State of California
Office of Administrative Law

NOTICE OF APPROVAL OF REGULATORY ACTION
Government Code Section 11349.3
OAL File No. 2015-0820-01 S

In re:
Department of Health Care Services
Regulatory Action:
Title 22, California Code of Regulations

Adopt sections:	51315.1, 51315.2
Amend sections:	51161, 51315
Repeal sections:	[Blank]

In this rulemaking action, the Department adds definitions related to Orthotic and Prosthetic appliances and services. It also amends and establishes requirements that are specific for the prior authorization and reimbursement of Orthotic and Prosthetic appliances and services under Medi-Cal.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 1/1/2016.

Date: October 2, 2015

[Original Signed]
Thanh Huynh
Senior Attorney

For: DEBRA M. CORNEZ, Director

Original: Jennifer Kent
Copy: Lori Manieri

[Stamp]
[REGULAR]

STATE OF CALIFORNIA – OFFICE OF ADMINISTRATIVE LAW
NOTICE PUBLICATION/REGULATIONS SUBMISSION

STD. 400 (REV. 01-2013)
OAL FILE NUMBERS
NOTICE FILE NUMBER: **Z-** 2014-0813-01
REGULATORY ACTION NUMBER: 2015-0820-01S
EMERGENCY NUMBER: [Blank]

For use by Office of Administrative Law (OAL) only
NOTICE: [Blank]

REGULATIONS: [Date Stamp]
2015 AUG 20 A 10:47
OFFICE OF ADMINISTRATIVE LAW

For Use by Secretary of State Only
[Date Stamp]
Endorsed - Filed in the office of the Secretary of State of the State of California
OCT -2 2015
1:53 pm

AGENCY WITH RULEMAKING AUTHORITY: Department of Health Care Services
AGENCY FILE NUMBER (if any): DHCS-08-003

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE: [Blank]
   TITLES: [Blank]
   FIRST SECTION AFFECTED: [Blank]
2. REQUESTED PUBLICATION DATE: [Blank]
3. NOTICE TYPE
   Notice re Proposed Regulatory Action: [Blank]
   Other: [Blank]
4. AGENCY CONTACT PERSON: [Blank]
   TELEPHONE NUMBER: [Blank]
   FAX NUMBER (Optional): [Blank]

OAL USE ONLY
ACTION ON PROPOSED NOTICE
Approved as Submitted: [Blank]
Approved as Modified: [Blank]
Disapproved/Withdrawn: [Blank]
NOTICE REGISTER NUMBER: 2014, 35Z
PUBLICATION DATE: 08/29/14

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)
1a. SUBJECT OF REGULATIONS: Orthotic & Prosthetic Appliances and Services
1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBERS:
[Blank]
2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLES AND SECTIONS **(Including Title 26, if toxics related)**
SECTIONS AFFECTED **(List all section numbers individually. Attach additional sheet if needed.)**
ADOPT: 51315.1 and 51315.2
AMEND: 51161 and 51315
REPEAL: [Blank]
TITLES: 22

3. TYPE OF FILING
Regular Rulemaking (Gov. Code Section 11346): [Checked]
Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code Sections 11349.3, 11349.4): [Blank]
Emergency (Gov. Code, Section 11346.1(b)): [Blank]
Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code Sections 11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute: [Blank]
Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, Section 11346.1): [Blank]
Emergency Readopt (Gov. Code, Section 11346.1(h)): [Blank]
File & Print: [Blank]
Changes Without Regulatory Effect (Cal. Code Regs., Title 1, Section 100): [Blank]
Print Only: [Blank]
Other (Specify): [Blank]

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs, Title 1, Section 44 and Gov. Code Section 11347.1): April 23, 2015 through May 7, 2015

5. EFFECTIVE DATE OF CHANGES (Gov. Code, Sections 11343.4, 11346.1(d)); Cal. Code Regs, Title 1, Section 100):
Effective January 1, April 1, July 1, or October 1 (Gov. Code Section 11343.4(a)): [Checked]
Effective on filing with Secretary of State: [Blank]
Section 100 Changes Without Regulatory Effect: [Blank]
Effective other (Specify): [Blank]

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY.
Department of Finance (Form STD. 399) (SAM Section 6660): [Checked]

Fair Political Practices Commission: [Blank]
State Fire Marshal: [Blank]
Other (Specify): [Blank]

7. CONTACT PERSON: Lori Manieri
TELEPHONE NUMBER: 916-650-6825
FAX NUMBER (Optional): [Blank]
EMAIL ADDRESS (Optional): lori.manieri@dhcs.ca.gov

8. I certify that the attached copy of the regulations is a true and correct copy of the regulations identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE: [Original Signed]
TYPED NAME AND TITLE OF SIGNATORY: Jennifer Kent, Director
DATE: 8/12/15

For use by Office of Administrative Law (OAL) only

[Date Stamp]
Endorsed Approved
OCT 02 2015
Office of Administrative Law

METHOD OF INDICATING CHANGES

This Accessible PDF version of the proposed regulation text includes the phrase [begin underline] at the beginning of each addition, [end underline] at the end of each addition, [begin strikeout] at the beginning of each deletion, and [end strikeout] at the end of each deletion.

A standard PDF version of this proposed regulation text is also available on the Department's Office of Regulations Internet site.

(1) Amend Section 51161 as follows:

§ 51161. [begin underline] Orthotic and [end underline] Prosthetic [begin strikeout] ~~and Orthotic~~ [end strikeout] Appliances [begin underline] and Services. [end underline]

[begin strikeout] ~~Prosthetic and orthotic appliances means those appliances prescribed by a physician, dentist or podiatrist for the restoration of function or replacement of body parts.~~ [end strikeout]

[begin underline] The following definitions shall apply only to Sections 51315, 51315.1 and 51315.2: [end underline]

[begin underline] (a) "Abduction and Rotation Bar" means a rigid bar that is attached to the feet to maintain appropriate positioning of one or both feet.

(b) "Abduction Position, Custom Fitted Orthosis" means a custom-fitted shoulder-elbow-wrist-hand orthosis designed specifically to control abduction of these areas.

(c) "Above Elbow" means trans-humeral as it relates to prostheses or levels of amputation across the long axis of the humerus.

(d) "Above Knee" means trans-femoral as it relates to prostheses or levels of amputation across the long axis of the femur.

(e) "Activities of Daily Living" or "ADLs" means those activities performed by an individual for essential living purposes, such as bathing, eating, toileting, ambulation, dressing and transferring.

(f) "Addition" means any provision that is different from or not included in the base appliance that enhances or facilitates the intended function of the base appliance.

(g) "Ancillary Orthotic Device" means an orthosis that is not otherwise included under any other orthotic grouping.

(h) "Ankle-Foot Orthosis" means an orthosis that traverses the ankle and foot.

(i) "Anterior-Posterior-Lateral Control Orthosis" means an orthosis that traverses the cervical, thoracic, lumbar or sacral areas to provide control of anterior, posterior and lateral motion to these areas of the spine.

(j) "Appliance" means an orthosis or prosthesis that is applied to the appropriate body part to modify or replace the structural and functional characteristic of the neuromuscular and skeletal systems.

(k) "Attachment" means any provision that is different from or not included in the base appliance that changes the base appliance's function beyond its originally intended function.

(*l*) "Backup Appliance" means another of the same prosthetic or orthotic appliance for the purpose of being used in the event the patient's primary appliance is unable to be used.

(m) "Base Appliance" means an appliance that provides the essential or fundamental function designed for the appliance.

(n) "Below Elbow" means trans-radial as it relates to prostheses or levels of amputation across the long axis of the radius or ulna.

(o) "Below Knee" means trans-tibial as it relates to prostheses or levels of amputation across the long axis of the tibia or fibula.

(p) "Bilateral" means being of, or pertaining to both sides of the body.

(q) "Body Jacket" means a rigid or semi-rigid orthosis that encompasses the torso to limit spinal motion.

(r) "Cervical and Multiple Post Collar Orthosis" means a collar that fits around the neck to provide support and protection to the cervical spine.

(s) "Cervical Orthosis" means an orthosis that traverses the cervical vertebrae.

(t) "Cervical-Thoracic-Lumbar-Sacral Orthosis" means an orthotic grouping that includes sacroiliac orthoses, lumbar orthoses, lumbar-sacral orthoses, and anterior-posterior-lateral control orthoses; each individual orthosis traverses the cervical, thoracic, lumbar or sacral vertebrae.

(u) "Cervical-Thoracic Orthosis" means an orthosis that traverses the cervical and thoracic vertebrae.

(v) "Compression Burn Garment" means a stocking worn over a burned area(s) of the body that provides pressure as an aid to healing and reduction of scar tissue.

(w) "Computer Aided Design/Computer Aided Manufacture Model" or "CAD/CAM Model" means an appliance fabricated with the aid of a three-dimensional positive or negative image or digital scanning of the patient's limb(s).

(x) "Conventional Shoes" means non-orthopedic shoes.

(y) "Cranial Orthosis" means a helmet that fits over the head of the patient for the primary purpose of molding the skull, and may provide some protection.

(z) "Custom Fabricated Appliance" or "Custom Fabrication" means an appliance constructed for a specific patient by obtaining individual measurements, fashioning a pattern or creating a mold, using either a plaster cast, or with a positive or negative impression or using a scanning device.

(aa) "Custom Fitted Appliance" means a prefabricated appliance that requires individual adjustment, alteration or assembly for safe and optimal application to a specific patient.

(bb) "Custom Made" means the same as custom fabricated.

(cc) "Date of Service" means the date the appliance was received by the patient.

(dd) "Definitive Prosthetic Appliance" or "Definitive Prosthesis" means a prosthesis intended for long-term use containing components suitable for the full range of functional activities the amputee may be able to perform.

(ee) "Device" means the same as appliance.

(ff) "Direct Formed Appliance" means an appliance in which material is molded over the involved portion of the patient's body and ultimately becomes the appliance or an essential part of the appliance for that patient.

(gg) "Dynamic Flexor Hinge, Reciprocal Wrist Extension/Flexion, Finger Flexion/Extension Orthosis" means a custom-made orthosis that traverses the wrist, hand and fingers to control extension and flexion of these areas.

(hh) "Elbow Orthosis" means an orthosis that traverses the elbow.

(ii) "Endoskeletal Prosthesis" means a prosthesis that is composed of an internal pylon system that provides structural integrity to the appliance and provides the prosthesis' main support by accepting the stress of the body's weight or functional activities.

(jj) "Exoskeletal Prosthesis" means a prosthesis that is composed of a rigid external shell that provides structural integrity to the appliance and provides the prosthesis' main support by accepting the stress of the body's weight or functional activity.

(kk) "External Power" means an orthosis or prosthesis that relies on a force other than that from the user's body to operate, such as from a battery powered motor.

(*ll*) "Finger Orthosis" means an orthosis that traverses the finger.

(mm) "Foot Orthosis" means an orthosis that traverses the foot.

(nn) "Foot Prosthesis" means a prosthesis that replaces all or part of an amputated or deformed foot.

(oo) "Fracture Orthosis" means an orthosis that traverses the upper or lower extremity to stabilize and support an extremity fracture.

(pp) "Gradient Compression Stocking" means a garment with variable degrees of pressure, typically from highest pressure in the distal parts of the garment with a lower pressure in the proximal parts of the garment.

(qq) "Grouping," when used with "orthotic" or "prosthetic" means more than one appliance or service that has been placed together in the same procedural code classification.

(rr) "Hallux-Valgus Splint" means a device that fits over the big toe to maintain proper anatomical position of the toe.

(ss) "Halo Procedure" means a metal structure connected to a skull ring with pins inserted into the skull and attached to a body jacket or other orthosis to hold the metal structure in place in order to immobilize the cervical spine.

(tt) "Hand-Finger Orthosis" means an orthosis that traverses the hand and finger areas.

(uu) "Hand Orthosis" means an orthosis that encompasses the whole or any part of the hand.

(vv) "Hemipelvectomy Prosthesis" means a prosthesis for an amputation that is performed through a portion of the pelvis.

(ww) "Hip Disarticulation Prosthesis" means a prosthesis for an amputation through the hip joint.

(xx) "Hip-Knee-Ankle-Foot Orthosis" means an orthosis that traverses the hip, knee, ankle and foot areas.

(yy) "Hip Orthosis" means an orthosis that traverses the hip area.

(zz) "Immediate and Early Post Surgical Procedure" means amputation and prosthetic appliance management that begins immediately or very soon following surgical closure of the original amputation wound or a residual limb revision wound.

(aaa) "Infant Immobilizer" means a device that restricts movement of the infant in order to stabilize the infant's cervical and upper thoracic spine and airway.

(bbb) "Initial Prosthesis" means a direct formed temporary appliance provided as part of the immediate and early post surgical and prosthetic appliance management.

(ccc) "Insert" means the same as foot orthosis.

(ddd) "Instrumental Activities of Daily Living" or "IADLs" means those activities that support activities of daily living and the capacity for normal activity, including employment, such as outside mobility, shopping, transportation, housework, hygiene, laundry, meal preparation and medication management.

(eee) "Knee-Ankle-Foot Orthosis" means an orthosis that traverses the knee, ankle and foot areas.

(fff) "Knee Disarticulation Prosthesis" means a prosthesis for an amputation through the knee joint.

(ggg) "Knee Orthosis" means an orthosis that traverses the knee area.

(hhh) "Legg-Perthes Orthosis" means a hip orthosis that is designed especially for the patient with Legg-Perthes deformity.

(iii) "Lumbar Orthosis" means an orthosis that traverses the lumbar area.

(jjj) "Lumbar-Sacral Orthosis" means an orthosis that traverses the lumbar and sacral areas.

(kkk) "Mobile Arm Support" means an abduction position, custom fitted orthosis that is designed specifically for a patient who requires support attached to a wheelchair, chair or table.

(lll) "Molded to the Patient" means a custom fabricated appliance.

(mmm) "Off-the-Shelf Appliance" means an orthotic or prosthetic appliance that fits a patient without assembly or structural modification.

(nnn) "Orthopedic Footwear" means an orthotic grouping that includes stock orthopedic shoes, stock conventional shoes and custom-made orthopedic shoes.

(ooo) "Orthopedic Shoes" means an orthotic grouping that includes Hallux-Valgus splint, abduction and rotation bars, orthopedic footwear and shoe modifications of stock orthopedic shoes and stock conventional shoes; or shoes that have features that are designed for a medical condition(s) of the foot or ankle, such as extra room or depth, support, or ability to be modified.

(ppp) "Orthosis" means an externally applied appliance used to modify the structural and functional characteristics of the neuromuscular and skeletal systems.

(qqq) "Orthotic Devices – Lower Limb (Extremity)" means an orthotic grouping that includes hip orthoses, Legg Perthes orthoses, knee orthoses, ankle-foot orthoses, knee-ankle-foot orthoses – or any combination, torsion control: hip-knee-ankle-foot orthoses, torsion control: hip-knee-ankle-foot orthoses (tibial fracture casts), torsion control: hip-knee-ankle-foot orthoses (femoral fracture casts), reciprocating gait

orthoses, and orthotic devices – lower limb (extremity) (additions to lower extremity orthoses).

(rrr) "Orthotic Devices – Lower Limb (Extremity) (Additions to Lower Extremity Orthoses)" means an orthotic grouping that includes additions to fracture orthoses, additions to lower extremity orthoses: shoe-ankle-shin-knee, additions to straight knee or offset knee joints (knee joints), additions: thigh-weight bearing – gluteal/ischial weight bearing, additions: pelvic and thoracic control, additions: general, and custom foot orthoses.

(sss) "Orthotic Devices – Scoliosis Procedures" means an orthotic grouping that includes cervical-thoracic-lumbar-sacral orthoses, thoracic-lumbar-sacral orthoses (low profile) and other scoliosis procedures (body jackets).

(ttt) "Orthotic Devices – Upper Limb" means an orthotic grouping that includes shoulder orthoses; elbow orthoses; wrist-hand-finger orthoses; additions to upper limb orthoses; dynamic flexor hinge, reciprocal wrist extension/flexion, finger flexion/extension orthoses; external power orthoses and other wrist-hand-finger orthoses – custom fitted.

(uuu) "Prefabricated Appliance" means an appliance that has been manufactured from standard molds or patterns with no specific patient in mind.

(vvv) "Preparatory Prosthesis" means a temporary prosthetic appliance utilized to prepare the residual limb for eventual fitting and to evaluate the appropriateness of selected technology and the patient's ability to use a definitive prosthesis.

(www) "Primary Appliance" means the principal appliance intended to be used by the patient.

(xxx) "Procedure" or "Special Procedure" means an appliance, addition, attachment, adaptation or feature that is designed to meet a specific medical need.

(yyy) "Prosthesis" means an externally applied appliance used to replace wholly, or in part, an absent or deficient body part.

(zzz) "Reciprocating Gait Orthosis" means a bilateral hip-knee-ankle-foot orthosis that transfers motion energy from one leg to the other, aiding or enabling ambulation.

(aaaa) "Replacement Glove" means a passive partial hand prosthesis that is made from an existing mold or a cosmetic cover for a passive or functional hand prosthesis.

(bbbb) "Rigid" means not bending; inflexible during normal use and resistant to normal use forces.

(cccc) "Sacroiliac Orthosis" means an orthosis that traverses the pelvic and sacral areas.

(dddd) "Scoliosis Orthosis" means the same as scoliosis procedure.

(eeee) "Scoliosis Procedure" means a spinal orthosis that treats a curvature or other instability of the spine.

(ffff) "Semi-Rigid" means partially rigid; having some rigid elements.

(gggg) "Services" means activities, including medical examinations, that are related to the provision of prosthetic and orthotic appliances, such as repairs, laboratory work necessary for construction of the appliance, casting and cast changes, realignment or adjustment of appliances, application of dressings, measuring or fitting for appliances, training the patient on the use and care of the appliance and delivery of appliances.

(hhhh) "Shoe Modification" means an addition, modification or service to an off-the-shelf or custom-made shoe to improve its functionality.

(iiii) "Shoe Modifications of Stock Orthopedic Shoes and Stock Conventional Shoes" means an orthotic grouping that includes shoe modifications – lifts, shoe modifications – wedges, shoe modifications – heels, orthopedic shoe additions, and transfer or replacement.

(jjjj) "Shoulder-Elbow-Wrist-Hand Orthosis" means an orthotic grouping that includes abduction position, custom fitted orthoses; mobile arm supports; additions to mobile arm supports and fracture orthoses; or an orthosis that traverses the shoulder, elbow, wrist and hand areas.

(kkkk) "Shoulder Orthosis" means an orthosis that traverses the shoulder.

(*llll*) "Spinal Orthosis" means an orthotic grouping where each individual orthosis traverses some part of the spine that includes cranial orthoses, cervical and multiple post collar orthoses, thoracic orthoses (rib belts), thoracic orthoses (anterior-posterior-lateral-rotary control), thoracic orthoses (triplanar control – modular segmented spinal system [prefabricated]), thoracic orthoses (triplanar control – rigid frame), and thoracic orthoses (triplanar control – rigid plastic shell).

(mmmm) "Stock" when used with "orthopedic shoes" or "conventional shoes" means a shoe that fits a patient without assembly or structural modification.

(nnnn) "Tension Based Scoliosis Orthosis" means an orthosis that utilizes elastic strapping linked to control pads intended for treatment of adolescent idiopathic scoliosis.

(oooo) "Thoracic-Hip-Knee-Ankle Orthosis" means an orthosis that traverses the thoracic, hip, knee and ankle areas.

(pppp) "Thoracic-Lumbar-Sacral Orthosis" means an orthosis that traverses the thoracic, lumbar and sacral areas.

(qqqq) "Thoracic Orthosis" means an orthosis that traverses the thoracic area.

(rrrr) "Torsion Control Orthosis" means an orthosis that controls rotation of the joint in which it traverses.

(ssss) "Truss" means an orthosis used to reduce a hernia via direct external abdominal pressure.

(tttt) "Wrist-Hand-Finger Orthosis" means an orthosis that traverses the wrist, hand and finger areas.

(uuuu) "Wrist-Hand Orthosis" means an orthosis that traverses the wrist and hand areas.

(vvvv) "Wrist Orthosis" means an orthosis that traverses the wrist. [end underline]

NOTE: Authority cited: [begin underline] Section 20, Health and Safety Code; and [end underline] Section [begin underline]s[end underline] [begin strikeout] ~~14105~~ [end strikeout] [begin underline] 10725, 14103.7 and 14124.5, [end underline] Welfare and Institutions Code. Reference: Sections [begin underline] 14103.7, 14105.21, [end underline] 14131[begin underline],[end underline] [begin strikeout] ~~and~~ [end strikeout]14132 [begin underline] , 14133.3 and 14133.9 [end underline], Welfare and Institutions Code.

(2) Amend Section 51315 as follows:

§ 51315. [begin underline] Amount, Scope, Duration, Limitation and Prior Authorization of Benefits for Orthotic and [end underline] Prosthetic [begin strikeout] ~~and Orthotic~~ [end strikeout] Appliances [begin underline] and Services [end underline].

(a) [begin underline] Orthotic and prosthetic appliances and services, to the extent necessary for the restoration of function or replacement of a body part(s), or to support a weakened or deformed body member, are covered under the Medi-Cal program as follows:

(1) Except as specified in subsection (a)(2), and subject to Welfare and Institutions Code, Section 14131.10, which excludes coverage for podiatric and adult dental services (with exemptions), [end underline] [begin strikeout] ~~All prosthetic and orthotic appliances necessary for the restoration of function or replacement of body parts as~~ [end strikeout] [begin underline] when [end underline] prescribed by a licensed physician, [begin underline] a licensed [end underline] podiatrist [begin underline],[end underline] [begin strikeout] ~~or~~ [end strikeout] [begin underline] a licensed [end underline] dentist [begin strikeout] ~~,~~ [end strikeout] [begin underline] or a licensed non-physician medical practitioner, [end underline] within the scope of their license, [begin strikeout] ~~are covered when provided~~ [end strikeout][begin underline] and furnished [end underline] by [begin underline] a certified orthotist, [end underline] a [begin underline] certified [end underline] prosthetist, [begin underline] a certified [end underline] orthotist [begin underline] /prosthetist, [end underline] [begin strikeout] ~~or the~~ [end strikeout] [begin underline] a [end underline] licensed [begin underline] physician, a licensed dentist, a licensed podiatrist [end underline] [begin strikeout] ~~practitioner, respectively~~ [end strikeout] [begin underline] or a certified pharmacy pursuant to

subsection (a)(3) below. A certified orthotist, prosthetist and orthotist/prosthetist shall hold current certification from The American Board for Certification in Orthotics, Prosthetics and Pedorthics or the Board of Certification/Accreditation or their successor organizations. [end underline] [begin strikeout] ~~A written prescription signed by a physician, podiatrist, or dentist is always required. In addition, this written, signed prescription shall accompany any request for prior authorization, which is required under the following circumstances:~~ [end strikeout]

[begin underline] (2) Stock orthopedic and stock conventional shoes, pursuant to Section 51315.1(k)(3)(A), are covered when prescribed by a licensed physician or a licensed podiatrist and furnished by a certified orthotist, a certified prosthetist or a certified orthotist/prosthetist.

(3) Orthotic and prosthetic appliances and services listed in the Medi-Cal provider manual, pursuant to Welfare and Institutions Code Section 14105.21, may be furnished and billed by pharmacies, when the pharmacy is certified and enrolled in the Medi-Cal program as a provider.

(b) A written prescription signed by a licensed physician, a licensed podiatrist, a licensed dentist or a licensed non-physician medical practitioner, and clinical notes/medical professional records that document the medical necessity of the appliance or service, shall be maintained by the provider in the patient's medical record, pursuant to Section 51476. A copy of the written, signed prescription or the electronic image/data transmission prescription in accordance with Health and Safety Code, Section 11027 and documentation of medical necessity, as specified in subsection (c), shall accompany the request for prior authorization, which is required under the following circumstances: [end underline]

(1) For orthotic appliances [begin strikeout] ~~(procedure codes L0100-L4999)~~ [end strikeout] each time the cumulative costs of purchase, replacement, and repair exceed $250.00 per [begin strikeout] ~~beneficiary~~ [end strikeout] [begin underline] patient [end underline], per provider, per 90-day period. This 90-day period of time [begin underline] shall [end underline] begin [begin strikeout]~~s~~[end strikeout] on the date of [begin strikeout] ~~payment of~~ [end strikeout] the first [begin strikeout] ~~claim~~ [end strikeout] [begin underline] service [end underline] after the close of the previous 90-day period of time during which a [begin strikeout] ~~claim~~ [end strikeout] [begin underline] service [end underline], if any, was [begin strikeout] ~~paid~~ [end strikeout] [begin underline] provided [end underline].

(2) For prosthetic appliances [begin strikeout] ~~(procedure codes L5000-L8499)~~ [end strikeout] each time the cumulative costs of purchase, replacement, and repair exceed $500.00 per [begin strikeout] ~~beneficiary~~ [end strikeout] [begin underline] patient, [end underline] per provider, per 90-day period. This 90-day period of time [begin underline] shall [end underline] begin[begin strikeout]~~s~~[end strikeout] on the date of [begin strikeout] ~~payment of~~ [end strikeout] the first [begin strikeout] ~~claim~~ [end strikeout] [begin underline] service [end underline] after the close of the previous 90-day period of time during which a [begin strikeout] ~~claim~~ [end strikeout] [begin underline] service [end underline], if any, was [begin strikeout] ~~paid~~ [end strikeout] [begin underline] provided [end underline].

(3) For [begin strikeout] ~~all~~ [end strikeout] [begin underline] orthotic and prosthetic appliances and services where there is no allowable listed procedure code or rate of reimbursement pursuant to Welfare and Institutions Code Section 14105.21(c)

[end underline] [begin strikeout] ~~unlisted, By Report, and By Invoice prosthetic and orthotic appliances~~[end strikeout].

([begin strikeout]~~b~~[end strikeout] [begin underline]c)[end underline] The [begin underline] prior [end underline] authorization request [begin underline] for orthotic and prosthetic appliances and services [end underline] shall [begin underline] be authorized when documentation includes [end underline] [begin strikeout] ~~specify~~ [end strikeout] the type of appliance [begin underline] or service; [end underline] [begin strikeout] ~~and include~~ [end strikeout] the medical diagnosis, [begin underline] and [end underline] prognosis[begin underline] ; [end underline] [being strikeout] ~~, and~~ [end strikeout] an explanation of the purpose [begin strikeout] ~~that~~ [end strikeout] [begin underline] for [end underline] the appliance [begin underline] or service; [end underline] [begin strikeout] ~~will serve~~ [end strikeout] [begin underline] and substantiation that the criteria specified in subsection (c)(1) through (5) below, and the criteria specified in Section 51315.1 for orthotic appliances and services, or the criteria specified in Section 51315.2 for prosthetic appliances and services are met.

(1) The appliance or service is medically necessary for the restoration of bodily functions, to support a weakened or deformed body member or for the replacement of a body part and is reasonable and necessary to protect life, to prevent significant illness or disability, or to alleviate severe pain.

(2) The appliance or service is essential to performing activities of daily living or instrumental activities of daily living.

(3) The appliance or service is consistent with the patient's previous abilities and limitations, as they relate to activities of daily living or instrumental activities of daily

living, prior to the onset of disability or injury, or as appropriate to the patient's chronological and developmental age.

(4) The appliance or service is consistent with the patient's overall medical condition.

(5) The appliance or service is the lowest cost appliance or service that meets the patient's medical need(s).

(d) Prior authorization of orthotic and prosthetic appliances and services shall not be granted for any of the following:

(1) Backup appliances, except when the primary appliance must be worn by the patient 24 hours per day or when the appliance must be cleaned on a regular basis and cannot be dried overnight.

(2) Appliances or services for the sole purpose of cosmetic restoration in the absence of medical necessity as described in subsection (c)(1).

(3) Appliances or services for the sole purpose of restoring functions beyond activities of daily living or instrumental activities of daily living, such as athletic activities.

(4) Appliances or services when the appliance or service is a benefit that is included as part of the acute inpatient hospital stay and the date of service occurs during that stay.

(5) Repair of an appliance when the repair cost is equal to, or greater than, the cost of purchasing a new appliance.

(6) Purchase or replacement of an appliance when the patient's existing appliance can be repaired at a cost less than the cost of purchasing a new appliance, unless the existing appliance does not meet the patient's medical need(s), as

documented by the licensed physician, licensed podiatrist, licensed dentist or licensed non-physician medical practitioner.

(7) Fitting, measuring, training or delivery of the appliance separate from the prior authorization of the appliance itself. [end underline]

[begin strikeout] ~~(c) Authorization for repairs shall not be granted when the cost of repairs is equal to, or more than, the cost of purchasing a new appliance.~~

~~(d) Stock conventional and stock orthopedic shoes are covered when provided by a prosthetist or orthotist on the prescription of a physician or podiatrist and when at least one of the shoes will be attached to a prosthesis or brace.~~

~~(1) Modification of stock conventional or orthopedic shoes is covered when medically indicated.~~

~~(2) Custom-made orthopedic shoes may be authorized when there is a clearly established medical need that cannot be satisfied by the modification of stock conventional or stock orthopedic shoes.~~

~~(e) The only provider types authorized to furnish and bill for prosthetic and orthotic appliances are orthotists, as defined in Sections 51101 and 51225, prosthetists, as defined in Sections 51103 and 51230, physicians, as defined in Section 51053, dentists, as defined in Sections 51027 and 51223, and podiatrists, as defined in Section 51075, acting within the scope of their practice. Prosthetic and orthotic appliance codes are listed in the Medi-Cal provider manual, pursuant to Welfare and Institutions Code section 14105.21. Appliances listed in the provider manual and designated by double asterisks (**) may be furnished and billed by pharmacists.~~ [end strikeout]

([begin strikeout]~~f~~[end strikeout] [begin underline]e[end underline])

Reimbursement for [begin underline] orthotic and [end underline] prosthetic

[begin strikeout] ~~and orthotic~~ [end strikeout] appliances [begin underline] and services shall be subject to the following: [end underline]

(1) Shall not exceed 80 percent of the lowest maximum allowance for California established by the federal Medicare program for the same or similar appliances [begin underline] or services [end underline].

(2) When there is no comparable Medicare-reimbursed appliance [begin underline] or service[end underline], reimbursement shall not exceed an amount that is the [begin strikeout] ~~lesser~~ [end strikeout] [begin underline] lowest [end underline] of:

(A) The usual charges made to the general public for the provision of the same or similar appliances [begin underline] or services [end underline], or

(B) The maximum reimbursement rates listed in the Medi-Cal provider manual.

(3) Maximum reimbursement rates are for the [begin strikeout] ~~basic~~ [end strikeout] [begin underline] base [end underline] appliance [begin strikeout]~~s~~[end strikeout] and for any component parts that may be added to the[begin strikeout]~~se~~[end strikeout] ~~basic~~ [begin underline] base [end underline] appliance [begin strikeout]~~s~~[end strikeout]. When applicable, billings shall include both the [begin strikeout] ~~basic~~ [end strikeout] [begin underline] base [end underline] appliance and the component parts necessary to complete the prescribed appliance.

[begin underline] (4) Orthotic and prosthetic appliances and services that do not require prior authorization shall meet the requirements under Section 51315(c). [end underline]

[begin strikeout] ~~(4) No separate reimbursement for fitting, measuring, or delivery of appliances shall be made.~~ [end strikeout]

NOTE: Authority cited: [begin underline] Section 20, Health and Safety Code; and [end underline] Sections [begin underline] 10725, [end underline] [begin strikeout] ~~14043.75,~~ [end strikeout] 14105, [begin underline] and [end underline]14124.5, [begin strikeout] ~~14132, 14132.76, 14132.765 and 14133,~~ [end strikeout] Welfare and Institutions Code [begin strikeout] ~~; Chapter 328, Statutes of 1982; Chapter 1381, Statutes of 1990; and Section 78, Chapter 146, Statutes of 1999~~ [end strikeout]. Reference: Sections [begin strikeout] ~~14053,~~ [end strikeout] [begin underline] 14103.7, 14105, [end underline] 14105.21, 14132[begin strikeout]~~(k)~~[end strikeout], [begin strikeout] ~~14132.76,~~ [end strikeout] [begin underline]14132.10, [end underline] 14132.765, 14133[begin underline],[end underline] [begin strikeout] ~~and~~ [end strikeout] 14133.1[begin strikeout]~~(c)~~[end strikeout] [begin underline], 14133.3 and 14133.9[end underline], Welfare and Institutions Code.

(3) Adopt Section 51315.1 as follows:

[begin underline] § 51315.1. Requirements Applicable to the Prior Authorization of Orthotic Appliances and Services.

Orthotic appliances and services shall be authorized under the Medi-Cal program when the supporting documentation and all other requirements specified in Section 51315 and in this section are met.

For purposes of this section, medical conditions cited with each appliance/service or group of appliances/services shall not be construed to represent an exhaustive list of medical conditions appropriate to each appliance/service or group of appliances/services. Likewise, such medical conditions may not be appropriate for authorization of the requested appliance/service if medical necessity for the specific appliance/service is not documented.

(a) Shoe Supplies for Diabetics shall include shoes and their fitting(s), modifications and inserts; and shall be authorized when the patient has a diagnosis of diabetes mellitus and requires one or more of the following shoe(s), shoe modification(s) or shoe insert(s) to accommodate for or prevent foot ulceration and related foot conditions:

(1) For prefabricated shoe(s) or shoe insert(s), or modification(s) to prefabricated shoe(s) or shoe insert(s), the patient has one or more of the following medical conditions, appropriate to the requested procedure code(s):

(A) Foot ulcer(s).

(B) Previous amputation of the contralateral foot, or part of either foot, due to microvascular disease secondary to diabetes.

(C) History of foot ulceration(s) of either foot.

(D) Peripheral neuropathy with evidence of callous formation of either foot.

(E) Deformity of either foot, such as rocker bottom foot or Charcot foot.

(F) Compromised vascular disease in either foot.

(G) Positive monofilament examination indicating diabetic neuropathy.

(2) For custom-made shoe(s) or shoe insert(s), or modification(s) to custom-made shoe(s) or shoe insert(s), the patient has one or more of the listed medical conditions in subsection (a)(1), and one or more of the following, appropriate to the requested procedure code(s):

(A) Neurological manifestation(s).

(B) Peripheral circulatory disorder(s).

(C) Treatment or prevention of other foot conditions secondary to diabetes mellitus.

(b) Compression Burn Garments shall be authorized when the patient requires a custom-fabricated garment to provide physician-ordered compression to facilitate the healing of burn tissue or a similar injury, or to prevent scarring.

(c) Gradient Compression Stockings shall include custom-made stockings and garter belts and shall be authorized when one or both of the following criteria is met, appropriate to the requested procedure code(s):

(1) For custom-made compression stockings, the patient has a medical condition that results in symptomatic venous insufficiency or lymphedema in one or both lower extremities that requires the use of a custom-made compression stocking(s).

(2) For garter belts, the patient has an existing or authorized compression stocking or residual limb shrinker and requires the use of a garter belt to hold the compression stocking or shrinker in place.

(d) Spinal Orthoses shall include all of the following:

(1) Cranial Orthoses (helmets) shall be authorized when cranial molding is required in children two years of age and younger with plaglocephaly or craniosynostosis. For purposes of cranial molding in children, the appliance shall be manufactured by a Federal Drug Administration-approved laboratory.

(2) Cervical and Multiple Post Collar Orthoses (collars) shall be authorized when the patient has a medical condition(s) or a medical need(s) that requires support to the cervical spine to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, such as one of the following, appropriate to the requested procedure code(s):

(A) Whiplash or other injury to the neck.

(B) Post-surgical repair of a cervical fracture.

(C) Post-surgical treatment of a ligamentis injury or torticollis.

(D) Treatment in place of surgical intervention for a cervical fracture or ligamentis injury.

(E) Any related medical condition that requires support to the cervical spine.

(3) Thoracic Orthoses (rib belts) shall be authorized when the patient has a medical condition that requires support to the thoracic area to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, such as for fractured ribs or torn intercostal ligaments.

(4) Thoracic Orthoses (anterior-posterior-lateral-rotary control) shall be authorized when both of the following criteria are met:

(A) The patient has one of the following medical conditions:

1. A slipped or herniated disk.

2. Osteoporosis of the thoracic area.

3. A vertebral fracture, with or without surgery.

4. A related medical condition of the thoracic area.

(B) The patient requires one or more of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

1. Trunk support.

2. Reduction of load on the intervertebral discs.

3. Reduction of gross trunk motion in the sagittal plane.

(5) Thoracic Orthoses (triplanar control – modular segmented spinal system [prefabricated]) shall be authorized when both of the following criteria are met:

(A) The patient has one or more of the following medical conditions:

1. Post neck or back surgery.

2. Post laminectomy.

3. A vertebral fracture.

4. A related medical condition of the thoracic area.

(B) The patient requires one or both of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury:

1. Reduction of gross trunk motion in three planes (sagittal, coronal and transverse).

2. Spinal support and stabilization or immobilization of the spine.

(6) Thoracic Orthoses (triplanar control – rigid frame) shall be authorized when the patient has a medical condition that requires one or more of the following

treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

(A) Reduction of load on the intervertebral discs.

(B) Reduction of gross trunk motion in three planes (sagittal, coronal and transverse).

(C) Hyperextension of the thoracic, lumbar and sacral areas of the back.

(7) Thoracic Orthoses (triplanar control – rigid plastic shell) shall be authorized when the patient has one of the following medical conditions that requires reduction of gross trunk motion in three planes (sagittal, coronal and transverse) when spinal support and immobilization are required to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury:

(A) Post neck surgery.

(B) Post back surgery (laminectomy or vertebral fracture).

(C) A related medical condition of the neck or back.

(e) Thoracic Orthoses (sagittal or sagittal-coronal control) shall be authorized when the patient has a medical condition that requires one or more of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

(1) Reduction of load on the intervertebral discs.

(2) Reduction of gross trunk motion in the sagittal plane.

(3) Reduction of gross trunk motion in the sagittal and coronal planes.

(f) Cervical-Thoracic-Lumbar-Sacral Orthoses shall include all of the following:

(1) Sacroiliac Orthoses shall be authorized when the patient has a medical condition that requires one or more of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury:

(A) Support to the pelvic-sacral area.

(B) Reduction of gross trunk motion of the sacroiliac joint.

(C) Pendulous abdomen support, such as in severe ptosis.

(2) Lumbar Orthoses shall be authorized when the patient has a medical condition that requires one or more of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

(A) Support to the lumbar area.

(B) Reduction of load on the intervertebral discs.

(C) Reduction of gross trunk motion in the sagittal plane.

(D) Pendulous abdomen support, such as in severe ptosis.

(3) Lumbar-Sacral Orthoses shall be authorized when the patient has a medical condition that requires one or more of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

(A) Support to the lumbar-sacral areas.

(B) Reduction of load on the intervertebral discs.

(C) Reduction of gross trunk motion in the sagittal or coronal plane.

(D) Flexion of the lumbar spine.

(E) Pendulous abdomen support, such as in severe ptosis.

(4) Anterior-Posterior-Lateral Control Orthoses shall be authorized when the patient has a medical condition that requires support and maximum external restriction of anterior, posterior and lateral motion to the cervical, thoracic, lumbar and sacral spine to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury.

(g) Halo Procedures shall include the base appliance and additions, and shall be authorized when one or both of the following criteria is met, appropriate to the requested procedure code(s):

(1) For the base appliance, the patient has a medical condition that requires support and maximum external restriction of anterior, posterior and lateral motion to the cervical, thoracic, lumbar and sacral spine to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury.

(2) For the addition(s), all of the following are met:

(A) The patient's medical condition requires the specific function for which the addition(s) was designed.

(B) The addition(s) is required by the patient to improve the functionality of the halo procedure, without which the patient's medical need(s) would not be met.

(C) The patient has an existing or authorized halo procedure that is compatible with the addition(s).

(h) Additions to Spinal Orthoses shall be authorized when all of the following criteria are met:

(1) The patient's medical condition requires the specific function for which the addition(s) was designed.

(2) The addition(s) is required by the patient to improve the functionality of the spinal orthosis, without which the patient's medical need(s) would not be met.

(3) The patient has an existing or authorized spinal orthosis that is compatible with the addition(s).

(i) Orthotic Devices – Scoliosis Procedures shall include all of the following:

(1) Cervical-Thoracic-Lumbar-Sacral Orthoses.

(A) Shall include all of the following:

1. The Infant Immobilizer shall be authorized only for children under one year of age for stabilization of the cervical spine, upper thoracic spine and airway. The infant immobilizer shall not be authorized for use in restraining infants during surgical or radiological procedures.

2. The Tension Based Scoliosis Orthosis shall be authorized only for a child diagnosed with adolescent idiopathic scoliosis or a similar deformity or disease.

3. Additions to Cervical-Thoracic-Lumbar-Sacral Orthoses or Scoliosis Orthoses shall be authorized when all of the following criteria are met:

a. The patient's medical condition requires the specific function for which the addition(s) was designed.

b. The addition(s) is required by the patient to improve the functionality of the cervical-thoracic-lumbar-sacral orthosis or scoliosis orthosis, without which the patient's medical need(s) would not be met.

c. The patient has an existing or authorized cervical-thoracic-lumbar-sacral orthosis or scoliosis orthosis that is compatible with the addition(s).

(B) Shall be authorized when both of the following criteria are met:

1. The patient has a diagnosis of scoliosis or other curvature or instability of the spine.

2. The appliance is appropriate for the patient's degree and type of scoliosis, or spinal curvature or instability in which the degree of spinal curvature or instability, any lower extremity length discrepancy, and goals of treatment are considered.

(2) Thoracic-Lumbar-Sacral Orthoses (Low Profile) shall include the base appliance and additions, and shall be authorized when one or both of the following criteria is met, appropriate to the requested procedure code(s):

(A) For the base appliance, both of the following criteria are met:

1. The patient has a diagnosis of scoliosis or other curvature or instability of the spine.

2. The base appliance is appropriate for the patient's degree and type of scoliosis or spinal curvature or instability in which the degree of spinal curvature or instability, any lower extremity length discrepancy, and goals of treatment are considered.

(B) For the addition(s), all of the following criteria are met:

1. The patient has a diagnosis of scoliosis or other curvature or instability of the spine.

2. The patient's medical condition requires the specific function for which the addition(s) was designed.

3. The addition(s) is required by the patient to improve the functionality of the thoracic-lumbar-sacral orthosis, without which the patient's medical need(s) would not be met.

4. The patient has an existing or authorized thoracic-lumbar-sacral orthosis that is compatible with the addition(s).

(3) Other Scoliosis Procedures (body jackets) shall be authorized when both of the following criteria are met:

(A) The patient has a diagnosis of scoliosis or other curvature or instability of the spine.

(B) The appliance is appropriate for the patient's degree and type of scoliosis or spinal curvature or instability in which the degree of spinal curvature or instability, any lower extremity length discrepancy, and goals of treatment are considered.

(j) Orthotic Devices – Lower Limb (Extremity) shall include all of the following:

(1) Hip Orthoses – Flexible shall be authorized when both of the following criteria are met:

(A) The patient has one of the following medical conditions:

1. Congenital hip dislocation or hip dysplasia in infants and children.

2. Post total hip replacement when post-operative hip stabilization is necessary to prevent dislocation or to facilitate healing of a fracture.

3. An injured or previously dislocated hip that requires rehabilitation as an alternative to surgery.

4. A related medical condition that requires control and stabilization of the hip(s).

(B) The patient requires one of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

1. Abduction control, with or without ambulation.

2. Post-operative control of hip motion.

3. Control of adduction or rotational guidance of both hips.

(2) Legg Perthes Orthoses shall be authorized when the patient has a diagnosis of Legg-Calve-Perthes deformity or similar deformity or disease, and requires control of hip abduction, adduction or weight bearing, appropriate to the requested procedure code(s).

(3) Knee Orthoses shall be authorized when both of the following criteria are met:

(A) The patient has a deformity or injury of, or affecting the knee, such as one of the following:

1. Post surgical repair of ligament tears.

2. Post arthroscopy.

3. Osteoarthritis or other degenerative joint disease.

4. Post polio.

5. Rehabilitation of an injured knee.

6. Any related medical condition affecting the knee.

(B) The patient requires one or more of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

1. Support or protection of the knee.

2. Control or restriction of motion of the knee.

3. Medial-lateral and rotation control of the knee.

4. Sagittal plane control of the knee.

5. Prevention or control of recruvatum (hyperextension of the knee).

6. Control of hip flexion in bed.

(4) Ankle-Foot Orthoses shall be authorized when the patient has a disease, deformity, injury or condition of, or affecting the lower extremity in which the patient experiences pain or diminished functional capacity of the lower extremity and requires one or more of the following treatments, appropriate to the requested procedure code(s):

(A) Assistance in specific movements of the ankle and foot.

(B) Support to the ankle and foot.

(C) Maintenance of the foot in a neutral or functional position.

(D) Stabilization of the knee or hip.

(E) Control of movement of the ankle and foot.

(5) Knee-Ankle-Foot Orthoses – or Any Combination shall be authorized when the patient has a disease, deformity, injury or condition of, or affecting the knee or ankle joint(s) in which the patient experiences pain or diminished functional capacity of the knee or ankle joint(s) and requires one or more of the following treatments, appropriate to the requested procedure code(s):

(A) Control of motion of the knee, ankle or foot.

(B) Maintenance of the ankle and foot in a fixed position.

(C) Correction of contractures of the knee and ankle joints.

(6) Torsion Control: Hip-Knee-Ankle-Foot Orthoses shall be authorized when the patient has a disease, deformity, injury or condition of, or affecting the hip, knee or ankle joint(s) in which the patient experiences pain or diminished functional capacity of the hip, knee or ankle joint(s) and requires control in rotation of one or both hips, appropriate to the requested procedure code(s).

(7) Torsion Control: Hip-Knee-Ankle-Foot Orthoses (Tibial Fracture Cast) shall be authorized when the patient has a fracture of the tibia or fibula and requires support and stabilization of the fracture site to facilitate healing, to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury.

(8) Torsion Control: Hip-Knee-Ankle-Foot Orthoses (Femoral Fracture Cast) shall be authorized when the patient has a fracture of the femur and requires support and stabilization of the fracture site to facilitate healing, to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury.

(9) Reciprocating Gait Orthoses shall be authorized when chronologically and developmentally appropriate (beginning around two years of age and up) and all of the following criteria are met:

(A) The patient has both of the following conditions:

1. Thoracic or upper lumbar spine lesions with spasticity.

2. Range of motion limitations that nevertheless allow joints to be put in appropriate position for ambulation.

(B) The patient does not have any of the following conditions or contraindications:

1. Severe irreducible contractures that prevent establishing normal alignment.

2. Severe spasticity or other involuntary muscle activity that prevents free and coordinated mobility.

3. Severe obesity.

4. Poor upper extremity strength.

5. Advanced osteoporosis.

6. A fracture(s) or a history of fracture(s).

7. History of not following treatment plans (noncompliance).

8. A pressure sore(s) in an area(s) that would be in contact with the orthosis.

(C) Documentation in the patient's medical record substantiates all of the following:

1. Cardiopulmonary integrity.

2. That no other orthosis will meet the patient's medical need(s).

3. Spinal cord injury level above the third lumbar vertebrae.

4. No contractures and muscle atrophy that would preclude the use of the reciprocating gait orthosis.

5. Stability of the spine.

6. No advanced osteoporosis or fracture(s).

7. One of the following diagnoses:

a. Paraplegia (diagnosis code 344.1).

b. Spina bifida, without mention of hydrocephalus, dorsal [thoracic] region (diagnosis code 741.92).

c. Spina bifida, without mention of hydrocephalus, lumbar region (diagnosis code 741.93).

d. Any related medical condition affecting the spine.

(D) For patients 21 years of age and older, in addition to the documentation requirements specified in subsection (j)(9)(C)1. through 7., all of the following shall also be documented in the patient's medical record:

1. Plantigrade feet.

2. Minimal contractures in the knees and hips.

3. Flexible hips without rigidity or spasticity.

4. Good upper extremity strength.

5. Realistic goals and expectations and a family or other support system.

(10)(A) Orthotic Devices – Lower Limb (Extremity) (Additions to Lower Extremity Orthoses) shall include all of the following:

1. Additions to Fracture Orthoses.

2. Additions to Lower Extremity Orthoses: Shoe-Ankle-Shin-Knee.

3. Additions to Straight Knee or Offset Knee Joints (Knee Joints).

4. Additions: Thigh-Weight Bearing – Gluteal/Ischial Weight Bearing.

5. Additions: Pelvic and Thoracic Control.

6. Additions: General.

7. Custom Foot Orthoses.

(B) Shall be authorized when all of the following criteria are met, appropriate to the requested procedure code(s):

1. The patient's medical condition requires the specific function for which the addition(s) was designed.

2. The addition(s) is required by the patient to improve the functionality of the lower extremity orthosis, without which the patient's medical need(s) would not be met.

3. The patient has an existing or authorized lower extremity orthosis that is compatible with the addition(s).

(C) In addition to the criteria specified in paragraph (B) above, paragraph (A)7. (Custom Foot Orthoses) shall be authorized when the orthosis is fabricated for a patient using the patient's individual measurements or pattern. This fabrication shall be constructed using a plaster casting of the patient's foot to create a mold, or with a three-

dimensional negative impression or digital scanning (Computer-Aided Design/Computer Aided Manufacture Model [CAD/CAM]). The use of foam boxes shall not be an acceptable fabrication method.

(k) Orthopedic Shoes shall include all of the following:

(1) Hallux-Valgus Splint shall be authorized when the patient has a medical condition of the foot that requires a custom fitted orthosis to hold the big toe in the proper anatomical position.

(2) Abduction and Rotation Bars shall be authorized when the patient has a medical condition of the foot (feet) that requires one or both of the following treatments to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s):

(A) Increased internal or external rotation of the foot (feet).

(B) Independent positioning of the hind foot and forefoot for adduction or abduction.

(3) Orthopedic Footwear shall include both of the following:

(A) Stock Orthopedic Shoes and Stock Conventional Shoes shall include in-depth shoes, and shall be authorized when both of the following criteria are met:

1. At least one of the shoes is attached to a prosthesis or brace. For purposes of this subsection, the following definitions shall apply:

a. A “brace” means an orthosis involving the foot that extends above the ankle and is made of metal or other durable rigid material that immobilizes, restricts movement in a given direction, controls mobility, assists with movement, reduces weight-bearing forces or holds body parts in the correct position.

b. "Attached to a prosthesis or brace" means the prosthesis or brace is permanently affixed to the shoe as an integral part of the shoe.

2. The patient has a medical condition of the foot (feet) that requires one or more of the following treatments, appropriate to the requested procedure code(s):

a. Increased pronation or supination of the foot (feet).

b. Post surgical footwear to allow for changes in volume of the foot (feet).

c. A shoe that holds the heel firmly in place.

d. A firm heel counter and a strong shank.

e. Accommodation of a deformed foot (feet) or a foot orthosis(es).

f. Footwear to allow for changes in volume, fractures, amputation or ulcers of the foot (feet).

(B) Custom-Made Orthopedic Shoes shall include both the base shoe(s) and any required addition(s) to the base shoe(s):

1. The base shoe(s) shall be authorized when both of the following criteria are met:

a. The patient does not require a shoe(s) provided under the diabetic footwear program covered under subsection (a), but has a medical need(s) that cannot be met by modification(s) to a stock orthopedic or stock conventional shoe(s) covered under subsections (k)(3)(A) and (k)(4). The prescribing practitioner shall document the nature, cause and severity of the foot problem(s) that substantiates the requirement for a custom-made shoe(s), such as one of the following medical conditions:

i. Charcot or rheumatoid foot deformities.

ii. Partial foot amputation.

iii. Post muscle flap surgery to cover a large or unusual soft tissue foot defect.

iv. A related medical condition that requires a custom-made orthopedic shoe(s),

b. The patient's medical condition of the foot (feet) requires one or more of the following accommodations, appropriate to the requested procedure code(s):

i. A severely deformed foot (feet).

ii. A toe or distal partial foot amputation.

iii. A sensitive foot (feet), or a pressure sore(s) or area(s).

iv. A related foot condition.

2. The base shoe(s) shall be authorized when it has all of the following characteristics:

a. Made and molded to the patient model for a specific patient.

b. Constructed over a positive model of the patient's foot.

c. Made from leather or other suitable material of equal or better quality.

d. Has removable inserts as an integral part of the shoe that can be altered or replaced as the patient's condition warrants.

e. Has some form of shoe closure.

3. The addition(s) to the base shoe shall be authorized when all of the following criteria are met:

a. The patient's medical condition requires the specific function for which the addition(s) was designed.

b. The addition(s) is required by the patient to improve the functionality of the custom-made orthopedic shoe(s), without which the patient's medical need(s) would not be met.

c. The patient has an existing or authorized custom-made orthopedic shoe(s) that is compatible with the addition(s).

(4) Shoe Modifications of Stock Orthopedic Shoes and Stock Conventional Shoes, including additions, modifications and services:

(A) Shall include all of the following:

1. Shoe Modifications – Lifts.

2. Shoe Modifications – Wedges.

3. Shoe Modifications – Heels.

4. Orthopedic Shoe Additions.

5. Transfer or Replacement. For purposes of subsection (k)(4), the terms "Transfer" and "Replacement" mean standard laboratory procedures for general shoe work for the purpose of transfer and fixation of an orthosis from one shoe to another.

(B) Shall be authorized when all of the following criteria are met:

1. The patient's medical condition requires the specific function for which the addition(s), modification(s) or service(s) was designed.

2. The addition(s), modification(s) or service(s) is required by the patient to improve the functionality of the shoe(s), without which the patient's medical need(s) would not be met.

3. The patient has an existing or authorized shoe(s) that is compatible with the addition(s), modification(s) or service(s).

(*l*) Orthotic Devices – Upper Limb shall include all of the following:

(1) Shoulder Orthoses shall be authorized when the patient has a medical condition of, or affecting the shoulder joint that requires that the shoulder be held in place to prevent or limit motion in order to protect the shoulder joint from injury or provide support/stabilization during functional activities.

(2) Elbow Orthoses shall include elbow orthoses, elbow-wrist-hand orthoses and elbow-wrist-hand-finger orthoses, and shall be authorized when the patient has a medical condition of, or affecting the elbow, wrist, hand or finger joint(s) that requires support, stabilization, restriction or enhancement of movement of the elbow, wrist, hand or finger joint(s) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s).

(3) Wrist-Hand-Finger Orthoses shall be authorized when the patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires support, stabilization, restriction or enhancement of movement of the wrist, hand or finger(s) to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s).

(4) Additions to Upper Limb Orthoses shall be authorized when all of the following criteria are met:

(A) The patient's medical condition requires the specific function for which the addition(s) was designed.

(B) The addition(s) is required by the patient to improve the functionality of the upper extremity wrist, finger or elbow joint(s), without which the patient's medical need(s) would not be met.

(C) The patient has an existing or authorized upper extremity orthosis that is compatible with the addition(s).

(5) Dynamic Flexor Hinge, Reciprocal Wrist Extension/Flexion, Finger Flexion/Extension Orthoses shall be authorized when the patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-made orthosis to hold the hand, finger or wrist in a prescribed position and to enhance and control movement of the hand, finger or wrist.

(6) External Power shall be authorized when both of the following criteria are met:

(A) The patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-made, electrically powered wrist-hand-finger orthosis to allow effective movement of the wrist, hand or finger(s) in the performance of activities of daily living or instrumental activities of daily living.

(B) The patient is not able to otherwise effectively use a manually operated orthosis.

(7) Other Wrist-Hand-Finger Orthoses – Custom Fitted shall include both of the following:

(A) Custom Fitted Wrist-Hand-Finger Orthoses shall be authorized when the patient has a medical condition of, or affecting the wrist, hand or finger(s) that requires a custom-fitted orthosis to provide support, stabilization, restriction or enhancement of movement of the wrist, hand or finger(s), appropriate to the requested procedure code(s).

(B) Addition of a joint(s) to an upper extremity orthosis shall be authorized when all of the following criteria are met:

1. The patient has a medical condition that requires the specific function for which the joint(s) was designed.

2. The joint(s) is required by the patient to improve the functionality of the upper extremity orthosis, without which the patient's medical need(s) would not be met.

3. The patient has an existing or authorized upper extremity orthosis that is compatible with the joint(s).

(m) Shoulder-Elbow-Wrist-Hand Orthoses shall include all of the following:

(1) Abduction Position, Custom Fitted Orthoses shall be authorized when both of the following criteria are met:

(A) The patient has a medical condition of, or affecting the shoulder, elbow, wrist or hand, such as one of the following:

1. Post surgery of the shoulder, elbow or wrist joint(s).

2. Treatment of Erbs Palsy.

3. A related medical condition of the shoulder, elbow or wrist joints.

(B) The patient requires a custom-fitted orthosis to provide positioning, stabilization or restriction of movement of the shoulder, elbow, wrist or hand, appropriate to the requested procedure code(s).

(2) Mobile Arm Supports shall be authorized when the patient meets the criteria specified in paragraph (1) above and requires such support attached to a wheelchair, chair or table.

(3) Additions to Mobile Arm Supports shall include both additions and adaptations to the mobile arm support or the addition(s), and shall be authorized when all of the following criteria are met:

(A) The patient's medical condition requires the specific function for which the addition(s) or adaptation(s) was designed.

(B) The addition(s) or adaptation(s) is required by the patient to improve the functionality of the mobile arm support, without which the patient's medical or functional need(s) would not be met.

(C) The patient has an existing or authorized mobile arm support that is compatible with the addition(s) or adaptation(s).

(4) Fracture Orthoses shall be authorized when the patient has a fracture of the upper extremity and requires support and stabilization of the fracture site to facilitate healing, to decrease pain, to increase functional capacity, or to prevent or ameliorate further injury, appropriate to the requested procedure code(s).

(n) Repairs for orthotic appliances shall include repairs, maintenance, replacements and associated labor, and shall be authorized when all of the following criteria are met:

(1) The patient has an existing orthosis that requires repair, maintenance or replacement.

(2) The repair, maintenance or replacement cost(s), including the associated labor is less than the cost(s) of purchasing a new orthotic appliance.

(3) The request or claim includes a list of the components to be repaired or replaced and a statement explaining the necessity for the repair or replacement.

(o) Ancillary Orthotic Devices shall be authorized when the patient has a medical condition that requires an upper or lower extremity orthosis not otherwise covered under this section to provide support and positioning to an upper or lower extremity joint(s), appropriate to the requested procedure code(s).

(p) Trusses shall be authorized when the patient has an abdominal hernia or a similar deformity or disease and requires a truss to reduce the hernia.

NOTE: Authority cited: Section 20, Health and Safety Code; and Sections 10725 and 14124.5, Welfare and Institutions Code. Reference: Sections 14103.7, 14105.21, 14132, 14133, 14133.1, 14133.3 and 14133.9, Welfare and Institutions Code.
[end underline]

(4) Adopt Section 51315.2 as follows:

[begin underline] § 51315.2. Requirements Applicable to the Prior Authorization of Prosthetic Appliances and Services.

Prosthetic appliances and services shall be authorized under the Medi-Cal program when supporting documentation and all other requirements specified in Section 51315 and in this section are met.

For purposes of this section, medical conditions cited with each appliance/service or group of appliances/services shall not be construed to represent an exhaustive list of medical conditions appropriate to each appliance/service or group of appliances/services. Likewise, such medical conditions may not be appropriate for authorization of the requested appliance/service if medical necessity for the specific appliance/service is not documented.

(a) Lower Limb Prostheses:

(1) Shall be authorized when the patient has a functional level of “one” or higher (potential for ambulation or other functional activites). Lower limb prostheses shall not be authorized when the patient has a functional level of “zero” (no potential for ambulation or other functional activites).

(2) Shall include all of the following:

(A) Partial Foot Prostheses shall be authorized when the patient has had an amputation of part or all of the foot and requires a definitive prosthesis to permit ambulation or other functional activities.

(B) Ankle Prostheses shall be authorized when the patient has had an amputation through or at the ankle, such as a Syme’s procedure and requires a definitive prosthesis to permit ambulation or other functional activities.

(C) Below Knee Prostheses shall be authorized when the patient has had an amputation between the ankle and knee and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities.

(D) Knee Disarticulation Prostheses shall be authorized when the patient has had an amputation through or near the knee and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities.

(E) Above Knee Prostheses shall be authorized when the patient has had an amputation between the knee and hip and requires a definitive prosthesis to permit ambulation or other functional activities.

(F) Hip Disarticulation Prostheses shall be authorized when the patient has had an amputation through or near the hip and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities.

(G) Hemipelvectomy Prostheses shall be authorized when the patient has had an amputation with removal of half the pelvis and requires an exoskeletal definitive prosthesis to permit ambulation or other functional activities.

(H) Endoskeletal Prostheses shall be authorized when the patient has had a lower limb amputation and requires an endoskeletal definitive prosthesis to permit ambulation or other functional activities, appropriate to the requested procedure code(s).

(I) Immediate and Early Post Surgical Procedures shall be authorized when the patient has had a lower limb amputation and requires one or more of the following, appropriate to the requested procedure code(s):

1. A temporary prosthesis shall be authorized when it is applied soon after amputation before the original amputation wound or residual limb revision(s) wound has completely healed to permit some lower extremity function.

2. An additional cast change(s) and realignment(s) of the temporary prosthesis specified in paragraph 1. above shall be authorized when the patient has an existing or authorized temporary prosthesis that requires these services.

3. A temporary application of a non-weight bearing rigid dressing shall be authorized when it is applied soon after amputation before the original amputation wound or the residual limb revision(s) wound has completely healed, and when there is no expectation of use of a prosthesis until the wound has completely healed.

(J) Initial Prostheses shall be authorized when the patient has had a lower limb amputation that requires a temporary prosthesis, and when the prosthesis is applied after the original amputation wound or the residual limb revision(s) wound has healed but the residual limb has not reached its final shape, appropriate to the requested procedure code(s).

(K) Preparatory Prostheses – Below Knee shall be authorized when the patient has had a below-the-knee amputation and requires a temporary prosthesis to permit some ambulation or other functional activities in preparation for the fitting of a definitive prosthesis, and when the prosthesis is applied after the original amputation wound or the residual limb revision(s) wound has healed but the residual limb has not reached its final shape.

(L) Preparatory Prostheses – Above Knee shall be authorized when the patient has had an above-the-knee amputation and requires a temporary prosthesis to permit some ambulation or other functional activities in preparation for the fitting of a

definitive prosthesis, and when the prosthesis is applied after the original amputation wound or the residual limb revision(s) wound has healed but the residual limb has not reached its final shape, appropriate to the requested procedure code(s).

(M) Additions to Lower Limb Prostheses:

1. Shall include all of the following:

a. Endoskeletal System – Above Knee.

b. Test Sockets.

c. Socket Variations.

d. Socket Inserts.

e. Suspension – Below Knee.

f. Suspension – Above Knee.

g. Exoskeletal Knee-Shin System.

h. Endoskeletal Knee-Shin System.

i. Miscellaneous.

2. Shall be authorized when all of the following criteria are met:

a. The patient's medical condition requires the specific function for which the addition(s) was designed.

b. The addition(s) is required by the patient to improve the functionality of the prosthesis, without which the patient's medical need(s) would not be met.

c. The patient has an existing or authorized lower limb prosthesis that is compatible with the addition(s).

(N) Replacements – Feet-Ankle Units shall be authorized when both of the following criteria are met:

1. The cost(s) of the replacement is less than the cost(s) of purchasing a new prosthesis.

2. The patient has an existing or authorized lower limb prosthesis that is compatible with the replacement(s).

(b) Upper Limb Prostheses shall include all of the following:

(1) Partial Hand Prostheses shall be authorized when the patient has had an amputation of part or all of the hand and requires a definitive prosthesis to permit functional use of the upper extremity, appropriate to the requested procedure code(s).

(2) Wrist Disarticulation Prostheses shall be authorized when the patient has had an amputation through or near the wrist and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity.

(3) Elbow Prostheses shall be authorized when the patient has had an amputation near the elbow and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity, appropriate to the requested procedure code(s).

(4) Shoulder Prostheses shall be authorized when the patient has had an amputation through or near the shoulder and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity.

(5) Interscapular Thoracic Prostheses shall be authorized when the patient has had an amputation with removal of both the shoulder joint and the scapula and requires an exoskeletal definitive prosthesis to permit functional use of the upper extremity.

(6) Immediate and Early Post Surgical Procedures shall be authorized when the patient has had an upper limb amputation and requires one or more of the following, appropriate to the requested procedure code(s):

(A) A temporary prosthesis shall be authorized when it is applied soon after amputation before the original amputation wound or the residual limb revision(s) wound has completely healed to permit some upper extremity function.

(B) An additional cast change(s) and realignment(s) of the temporary prosthesis specified in paragraph (A) above shall be authorized when the patient has an existing or authorized temporary prosthesis that requires these services.

(C) A temporary application of a non-weight bearing rigid dressing shall be authorized when it is applied soon after amputation before the original amputation wound or the residual limb revision(s) wound has completely healed, and when there is no expectation of use of a prosthesis until the wound has completely healed.

(7) Endoskeletal – Elbow or Shoulder Area Prostheses shall be authorized when the patient has had an upper extremity amputation and requires a definitive prosthesis to permit functional use of the upper extremity, appropriate to the requested procedure code(s).

(8) Endoskeletal – Interscapular Thoracic Prostheses shall be authorized when the patient has had an upper limb amputation and requires a temporary or preparatory prosthesis to permit some upper extremity function in preparation for the fitting of a definitive prosthesis; and when the prosthesis is applied after the original amputation wound or the residual limb revision(s) wound has healed but the residual limb has not reached its final shape, appropriate to the requested procedure code(s).

(9) Additions to Upper Limb Prostheses shall be authorized when all of the following criteria are met:

(A) The patient's medical condition requires the specific function for which the addition(s) was designed.

(B) The addition(s) is required by the patient to improve the functionality of the prosthesis, without which the patient's medical need(s) would not be met.

(C) The patient has an existing or authorized upper limb prosthesis that is compatible with the addition(s).

(10) Replacements for Upper Limb Prostheses shall be authorized when both of the following criteria are met:

(A) The cost(s) of the replacement is less than the cost(s) of purchasing a new prosthesis.

(B) The patient has an existing or authorized upper limb prosthesis that is compatible with the replacement(s).

(c) Terminal Devices shall include all of the following:

(1) Hooks shall include both the base appliance or device and any required addition(s) or attachment(s) and shall be authorized when one or both of the following criteria is met, appropriate to the requested procedure code(s):

(A) For the requested base appliance or device, both of the following criteria are met:

1. The patient requires a terminal device to permit functional use of the upper extremity.

2. The patient has an existing or authorized upper extremity prosthesis that is compatible with the terminal device.

(B) For the requested addition(s) or attachment(s), all of the following criteria are met:

1. The patient's medical condition requires the specific function for which the addition(s) or attachment(s) was designed.

2. The addition(s) or attachment(s) is required by the patient to improve the functionality of the terminal device, without which the patient's medical need(s) would not be met.

3. The patient has an existing or authorized terminal device that is compatible with the addition(s) or attachment(s).

(2) Hands shall include both the base appliance or device and any required addition(s) or attachment(s) and shall be authorized when one or both of the following criteria is met, appropriate to the requested procedure code(s):

(A) For the base appliance or device, both of the following criteria are met:

1. The patient requires a terminal device to permit functional use of the upper extremity.

2. The patient has an existing or authorized upper extremity prosthesis that is compatible with the terminal device.

(B) For the addition(s) or attachment(s), all of the following criteria are met:

1. The patient's medical condition requires the specific function for which the addition(s) or attachment(s) was designed.

2. The addition(s) or attachment(s) is required to improve the functionality of the terminal device, without which the patient's medical need(s) would not be met.

3. The patient has an existing or authorized terminal device that is compatible with the addition(s) or attachment(s).

(3) Hand Restoration Procedures shall include casts, shading and measurements and shall be authorized when one or more of the following criteria is met, appropriate to the requested procedure code(s):

(A) For the partial hand prosthesis, both of the following criteria are met:

1. The patient requires a partial hand prosthesis to permit functional use of the upper extremity.

2. The patient has an existing or authorized upper extremity prosthesis that is compatible with the partial hand prosthesis.

(B) For the replacement glove(s), both of the following criteria are met:

1. The patient requires a replacement glove(s) for a hand prosthesis.

2. The patient has an existing or authorized hand prosthesis that is compatible with the replacement glove(s).

(d) External Power shall include all of the following:

(1) Base Devices shall be authorized when both of the following criteria are met:

(A) The patient requires an upper extremity prosthesis with one or more electrically powered functional parts or electronic circuitry that is activated by the patient to allow effective movement of the upper extremity in the performance of activities of daily living and instrumental activities of daily living, appropriate to the requested procedure code(s).

(B) The patient is not able to otherwise effectively use a manually operated prosthesis.

(2) Terminal Devices shall be authorized when all of the following criteria are met:

(A) The patient requires a terminal device with one or more electrically powered functional parts or electronic circuitry that is activated by the patient to allow effective movement of the upper extremity in the performance of activities of daily living

and instrumental activities of daily living, appropriate to the requested procedure code(s).

(B) The patient is not able to otherwise effectively use a manually operated prosthesis.

(C) The patient has an existing or authorized upper extremity prosthesis that is compatible with the terminal device.

(3) Elbow Attachments shall be authorized when all of the following criteria are met:

(A) The patient requires an elbow joint attachment with one or more electrically powered functional parts or electronic circuitry that is activated by the patient to allow effective movement of the upper extremity in the performance of activities of daily living and instrumental activities of daily living.

(B) The patient is not able to otherwise effectively use a manually operated prosthesis.

(C) The patient has an existing or authorized upper extremity prosthesis that is compatible with the elbow attachment.

(4) Control Modules and Battery Components shall be authorized when the patient has an existing or authorized upper extremity electrically powered prosthesis that requires a control module or battery component for functional use of the prosthesis.

(e) Breast Prostheses shall be authorized when the patient requires a prosthesis, component or attachment to replace a breast(s) after surgical removal, to support the surgical recovery or to hold the prosthesis in place.

(f) General Items shall include all of the following:

(1) Prosthetic Socks shall be authorized when both of the following criteria are met:

(A) The patient requires one or more of the following appliances, appropriate to the requested procedure code(s):

1. A prosthetic sheath that is placed over a residual limb and under a prosthetic sock while the prosthesis is being worn to decrease the irritation of the residual limb.

2. A prosthetic sock that is worn between the residual limb and the prosthesis to decrease the irritation of the residual limb.

3. A prosthetic shrinker that is worn over the residual limb to provide pressure against the residual limb to decrease accumulation of fluid in the residual limb.

4. A thinly woven sock that is used over the residual limb during the fitting of a prosthesis.

(B) The patient has an existing or authorized lower extremity prosthesis that is compatible with the prosthetic sheath, sock or shrinker.

(2) Repairs for Prosthetic Appliances shall include repairs, maintenance, replacements and associated labor and shall be authorized when all of the following criteria are met:

(A) The patient has an existing prosthesis that requires repair, maintenance or replacement.

(B) The repair, maintenance or replacement cost(s), including the associated labor is less than the cost(s) of purchasing a new prosthetic appliance.

(C) The request or claim includes a list of the components to be repaired or replaced and a statement explaining the necessity for the repair or replacement.

(g) Miscellaneous Prosthetic Appliances shall be authorized when the patient has had an amputation or removal of a body part and requires one or more of the following appliances or devices, appropriate to the requested procedure code(s):

(1) A prosthetic appliance or service that is not functionally equivalent to, or does not meet the descriptor for, an existing prosthetic appliance or service procedure code(s).

(2) A device to enable speaking in the absence of the larynx.

(3) A device to enable speaking with a tracheostomy.

(4) A replacement battery or accessory for an artificial larynx.

(5) A trachea-esophageal voice prosthesis.

(6) A voice amplifier.

NOTE: Authority cited: Section 20, Health and Safety Code; and Sections 10725 and 14124.5, Welfare and Institutions Code. Reference: Sections 14103.7, 14105.21, 14132, 14133, 14133.1, 14133.3 and 14133.9, Welfare and Institutions Code.
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