more nontorsion joint(s), turnbuckles, elastic bands/springs, may include soft interface material, straps, prefabricated, off-the-shelf		New-Split Pair with L3929	Clinic Care Needed for: for those with documented structural instabilities/ damage of the hand and fingers, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, malalignment, or fixed hand deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage to the structures within the hand or fingers. Patient lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Experienced clinical care required to accurately identify anatomical ladmarks for measurement and fitting. Inadequate support or pressure at incorrect locations could fail to address condition, or cause additional pain, discomfort, or injury. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L4350	Ankle control orthosis, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, off-the-shelf	Ankle control orthosis, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and senstation of the ankle/foot, and abnormal anatomy for education on how to adjust, use device. Clinical Care Not Required for: All other patients	abnormal anatomy or irregular size and shape; indication for custom alteration of device for correct donning and doffing	mal-alignment and inproper fitting of device can: inhibit post operativehealing and cause damage to surgical site; reinjury; pain and skin breakdown; non-compliance; patient rejection	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4360	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L4361	Clinic Care Needed for: for those with documented structural instabilities/ damage of the leg, foot, or ankle, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, malalignment, or fixed hand deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage to the structures within the foot or ankle. Patient lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Experienced clinical care required to accurately identify anatomical ladmarks for measurement and fitting. Inadequate support or pressure at incorrect locations could fail to address condition, or cause additional pain, discomfort, or injury. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4361	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, off-the-shelf		New-Split Pair with L4360	Clinic Care Needed for: for those with documented structural instabilities/ damage of the leg, foot, or ankle, post-OP status, or need to alter form of the device to accommodate abnormal anatomy or size. *Clinical care for those with significant pain, malalignment, or fixed hand deformities. Clinic Care Not Needed for: those with muscle sprains and strains or injuries that do not appear tomographically, or for those where optimal device fit and function can be compromised due mild patient condition.	Documented structural instabilities or damage to the structures within the foot or ankle. Patient lacking protective sensation. Post-OP patients. Abnormal size or anatomy. Patient's lacking cognitive or physical ability to care for self or maintain own well being. Lack of muscle strength or ROM to don device as normal. Those with high tone, spasticity, or strong involuntary movements.	Experienced clinical care required to accurately identify anatomical ladmarks for measurement and fitting. Inadequate support or pressure at incorrect locations could fail to address condition, or cause additional pain, discomfort, or injury. Potential lack of patient education on appropriate use, function, fitting issues, and how/ whom to report problems related to device/ change in physical condition.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4370	Pneumatic full leg splint, prefabricated, off-the-shelf	Pneumatic full leg splint, prefabricated includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Required for: Patients with documented poor circulation and senstation of the leg, ankle, or foot, and abnormal anatomy for education on how to adjust, use device. Clinical Care Not Required for: All other patients			Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4386	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated includes fitting and adjustment	Descriptor Change-Split Pair with L4387	Clinical Care Needed for: Independent patients on device function, care/cleaning, and demonstration into the proper positioning and adjustment required. Observational gait analysis to insure proper alignment and control of ankle. Extra training and care required for patients with documented sensation loss and poor circulation. Clinical Care Not Needed for: Patients that will be in a long term health care facility with consistent inspection of their skin, cleaning of the device, and donning/adjustment.	Sensation loss, poor circulation, abnormal size and anatomy, gait kinematics, patient education for positioning and adjustment, pt education on expectations of results and normal use, patient education on how to receive care if device is not working properly, patient education on cleaning, care, and use of device.	Improper fit/adjustment can cause excessive pressure on injury sites leading to reinjury, prolonged healing time, compensatory movement patterns, and pain requiring additional medical/pharmacutical intervention. Risk of skin breakdown/ulceration and infection of tissue/bone.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4387	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, off-the-shelf		New-Split Pair with L4386	Clinical Care Needed for: Independent patients on device function, care/cleaning, and demonstration into the proper positioning and adjustment required. Observational gait analysis to insure proper alignment and control of ankle. Extra training and care required for patients with documented sensation loss and poor circulation. Clinical Care Not Needed for: Patients that will be in a long term health care facility with consistent inspection of their skin, cleaning of the device, and donning/adjustment.	Sensation loss, poor circulation, abnormal size and anatomy, gait kinematics, patient education for positioning and adjustment, pt education on expectations of results and normal use, patient education on how to receive care if device is not working properly, patient education on cleaning, care, and use of device.	Improper fit/adjustment can cause excessive pressure on injury sites leading to reinjury, prolonged healing time, compensatory movement patterns, and pain requiring additional medical/pharmacutical intervention. Risk of skin breakdown/ulceration and infection of tissue/bone.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.

L4396	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise	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	Descriptor Change-Split Pair with L4397	Clinical Care Needed for: Independent patients on device function, care/cleaning, and demonstration into the proper positioning and adjustment required. Abnormal anatomy and size will necessitate modification of device in order to avoid injury or failed use of device. Extra training and care required for patients with documented sensation loss and poor circulation. Modification of device required when patient will be ambulating on the device and the foot plate differs significantly from the anatomy of the patient. Clinical Care Not Needed for: Patients that will be in a long term health care facility with consistent inspection of their skin, cleaning of the device, and donning/adjustment.	Sensation loss, poor circulation, abnormal size and anatomy, patient education for positioning and adjustment, pt education on expectations of results and normal use, patient education on how to receive care if device is not working properly, patient education on cleaning, care, and use of device.	Improper fit/adjustment can lead to contracture of plantar flexors requiring additional intervention beyond prophylactic bracing. Risk of skin breakdown/ulceration and infection of tissue/bone.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4397	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated, off-the-shelf		New-Split Pair with L4396	Clinical Care Needed for: Independent patients on device function, care/cleaning, and demonstration into the proper positioning and adjustment required. Extra training and care required for patients with documented sensation loss and poor circulation. Modification of device required when patient will be ambulating on the device and the foot plate differs significantly from the anatomy of the patient. Clinical Care Not Needed for: Patients that will be in a long term health care facility with consistent inspection of their skin, cleaning of the device, and donning/adjustment.	Sensation loss, poor circulation, abnormal size and anatomy, patient education for positioning and adjustment, pt education on expectations of results and normal use, patient education on how to receive care if device is not working properly, patient education on cleaning, care, and use of device.	Improper fit/adjustment can lead to contracture of plantar flexors requiring additional intervention beyond prophylactic bracing. Risk of skin breakdown/ulceration and infection of tissue/bone.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.
L4398	Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf	Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf includes fitting and adjustment	Descriptor Change-Always OTS	Clinical Care Needed for: Independent patients on device function, care/cleaning, and demonstration into the proper positioning and adjustment required. Abnormal anatomy and size will necessitate modification of device in order to avoid injury or failed use of device. Extra training and care required for patients with documented sensation loss and poor circulation. Clinical Care Not Needed for: Patients that will be in a long term health care facility with consistent inspection of their skin, cleaning of the device, and donning/adjustment.	Sensation loss, poor circulation, abnormal size and anatomy, patient education for positioning and adjustment, pt education on expectations of results and normal use, patient education on how to receive care if device is not working properly, patient education on cleaning, care, and use of device.	Improper fit/adjustment can lead to contracture of plantar flexors requiring additional intervention beyond prophylactic bracing. Risk of skin breakdown/ulceration and infection of tissue/bone.	Clinical notes including: Documentation of clinical evaluation; measurements and/or test results relevant to the orthopedic status of the patient; rationale for prescribed device; and a statement outlining modifications if any made to device to meet prescribed goals; patient education including instructions for use, wear and care, donning, doffing, warranty, and who to contact with problems. Other necessary documentation including: Notice of HIPAA practices; supplier standards; and signed verification of receipt.	Documentation from the physician regarding: Treating diagnosis codes; prescription including alignment requirements, wear schedule, and therapeutic goals; provider can obtain additional data if needed. Documentation from provider regarding fit and function of device; instructions given to patient to be included in clinical record if needed.