Commenter Name, Title, Organization and Date of Comment(s)

1. Steven D. K. Ross, M.D., Chair, Allied Health Committee, California Orthopaedic Association, (Dated/Received September 15, 2014)

Comment

The California Orthopaedic Association is the statewide association representing over 70% of all orthopaedic surgeons practicing in California. We appreciate the opportunity to comment on these regulations. We offer the following comments.

Response

Please see Responses below.

Comment

1. Page 5 (oo): This subsection refers to orthosis that traverses the upper extremity. We agree with this statement, but need to point out that the orthosis could also traverse to the lower extremity.

   We recommend that the section be amended to read: "Fracture Orthosis" means an orthosis that traverses the upper or lower extremity to stabilize and support an extremity fracture."

Response

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added the phrase "or lower" and removed "upper" to clarify that the orthosis can also traverse to the lower extremity.

Comment

2. Page 5 (rr): While there are times you might see the term "hallus" used to describe the big toe, more commonly the Latin spelling is used, "hallux."

   We recommend that "hallus" be changed to "hallux" on this page and throughout the document.

Response

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment corrected the spelling of "hallus" to "hallux" in subsection (rr) for the definition of "Hallus-Valgus Splint," and throughout the regulation text.

Comment

3. Page 7 (ooo): Typographical errors.

   "orthopedic shoes" means an orthotic…includes Hallux, Valgus splint…"

Response

This subsection was not amended based on comment. The hyphen between "Hallus-Valgus Splint…" will not be removed because the Department does not agree with this suggestion.

Comment

4. Page 12-13 (a) (3): This section indicates that a pharmacist or pharmacy may furnish and bill for orthotic and prosthetic appliances and services as long as they are a Medi-Cal provider. We just want to make sure that a pharmacist could not also be the prescriber of the device.

   We recommend a clarification that "furnish" does not mean that a pharmacist or pharmacy could also prescribe the device.

Response

The Department concurs that pharmacists cannot prescribe O&P appliances.

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendments removed provisions in subsections (a)(1) and (a)(3) that provided for "licensed pharmacists" to furnish selected O&P appliances. However, subsection (a)(3) continues to provide that certified pharmacies enrolled in the Medi-Cal program may furnish (not prescribe) those appliances listed in the Medi-Cal Provider Manual.

Comment

5. Page 19 – (c) (1): This section refers to "custom-made compression stockings," we are unclear what would be the criteria to determine whether the compression stockings are "custom-made."

   We recommend adding criteria defining custom-made compression stockings.

Response

This subsection was not amended based on comment.

The term "Custom-made" is clearly defined in Section 51161, subsection (bb) and also as referred to in subsections (z) and (aa), so additional "criteria" is not necessary.

Comment

6. Page 20 – (E)(3): Thoracic Orthoses This section allows thoracic orthosis when the patient has a medical condition that requires support to the thoracic area. We are unaware of any scientific studies that support this statement.

   Please advise the scientific evidence used to support the use of thoracic orthosis.

Response

The assumption is that this comment is in reference to Section 51315.1(d)(3).

Medi-Cal reimburses for thoracic orthoses. One example of these orthoses is a "rib belt." The Department is not aware of "scientific studies" that support or refute the use of thoracic orthoses. However, the purpose of this regulatory action is to amend and establish requirements (including medical necessity) that are specific for the prior authorization and reimbursement of O&P appliances and services that are currently available under the Medi-Cal program.

In consideration of this comment and upon further review, this subsection was amended through a 15-day Public Availability published on April 23, 2015; the introduction under Section 51315.1 was amended to clarify that the lists of medical conditions provided under each type of appliance are not intended to be complete lists, and a specific appliance is not necessarily needed in

all cases, even when the patient's condition is on the list. Explanation of medical necessity for the specific patient and appliance would still need to accompany the Treatment Authorization Request (TAR) when submitting for approval and reimbursement of the requested appliance.

Comment

7. Page 28 (A) (2): Post Arthroscopy – bracing would not be required for all arthroscopic conditions. For example, a simple menisectomy does not need a brace.

   We recommend a more precise statement as to when bracing would be needed following an arthroscopy procedure.

Response

The assumption is that this comment is in reference to Section 51315.1(j)(3)(A)2.

The Department concurs that not all arthroscopy procedures would require bracing.

In consideration of this comment and upon further review, this subsection was amended through a 15-day Public Availability published on April 23, 2015, to clarify that the lists of medical conditions provided under each type of appliance are not intended to be complete lists, and a specific appliance is not necessarily needed in all cases, even when the patient's condition is on the list. Explanation of medical necessity for the specific patient and appliance would still need to accompany the TAR when submitting for approval and reimbursement of the requested appliance.

Comment

8. Page 28 (A) (3): Osteoarthritis or other degenerative joint disease – we don't believe that the scientific literature supports the routine use of bracing for osteoarthritis.

   Please advise the scientific evidence used to support the routine use of bracing for osteoarthritis.

Response

The assumption is that this comment is in reference to Section 51315.1(j)(3)(A)3.

The Department concurs that not all osteoarthritic knees would require bracing.

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability published on April 23, 2015, to clarify that the lists of medical conditions provided under each type of appliance are not intended to be complete lists, and a specific appliance is not necessarily needed in all cases, even when the patient's condition is on the list. Explanation of medical necessity for the specific patient and appliance would still need to accompany the TAR when submitting for approval and reimbursement of the requested appliance.

Comment

9. Additional comments: Throughout the proposed regulations, they refer to which health care professionals may prescribe orthotic and prosthetic appliances and services for Medi-Cal patients. Podiatrists are included as one of the health care professionals who would be authorized to prescribe these devices.

   It is our understanding that currently, services rendered by podiatrists are considered an optional benefit and not covered under the Medi-Cal program. Because podiatrists are currently not able to treat Medi-Cal patients, it seems inappropriate for them to be able to prescribe orthotic and prosthetic appliances and services for Medi-Cal patients.

   We recommend the deletion of podiatrists as one of the health care professionals able to prescribe orthotic and prosthetic appliances and services to be consistent with their ability to treat Medi-Cal patients.

Response

Per Welfare & Institutions (W&I) Code Section 14131.10 and Title 22 California Code of Regulations (CCR) Section 51310, podiatry services are a Medi-Cal benefit, with some limitations. Podiatry services, though 'excluded from coverage,' continue to be available to exempted eligible Medi-Cal beneficiaries: children, those with pregnancy-related conditions, those residing in a skilled nursing facility or an acute hospital setting, and those admitted to an emergency department. In addition, podiatry remains a benefit for those eligible Medi-Cal beneficiaries seeking care in Federally Qualified Health Centers and Rural Health Clinics.

For non-exempted eligible Medi-Cal beneficiaries, the Department will continue to honor TARs for O&P appliances prescribed by a podiatrist when furnished by a Medi-Cal enrolled orthotist, prosthetist, and/or an orthotist/prosthetist.

Therefore, the Department will not consider removing podiatrists or podiatry from the list of health care professionals able to prescribe O&P appliances or from the benefits available to Medi-Cal beneficiaries.

Commenter Name, Title, Organization and Date of Comment(s)

2. Jeff Collins, CPA, President, California Orthotic & Prosthetic Association, (Dated/Received September 22, 2014)

Comment

On behalf of the California Orthotic & Prosthetic Association (hereafter; COPA), please accept the following comments regarding the DHCS proposed regulatory action.

1. By way of this notice and pursuant to Government Code Section 11346.8, COPA is requesting a public hearing on this proposed rulemaking by DHCS.

Response

The Department held a public hearing on October 23, 2014 at 10:00 a.m.

Comment

2. Representing the O&P field since 1970, COPA is the only statewide association dedicated to O&P business owners, individual practitioners and the California patients we serve. Orthotists and Prosthetists are medical professionals who are trained and certified to fabricate and fit O&P devices to patients, often times amputees, as prescribed by an appropriately licensed health care provider (i.e., physician and surgeon, podiatrist or another qualified non-physician practitioner). These O&P devices are designed to be worn on the patient to replace or assist the functioning of a natural part of the human body.

   Our ultimate goal is to ensure patients reach their full potential. One can only imagine what it must be like to manage the use of an O&P device on a daily basis. Only the users of these devices can define their daily challenges and way of life. What can only be worse are regulatory hurdles to receiving these devices or misguided Medi-Cal policies that will not ensure their ultimate safety and wellbeing.

   It is within this spirit of providing a positive patient experience that COPA elucidates the following questions and concerns regarding the aforementioned proposed rulemaking.

Response

Please see responses below.

Comment

3. Section 51315: Amount, Scope Duration, Limitation and Prior Authorization of Benefits for O&P Appliances and Services. Amended subsection (a)(1) establishes that licensed pharmacists and pharmacies may furnish O&P appliances and services pursuant to added subsection (a)(3). Added subsection (a)(3) references only appliances and services listed in the Medi-Cal provider manual, pursuant to Welfare & Institutions (W&I) code section 14105.21. Our understanding is the current list of double-asterisked (**) codes in the Medi-Cal provider manual established by the department for this purpose includes the following: L0120, L1902, L3908, L8300, L8310, L8320, L8330, L8000, L8001, L8002, L8010, L8015.

Response

Please see responses below.

Comment

3a. Are these the same codes that will still apply to added subsection (a)(3)?

Response

Yes, subsection (a)(3) will apply to the current eligible procedure codes. This regulatory action does not add or delete codes from the eligible procedure codes for Medi-Cal.

Comment

3b. Does the DHCS plan on changing and/or expanding the list of codes authorized by added subsection (a)(3)?

Response

This regulatory action does not add or delete codes from the eligible procedure codes for Medi-Cal.

Comment

3c. What statutory authority does the DHCS have to explicitly include "a licensed pharmacist" under amended subsection (a)(1)?

Response

The Department concurs that "licensed pharmacist" should be removed from this subsection.

Please see FSOR, Addendum 1, Commenter #1, Comment #4 for response.

Comment

3d. COPA is concerned that certified pharmacies would be authorized to furnish customized O&P appliances. Notwithstanding physicians and surgeons or podiatrists, only certified Orthotists and Prosthetists have the unique education and training to appropriately fit, fabricate, and furnish these appliances. Pharmacies should only be able to furnish the existing aforementioned codes currently authorized by DHCS and specifically identified in the Medi-Cal provider manual.

Response

The Department concurs with this comment.

Please see FSOR, Addendum 1, Commenter #1, Comment #4 for response.

Comment

3e. Furthermore, COPA believes by expanding existing law to include "a licensed pharmacist" would constitute an underground regulation. W&I Code section 14105.21 only references a certified pharmacy. COPA suggests DHCS seek legislation to provide the enabling statutory authority to expand this section to include "a licensed pharmacist." Any such legislation should also include a requirement that "a licensed pharmacist" also be certified in orthotics or prosthetics by either the Board of Orthotist Certification or the American Board of Certification in O&P. This same requirement applies to Orthotists and Prosthetists as a condition of participating in the Medi-Cal program pursuant to W&I Code section 14132.63.

Response

Please see FSOR, Addendum I, Commenter #1, Comment #4 for response.

Comment

4. Added subsection (b) includes language regarding record keeping and prior authorization requests.

Response

Please see responses below.

Comment

4a. What providers (i.e., licensed physician, podiatrist, and dentist or non-physician medical practitioner) are subject to the proposed medical record "clinical notes" requirement documenting medical necessity?

Response

This regulatory action, Section 51315(b), requires that a provider who prescribes and/or furnishes O&P appliances and services must document and maintain records that justify medical necessity for the requested appliances and services. Depending upon the provider type, medical necessity documentation may vary; however, since it is the O&P provider who submits the TAR for authorization of the requested appliances and services, the provider must maintain records, which may have been obtained through other health care providers. These records must justify medical necessity for authorization of the requested appliances and services.

Comment

4b. To what extent does this record keeping requirement apply to O&P practitioners?

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #4a. for response.

Comment

4c. Notwithstanding amended subsection (c), what specific documentation of medical necessity shall accompany a prior authorization request?

Response

Any documentation that justifies medical necessity for authorization of the requested O&P appliance and/or service shall be submitted with the TAR. The Department is aware that such documentation will vary depending upon the patient, his/her specific medical needs and the specific O&P appliance, and/or service being requested.

Comment

4d. COPA needs to specifically articulate and advise our members on how best to meet these record keeping requirements. In general, the prior authorization process can be fickle. We hope to minimize interruptions in providing O&P appliances and services to Medi-Cal beneficiaries by being abundantly clear on what specific documentation is necessary to expedite the prior authorization process articulated in this proposed rulemaking.

Response

The intent of this regulatory action is to specify requirements (criteria) that must be met for prior authorization, as well as accompanying documentation requirements. Specific documentation provided will vary based on each patient's medical needs and the appliance and/or service being requested.

Comment

5. Added Subsection (c)(2) and (3) applies to documentation necessary to determine prior authorization and medical necessity for O&P appliances and services.

Response

Please see responses below.

Comment

5a. Under added subsection (c)(2), who will be determining whether or not the appliance or service is essential to performing activities of daily living (ADLs) or instrumental ADLs (IADLs)?

Response

The provider of the O&P appliances and services is responsible for ensuring that the ADL and IADL criteria are met and documented to determine medical necessity, and that all appropriate documentation is submitted with the TAR. The Department's TAR adjudicator (Medical Consultant) will review and determine if the TAR and accompanying documentation demonstrate medical necessity to support prior authorization. This review will include the review of ADL and/or IADL needs. The Department recommends that the O&P provider work closely with the other health care professionals caring for the patient to ensure that medical necessity documentation is clear and adequate to substantiate the requested appliance/service.

Comment

5b. Under added subsection (c)(3), who will be determining whether or not the appliance or service is consistent with the patient's previous abilities and limitations, as they relate to ADLs, prior to the onset of disability or injury, or as appropriate to the patient's chronological and developmental age?

Response

Determination of the patient's prior abilities and limitations, as they relate to ADLs or is appropriate to the patient's chronological and developmental age, like the determination of ADL/IADL needs, is part of the determination of medical necessity as established by the health care professionals caring for the patient and by the O&P provider. This determination, as documented in the patient's clinical notes/medical professional records, shall be submitted with the TAR for authorization of the requested appliance and/or service.

The Department recommends that the O&P provider work closely with the other health care professionals caring for the patient to ensure that medical necessity documentation is sufficient to substantiate the TAR request.

Comment

5c. Under both added subsections (c)(2) and (3), what qualifications would this presumed individual have to make these determinations? For example, how would these determinations be made and what tests would be subject to these determinations?

Response

Health care professionals and O&P providers that prescribe and furnish O&P appliances and services have expertise in this area and knowledge of the specific medical needs of their patients, which enables them to determine whether an appliance and/or service is necessary.

Comment

5d. Determinations of ADLs and previous ability limitations can be highly subjective. Personnel relied upon by DHCS and the qualifications of these personnel and the quantitative analysis relied upon by these personnel is tantamount to COPA in terms of ensuring adequate and timely access to care for Medi-Cal beneficiaries.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment #5c. for response.

In addition, the assumption is that the information required to make these determinations is available for each patient and is considered prior to submission of the TAR. This regulatory action has a focus on documentation of this information to allow the Department's TAR adjudicator access to the information to make medical necessity decisions regarding the patient's condition and the TAR request.

The Department recommends that the O&P provider work closely with the other health care professionals caring for the patient to ensure that medical necessity documentation is sufficient to substantiate the TAR request.

Comment

5e. Furthermore, the Medi-Cal program may need to incur significant additional costs for "testing" and evaluation by a physical therapist, occupational therapist and/or physician. COPA is concerned that subjective determinations on ADLs would not only delay the prior authorization process and delay O&P care for Medi-Cal beneficiaries but also negatively impact the reimbursement timeline for providers that are already struggling with a challenging Medi-Cal reimbursement rate for these O&P appliances and services.

Response

Please refer to FSOR, Addendum 1, Commenter #2, Comment 5c. and 5d. for response.

The Department does not believe that this regulatory action materially changes any services or that it will cause a delay in the authorization of appliances, delay care for the patient or negatively impact the reimbursement timeline for O&P providers. The purpose of this regulatory action is to amend and establish requirements (including medical necessity) that are specific for the prior authorization and reimbursement of O&P appliances and services under Medi-Cal.

Comment

6. Added subsection (d)(4) addresses denials of prior authorization of O&P appliances and 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.

Response

Please see responses below.

Comment

6a. How will the O&P practitioner know or be able to determine if such an appliance or service is included in the hospital contract?

Response

The Department recommends that the O&P provider work closely with the referring hospital or health care provider to determine the contract inclusions.

Section 51315(d)(4) is necessary to protect Medi-Cal from providing reimbursement twice for the same O&P appliance or service.

Comment

6b. How and where is the “acute inpatient hospital stay” defined? For example, would prior authorization not be granted under this subsection if an appliance and service is also provided in the skilled nursing facility, long-term care facility or acute rehab facility?

Response

Health facilities are defined and described in the Health and Safety Code Section 1250.

Only acute inpatient hospitals are contracted to include medical devices. Other health facilities' reimbursement does not include medical devices. Therefore, for beneficiaries residing in health facilities other than an acute inpatient hospital, prior authorization would be considered through the TAR process and based on medical necessity.

Comment

6c. Existing Medi-Cal provisions in this regard are already confusing for many O&P practitioners and hospital facilities. O&P practitioners provide a bevy of appliances and services in many different facility settings. This specific provision may in fact create a detrimental delay in the provision of O&P care.

Response

Section 51315(d)(4) is necessary to protect Medi-Cal from providing reimbursement twice for the same O&P appliance or service.

The Department does not believe that this provision materially changes any services, including access or delays in the provision of O&P appliances or services to Medi-Cal beneficiaries.

Comment

7. Added subsection (d)(6) addresses denial of prior authorization for the purchase or replacement of an O&P 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.

Response

Please see responses below.

Comment

7a. How will this determination be made? For example, will the O&P practitioner be required to provide a repair estimate or will the appliance manufacturer/vendor be required to provide documented MSRP of a specific appliance? In the event an appliance must be returned to the manufacturer of a subcomponent for that appliance for a repair estimate, how does the O&P practitioner get paid and/or reimbursed for these costs? For example, some appliances can *ONLY* be repaired by the manufacturer (i.e., hydraulic units in prosthetic knees, some components of prosthetic feet, myoelectric hands, etc.). There are an increasing complex array of "non-field serviceable" appliances and systems on the market. In order to obtain a "repair estimate" for these appliances the O&P practitioner must remove the item, ship it to the manufacturer, pay the manufacturer to provide the repair estimate and return shipping if not repaired. These repair estimates from the manufacturer are only valid for a limited time – often less than the TAR processing requirement. Whom does the DHCS assume incurs these costs?

Response

Proposed Section 51315(d)(6) is an expansion of current provisions in Section 51315(a)(1) – (3) and (c), which have been successfully followed by O&P providers. Proposed Section 51315(d)(6) does not materially change the authorization process for O&P appliances and services. Proposed Section 51315(c)(5) states that Medi-Cal reimburses only the lowest cost appliance/service that meets the patient's medical need(s). Therefore, reimbursing for repair of an appliance when it would be less costly to purchase a new appliance would not be cost effective or appropriate under the Medi-Cal program.

Information regarding the cost of repair versus the cost of purchasing a new appliance can be submitted with the TAR requesting purchase or repair.

Costs incurred for obtaining the repair estimate and shipping of the appliance to and from the repairing entity can be reimbursed by Medi-Cal with an invoice that clearly states the costs and where/how they were incurred.

Comment

7b. COPA strongly believes that any additional unnecessary costs or labor for O&P practitioners to participate in Medi-Cal will force them to leave the program.

Response

The Department does not believe that this regulatory action will cause unnecessary costs or labor for O&P providers. Proposed Section 51315(d)(6) does not materially change the authorization of O&P appliances.

Comment

8. Added subsection (d)(7) addresses denials of prior authorization for fitting, measuring, training or delivery of an O&P appliance separate from the authorization of the appliance itself.

Response

Please see responses below.

Comment

8a. Quite frankly this subsection makes no sense to us and requires clarification. Does this mean that the O&P practitioner will get reimbursed separately for the appliance and the fitting, measuring, training and delivery? Or does this subsection mean there is no pathway or methodology for an O&P practitioner to get prior authorization for fitting, measuring, training and delivery of the appliance? This will be especially acute with the new "split codes." These are identical appliances that get billed using different codes if the appliance is "off the shelf" or "custom fitted." For example, if an "off the shelf" appliance is furnished to a beneficiary by an entity that cannot "custom fit" the appliance, how will that be resolved by DHCS? Coincidentally, O&P practitioners by and large do not adjust and/or repair appliances furnished by another provider – primarily due to product liability risks.

Response

Proposed Section 51315(d)(7) is similar to existing Section 51315 (f)(4). O&P providers are currently following these main provisions. O&P providers are not able to bill separately for the fitting, measuring, training or delivery of O&P appliances.

The fitting, measuring, training or delivery of an appliance is considered part of the appliance itself and therefore, included in reimbursement of the appliance. Such costs should be included on the TAR when it is submitted for authorization of the requested appliance. These costs are appropriate only with purchase or repair of the appliance and cannot be reimbursed when rendered separate from the appliance.

Comment

8b. Again, COPA is most concerned with making sure the Medi-Cal program functions properly to address the O&P needs of its beneficiaries. To that end, prior authorization for appliances *AND SERVICES* must be covered. An O&P appliance that is ill fitted, measured incorrectly or if the patient is not properly trained on how to use the appliance – can have a devastating impact on their ability to heal properly and/or restore the active daily living they sorely deserve.

Response

Section 51315(d)(7) does not materially change the authorization of O&P appliances. Medi-Cal has never reimbursed for such services separate from the appliance.

Fitting, measuring, training or delivery services are part of the authorization of the original appliance and can only be reimbursed again if the current appliance needs to be repaired or replaced.

Comment

9. Brief Commentary on Medi-Cal reimbursement of O&P appliances and services: Amended subsection (e) applies to reimbursement conditions for O&P appliances and services. The primary condition is that reimbursement shall not exceed 80 percent of the lowest maximum allowance for California established by Medicare for the same or similar services. (W&I Code section 14105.21)

COPA has relied upon data provided by DHCS over the years illustrating that the reimbursement for this category of O&P appliances and services has decreased at least $20 million, well in excess of 50 percent, over the past 10 years with at least 520,000 fewer appliances reaching Medi-Cal beneficiaries. Unfortunately, the resulting human costs of this ongoing trend can be devastating.

COPA believes that from a programmatic standpoint it is tantamount to understand specifically from DHCS why reimbursement for these appliances and services has decreased so dramatically over the past 10 years? COPA supported emergency regulations promulgated by DHCS years ago that removed a bulk of low cost items that were being fraudulently provided. COPA also understands that a large percentage of codes have decreased in utilization due to lack of increased reimbursement.

However, these two factors alone cannot solely contribute to the over $20 million cost reduction and corresponding 520,000 plus drop in furnished appliances jeopardizes the appropriate medical equipment needs that Medi-Cal patients deserve. Furthermore, conversion to Medi-Cal managed care may also be precipitating a further negative impact on furnishing of O&P appliances.

COPA specifically proposes pegging the O&P appliances and services reimbursement at 80 percent of the applicable Medicare allowable, in effect on the date of service, which is still consistent with existing law stating these rates cannot *EXCEED* that amount. New codes that are added by Medicare and eventually adopted by Medi-Cal are initially pegged at 80 percent of the maximum allowable and then those rates diminish over time. In fact, some current O&P codes are barely reimbursed at 15 percent of the Medicare allowable.

In order to ensure medically necessary access to care for this population, we would also ask for your technical assistance in how best to correct this reimbursement and appliance utilization disparity. COPA is prepared to pursue any means necessary, including legislative, in order to successfully accomplish this objective.

The prosthetic and orthotic appliances category has not received an increase in reimbursement in over 20 years – while the cost of materials, labor and overhead needed to produce the projects have skyrocketed. With reimbursement rates for many of these services pegged at less than the cost of their production factors, Medi-Cal is no longer accepted by an increasing number of O&P practitioners throughout California. This can be evidenced by the lack of new provider applications for this category. Therefore, Medi-Cal beneficiaries may be forced to recycle junked components or try to navigate the streets on crutches or carts and have limited or no local access to appropriate levels of care that increases needed access to other medical services.

Without a definitive and consistent reimbursement methodology rate for these appliances in the Medi-Cal program, vulnerable patients may continue to suffer from substantial and lasting disabilities. These patients, many of whom are amputees, will struggle to achieve proper use and maintenance of worn out and defective O&P devices, increasing the likelihood of chronic disability and injury.

Therefore, our overall objective is to ensure that the vulnerable and disabled Medi-Cal population will not be forced to continue using old and inferior appliances that fail to completely restore their function. Our secondary objective is to also ensure greater access to care for these medically compromised patients who are in jeopardy of not completely healing properly or recovering from surgery and therefore may eventually require more costly Medi-Cal services.

Response

Provisions related to reimbursement have remained unchanged and are outside the scope of this regulatory action.

Providing technical assistance regarding the options available to change reimbursement rates or utilization is outside the scope of this regulatory action.

Commenter Name, Title, Organization and Date of Comment(s)

3. Mitchell Dobson, CPO, FAAOP, Vice President, Compliance Hanger Clinic, (Dated/Received October 2, 2014)

Comment

Hanger Clinic delivers direct O&P patient care, and is the largest owner and operator of O&P patient care clinics, with in excess of 770 locations nationwide. Hanger Clinic and its subsidiary companies are current providers of Medi-Cal services.

On behalf of Hanger Clinic, please accept the following comments regarding DHCS proposed regulatory action.

Response

Please see responses below.

Comment

1. Comments for amended section 51161 (i): "'Anterior-Posterior-Lateral Control Orthosis' means an orthosis that traverses the cervical, thoracic, lumbar and sacral areas to provide control of anterior, posterior and lateral motion to these areas of the spine." – The phrase "Anterior-Posterior-Lateral Control" does not require that the device traverse all levels of the spine (i.e., cervical, thoracic, lumbar and sacral). We suggest changing this definition to include "/or", to read as follows: "'Anterior-Posterior-Lateral Control Orthosis' means an orthosis that traverses the cervical, thoracic, lumbar and/or sacral areas to provide control of anterior, posterior and lateral motion to these areas of the spine."

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment deleted “and” and added “or” to provide clarity and flexibility for the authorization and reimbursement of this appliance.

The Department concurs that the phrase “Anterior-Posterior-Lateral Control” does not require that the device traverse all levels of the spine.

Comment

2. Comments for amended section 51161: (zz): “’Immediate and Early Post Surgical Procedure’ means amputation and prosthetic appliance management that begins immediately after the following surgical closure of the original amputation wound or a residual limb revision wound.” – The definition of “early” post surgical implies that it differs from “immediate” and that the device may not be applied to the patient for some time after surgery. We suggest changing the current verbiage to the following: “’Immediate and Early Post Surgical Procedure means amputation and prosthetic appliance management that begins immediately or very soon after the surgical closure of the original amputation wound or a residual limb revision wound.”

Response

The assumption is that there is an error in the reference to proposed subsection (zz). The phrase “after the” is not part of the proposed definition of “Immediate and Early Post Surgical Procedure.”

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added: “or very soon” to clarify that “early” post surgical differs from “immediate” in that the device may not be applied to the patient for some time after surgery.

The Department concurs that this addition will more clearly specify when this management is intended to begin.

Comment

3. Comments for amended section 51161: (uuu): "'Prefabricated Appliance' means an appliance that has been manufactured from standard molds or patterns." – According to Medicare, the definition of a prefabricated device is one that is manufactured in quantity without any specific patient in mind. Since the proposed definition of "standard" is not clearly delineated, we suggest the following language. "'Prefabricated Appliance' means an appliance that has been manufactured from molds or patterns with no specific patient in mind."

Response

In consideration of this comment, upon further review, and to be consistent with DMEPOS Quality Standards developed and maintained by the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) (June 2014), this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added: "with no specific patient in mind" to specify that these appliances are standard molds and patterns manufactured in quantity without consideration of a specific patient type.

Comment

4. Comments for amended section 51161: (bbbb) "'Rigid' means not bending; inflexible." While rigid does mean "not bending or inflexible," it should be noted that the rigidity exists when the device is being used properly and is resistant to normal forces incurred during use. The description should not be applied outside of that context. Our recommendation is to revise to the following "'Rigid' means not bending, inflexible during normal use and/or resistant to normal use forces."

Response

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added: "during normal use and/or resistant to normal use forces" to specify that "rigidity" exists when appliances are being used properly and are resistant to normal forces incurred during use.

Comment

5. Comments for added section 51315: (a) Orthotic and prosthetic appliances and services, to the extent necessary for the restoration of function or replacement of a body part(s), are covered under the Medi-Cal program as follows:" – This definition is not consistent with published Medicare guidance defining an orthosis. We suggest adding "to support a weakened or deformed body member" within the definition to read "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:…"

Response

In consideration of this comment, upon further review, and to be consistent with DMEPOS Quality Standards developed and maintained by the Department of Health and Human Services, CMS (June 2014), this subsection was amended through a 15- Day Public Availability, published on April 23, 2015; the amendment added: "or to support a weakened or deformed body member."

Comment

6. Comments for added section 51315: (a)(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 pharmacists or pharmacies, when the pharmacist or pharmacy is licensed and enrolled in the Medi-Cal program as a provider." – Medicare has indicated that all devices that are not considered Off-The-Shelf (OTS) should only be provided by Certified Orthotists or those with specialized training. Medicare further defines those who constitute "with specialized training." This list does not include pharmacists. We believe that this omission reflects the lack of either training or capacity (such as equipment) to provide devices which would fall under the "additional training" requirement. Most pharmacists/ pharmacies generally provide only OTS devices, in which is in general keeping with previous limitation of pharmacists by Medi-Cal regulation. While the list of codes which are defined as OTS has expanded beyond the previous pharmacy limitation, it should be noted that the complete list of OTS devices would most likely fit well within the pharmacy model. Further, should a pharmacy wish to employ a Certified Orthotist, they would be able to provide and bill the codes not described by OTS within the code descriptor.

Response

Please refer to FSOR, Addendum 1, Commenter #1, Comment #4. for response.

Comment

7. Comments for added section 51315: (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 that document the medical necessity of the appliance or services, shall be maintained by the provider in the patient's medical record, pursuant to Section 51476." – It should be noted that "clinical notes' can be any part of the official medical record and may include an orthotist's notes. We suggest revising this language to include a definition of "clinical notes" which clearly identifies and includes all medical professional records.

Response

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "medical professional records."

The Department's intent for "clinical notes" is to include any medical/professional records that serve to describe the patient and justify medical necessity for the requested appliance or service.

Comment

8. Comments for added section 51315: (c)(1) "The appliance or service is medically necessary for the restoration of bodily functions 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." – In order to more closely match established definitions of orthosis, specifically as defined by Medicare, the phrase "or to support a weakened or deformed body member" should be added. As such it would read, "The appliance or service is medically necessary for the restoration of bodily functions, <u>to support a weakened or deformed body member,</u> 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."

Response

In consideration of this comment, upon further review, and to be consistent with DMEPOS Quality Standards developed and maintained by the Department of Health and Human Services, CMS (June 2014), this subsection was amended through a 15- Day Public Availability, published on April 23, 2015; the amendment added ", to support a weakened or deformed body member."

Comment

9. Comments for added section 51315: (d)(3) "Appliances or services for the purpose of restoring functions beyond activities of daily living or instrumental activities of daily living, such as athletic activities." – While we generally support this coverage statement, we recommend more clearly defining the statement. Some devices provide basic functionality which primarily meet the needs of the patient for activities of daily living or instrumental activities of daily living. However, some devices could be used to meet those needs and could also be used to provide exercise or other recreational benefit. By revising the statement to read "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", we believe that it meets the intent but would not inadvertently create a denial simply because the patient could use a device for activities beyond basic coverage purposes.

Response

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "sole," which is intended to bring further clarity to this provision and to prevent the authorization and reimbursement of O&P appliances and services beyond basic coverage.

Commenter Name, Title, Organization and Date of Comment(s)

4. James L. Hewlett, BOCO Chair, Board of Directors, Board of Certification/ Accreditation, (Dated/ Received October 13, 2014)

Comment

Thank you for the opportunity to comment on the proposed regulations that prescribe new prior authorization criteria and retool the method and manner by which O&P devices and services are to be furnished in the Medi-Cal Program. We have a suggestion and as the Chairperson of the Board of Directors for BOC and a COPA member, I would very much appreciate it being considered.

Response

Please see responses below.

Comment

1. The amendments to Section 51315, parts (1) and (2), include these words: "…furnished by a certified orthotist, a certified prosthetist, a certified orthotist/prosthetist…" To ensure added clarity, we suggest that the following be added to the definitions list, or that these definitions be added in parts (1) and (2): *"Certified orthotists are those orthotists who hold current orthotists certification from The American Board for Certification on Orthotics, Prosthetics, & Pedorthics (ABC) or the Board of Certification/Accreditceration (BOC) or their successor organizations.*

   Certified prosthetists are those prosthetists who hold current prosthetists certification from The American Board for Certification in Orthotics, Prosthetics, & Pedorthics (ABC) or the Board of Certification/Accreditation (BOC) or their successor organizations.

   Certified orthotists/prosthetists are those orthotists/prosthetists who hold current orthotist/prosthetist certification from The American Board for Certification in Orthotics, Prosthetics, & Pedorthics (ABC) or the Board of Certification/Accreditation (BOC) or their successor organizations.
   This will prevent those who have "certificates" from manufacturers' programs or other short-term classes from arguing that they are "certified."

Response

The assumption has been made that this comment is in reference to Section 51315(a)(1) and (a)(2).

In consideration of this comment and upon further review, the information suggested through this comment was added under subsection (a)(1) through a 15-Day Public Availability, published on April 23, 2015. This addition is intended to clarify the required credentials of a certified orthotist, prosthetist and orthotist/prosthetist.

Commenter Name, Title, Organization and Date of Comment(s)

5. Jorge Orozco, Chief Executive Officer, Rancho Los Amigos National Rehabilitation Center, (Dated/Received October 20, 2014)

Comment

Rancho Los Amigos National Rehabilitation Center (Rancho) is a Los Angeles County Department of Health Services hospital that provides specialized care for patients with a variety of life-changing injuries. As an internationally-recognized center for rehabilitation medicine and clinical research, O&P appliances and services are of central importance to Rancho.

While Rancho supports DHCS' efforts to facilitate access to and delivery of O&P appliances and services to beneficiaries by clearly outlining the criteria that must be met for prior authorization, Rancho is concerned that overly restrictive language in the proposed regulation may negatively impact patient outcomes.

Additionally, there is concern that the wording for the requirements of certain orthotic and prosthetic appliances is too restrictive and may preclude the possibility of prior authorization for appliances that are medically appropriate for multiple conditions. While utilization control is important, Rancho hopes that DHCS does not inadvertently restrict patient access to appliances and services that are medically appropriate and improve quality of life to our patients.

Please find attached to this document a list of specific concerns regarding the proposed regulation, including suggested changes. Amendments to DHCS 08-003:

Response

Please see responses below.

Comment

1. Section 51315 (c)(1) through (5):

(~~b~~ c) The prior authorization request for orthotic and prosthetic appliances and services shall be authorized when documentation includes ~~specify~~ the type of appliance or service; ~~and include~~ the medical diagnosis, and prognosis;~~, and~~ an explanation of the

purpose ~~that~~ for the appliance or service; will serve ~~will serve~~ ~~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 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).

Justification: This section regarding the five substantiation criteria should be deleted. As currently worded, this section is too restrictive and may preclude patients from access to prosthetic appliances and services that would facilitate social integration into the community and, in some cases, serve as a preventative measure to avoid further injury.

Response

This subsection was not amended based on comment.

The Department does not concur that the provisions requested to be deleted are restrictive. These criteria are specified and are necessary to ensure that patients receive the appropriate appliance or service that meets his/her medical needs without authorization of appliances that are not medically necessary.

The proposed provisions in Section 51315(c)(1) – (5) are necessary for the proper and efficient administration of the Medi-Cal program.

Comment

2. Section 51315 (d)(1) through (7):

((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 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.~~

Justification: This section should be deleted. As currently worded, the phrasing may preclude patients from access to prosthetic appliances and services that would facilitate social integration into the community and, in some cases, serve as a preventative measure to avoid further injury.

Response

This subsection was not amended based on comment.

The Department does not concur that the provisions requested to be deleted are restrictive. These criteria are specified and are necessary to ensure that patients receive the appropriate appliance or service that meets his/her medical needs without authorization of appliances that are not medically necessary.

The proposed provisions in Section 51315(d)(1) – (7) are necessary for the proper and efficient administration of the Medi-Cal program.

Comment

3a. Section 51161

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

Justification: Computed Aided Design/Computer Aided Manufacture Models can utilize both positive and negative models in the image capturing process.

Response

In consideration of this comment and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "or positive" to the definition to clarify that this appliance can utilize both positive and negative models in the image capturing process.

Comment

3b. (rr) "Halluxs-Valgus Splint" means a device that fits over the big toe to maintain proper anatomical position of the toe.

Justification: The correct spelling is "Hallux-Valgus." The spelling error reoccurs in section 51315.1 (k)(1)

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015 to correct this spelling error.

This spelling error was also corrected in Section 51315.1(k)(1) through the 15-Day Public Availability, published on April 23, 2015.

Comment

3c. (nnn) "Orthopedic Footwear" means an orthotic grouping that includes stock orthopedic shoes, stock conventional shoes, diabetic shoes to relieve pressure and custom-made orthopedic shoes.

Justification: This section should be amended to ensure that diabetic shoes are included.

Response

This subsection was not amended based on comment.

The Department does not concur with this requested addition. Diabetic shoes have their own section with separate procedure codes [see Section 51315.1(a)] and are not considered part of the grouping of orthopedic footwear.

Comment

3d. (uuu) "Prefabricated Appliance" (also known as "off-the-shelf") means an appliance that has been manufactured from standard molds or patterns.

Justification: "Off-the-shelf" is a common synonym for "prefabricated." This subsection was not amended based on comment.

Response

The Department does not concur with this requested addition. A prefabricated appliance may require some assembly before it can be fitted to a specific patient. An off-the-shelf appliance [see Section 51161 (mmm)] does not require assembly or structural modification to fit a specific patient.

Comment

3e. (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**.

Justification: "Replacement Glove" is also a cosmetic cover for a passive or functional hand prosthesis.

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "or a cosmetic cover for a passive or functional hand prosthesis" to specify that this appliance is also referred to as a cosmetic cover.

Comment

3f. (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, "rocker soles" – heels, orthopedic shoe additions, and transfer or replacement.

Justification: "Rocker soles" should be included as part of sole modifications.

Response

This subsection was not amended based on comment.

The Department does not concur that "rocker soles" should be included in this definition. Information supporting this request was not provided or able to be located by the Department.

Comment

4. 51315.1 (a) – Page 18

(a) Shoe Supplies for Pre-Diabetics and Diabetics shall include shoes and their fitting(s), modifications and inserts, including ankle-foot orthoses; and shall be authorized when the patient has a diagnosis of pre-diabetes or 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:

Justification: This section should be amended to list pre-diabetes as a medical condition and to include ankle-foot orthoses.

Response

This subsection was not amended based on comment.

Expansion of this benefit to "pre-diabetics" is beyond the scope of this regulatory action.

"Ankle-foot orthoses" is described in Section 51315.1(j)(4)), with specified medical necessity criteria that, if met, could be authorized for diabetics and pre-diabetics. Section 51315.1(a) is specific to shoes and their fittings, modifications, and inserts.

Comment

5. Section 51315.1 (j)(5)(A) – Page 29

(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 and**/or** foot

Justification: "And/or" is less restrictive.

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment replaced "and" with "or."

The Department concurs that using the word "or" would be less restrictive, as the comment suggests, and it would provide more clarity and flexibility in the authorization and reimbursement of this appliance.

Comment

6. Section 51315.1 (j)(9) – Page 30

(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:

Justification: The phrasing "(around two years of age)" implies that the aforementioned orthoses would only be authorized to patients around the age of two years. This section should be amended to include patients around the age of two years and older.

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "beginning" and "and up," to provide clarity and flexibility - that the appliance shall be authorized when it is developmentally appropriate, starting at around the age of two and up.

Comment

7. Section 51315.1 (j)(9)(D)5. – Page 32

5. **~~Good motivation with~~ R**~~r~~ealistic goals and expectations and a family or other support system.

Justification: The phrase "good motivation" is subjective and should be removed.

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment removed "Good motivation with," because this phrase is not relevant in the determination and authorization/reimbursement of this appliance.

Comment

8. Section 51315.1 (m)(2) – Page 40

(2) Mobile Arm Supports shall be authorized when the patient meets the criteria specified in paragraph (1) above **~~and uses a wheelchair~~**.

Justification: This section should be amended to remove the phrase "and uses a wheelchair," as some people benefit greatly from using a Mobile Arm Supports that are attached to a table or a chair. For example, people with Central Cord Syndrome may be ambulatory but also have severe shoulder weakness. Mobile arm supports help them to achieve functional goals.

Response

Upon further review, this subsection was amended, partially in consideration of this comment, through a 15-Day Public Availability, published on April 23, 2015; the amendment removed "uses" and added the phrases "requires such support attached to" and ", chair or table." Since mobile arm supports are specific for patients that require such support while in a seated position, additional clarification was added to this subsection to read, "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." This amendment will provide options, other than a wheelchair, in which to attach these supportive devices.

In addition, Section 51161(kkk), the definition of "Mobile Arm Support," was amended through a 15-Day Public Availability published on April 23, 2015, to be consistent with this subsection.

Comment

9. Section 51315.1 (m)(3)(B) – Page 40

(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 **and functional** need(s) would not be met.

Justification: This section should be amended to read "the patient's medical and functional need(s) would not be met." The current language is vague and may result in difficulties with trying to authorize a mobile arm support which is used for essential functional activities (since it's defined as *protecting* shoulder joint or *providing support/stabilization*). In some cases, the MAS is needed for function.

Response

Upon further review, this subsection was amended partially in response to comment, through a 15-Day Public Availability, published on April 23, 2015; the amendment added "or functional" to clarify that this appliance is used to support a patient's functional activities as well as medical needs.

Comment

10. Section 51315.2 (a)(2)(C) – Page 42

(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, including performance of transfers.

Justification: The expression "other functional activities" should be amended so that it includes performance of transfers for someone who might need the prosthesis as a stabilizing support, such as someone with complete paraplegia.

Response

This subsection was not amended based on comment.

The Department does not concur with this proposed addition. Section 51161(e) defines ADLs to include transferring. Since transferring is already included in the definition of ADLs, adding this phrase in this subsection is not necessary and would be redundant.

Comment

11. Section 51315.2 (a)(2)(L) – Page 44

(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, including performance of transfers, 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).

Justification: The expression "other functional activities" should be amended so that it includes performance of transfers for someone who might need the prosthesis as a stabilizing support, such as someone with complete paraplegia.

Response

This subsection was not amended based on comment.

The Department does not concur with this proposed addition. Section 51161(e) defines ADLs to include transferring. Since transferring is already included in the definition of ADLs, adding this phrase in this subsection is not necessary and would be redundant.

Commenter Name, Title, Organization and Date of Comment(s)

6. Abbi Coursolle, Staff Attorney, National Health Law Program, And on Behalf of Disability Rights California, Western Center on Law & Poverty, (Dated/Received October 24, 1014)

Comment

Thank you for the opportunity to comment on your proposed regulations concerning the authorization criteria for O&P appliances and services in Medi-Cal. The National Health Law Program (NHeLP) protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, the NHeLP advocates, educates and litigates at the federal and state

level. We have represented the plaintiffs in two major court cases involving access to O&P appliances in state Medicaid programs. Based on our experience in those cases, we write to suggest a few amendments to the regulations California is proposing. Our comments are joined by the Disability Rights California and the Western Center on Law & Poverty.

Response

Please see responses below.

Comment

1. Section 51161, 51315.1: Coverage of compression stockings. The proposed regulation provides a definition of "gradient compression stockings," but does not include a definition for the other predominant type of compression stocking, thromboembolism-deterrent hose (TED hose). *See id.* Section 51161 (pp). TED hose may be used to prevent deep vein thrombosis, especially for post-surgical patients, and also to treat varicose and spider veins. The proposed regulation also does not provide any criteria for the authorization of TED hose. *Cf. id.* Section 51315.1(c) (criteria for gradient compression stockings). This omission appears to limit coverage of compression stockings to gradient compression stockings, even when TED hose are medically necessary to treat a beneficiary's condition. We recommend that DHCS amend the section 51161 to include TED hose, and add criteria for the authorization of TED hose to section 51315.1.

Response

Criteria provided in this regulatory action pertains to those appliances and services currently covered by specific procedure codes under the Medi-Cal program. This regulatory action is not intended to expand the scope of coverage for O&P appliances and services. The addition of new appliances for coverage under Medi-Cal is outside the scope of this regulatory action.

Comment

2a. Sections 51161 (e) & (ddd): We are pleased that both activities of daily living and instrumental activities of daily living are defined and identified as relevant for medical necessity determinations. In accordance with W&I Section 14059, however, any functional capacity assessment relevant to medical necessity must include "conditions that …interfere with capacity for normal activity, including employment." Expressly incorporating the functional requirements of W&I Section 14059 is also required by the federal Medicaid managed care rules concerning coverage and authorization in managed care, which require the specification of medical necessity in terms of services related to "[t]he ability to achieve age-appropriate growth and development" and "[t]he ability to

attain, main, or regain functional capacity." 42 C.F.R. Section 438.210(a)(4)(ii)(B) & (C). The definition of IADL should be amended to reference the requirement to address the "capacity for normal activity, including employment."

Response

In consideration of this comment, and upon further review, amendments were made through a 15-Day Public Availability, published on April 23, 2015; the amendment added "and the capacity for normal activity, including employment" to Section 51161(ddd), to be consistent with W&I Code Section 14059 and 42, CFR, Section 438.210(a)(4)(ii)(B) and (C).

Comment

2b. We also recommend that the regulations include a "by report" section to cover newly available orthotics and prostheses to ensure that Medi-Cal beneficiaries may have access to all medically necessary equipment and supplies.

Response

Section 51315(b) contains criteria and instructions for requesting appliances that have not been assigned specific procedure codes (by report/miscellaneous codes). For this reason, the Department has determined that including a specific section to accommodate future appliances not yet included in the coverage under Medi-Cal is not necessary.

Comment

3. Section 51315(c), (d)(2) Limitations on coverage of services or appliances for cosmetic purposes. We are concerned that the proposed definition at section 41315(d)(2)* defines the limitation on services and appliances for cosmetic purposes too narrowly. Specifically, the definition fails to take into consideration the impact of having an appearance outside the norm of normal appearance on the ability to participate in normal activities including work, as required by W&I section 14059. The proposed definition could prohibit Medi-Cal beneficiaries from receiving facial prostheses that are individually fashioned so that with the prosthesis the facial appearance is normal. For someone with a gaping hole in the middle of the face where the nose should be, the medical necessity for a prosthetic nose is apparent – for instance, in order to wear glasses and to keep things outside of the body. In our experience, the cosmetics questions can arise when a beneficiary requires more than a duct tape cover with some breathing holes plus a screwed in cup holder between the eyes to hold up glasses. Absent a quality prosthetic nose that brings

the person within the normal range of appearance, that beneficiary is subjected to a significant disability and severe pain that only can be alleviated by access to a quality prosthesis so the person can engage in normal activities including employment. The regulation should be amended to clarify that prostheses for this purpose are not considered cosmetic.

Response

The assumption is that the comment is in reference to Section 51315(d)(2) related to "cosmetic restoration."

In Section 51161(ddd), the definition of IADLs was expanded through the 15-Day Public Availability published on April 23, 2015, to include "…means those activities that support activities of daily living *and the capacity for normal activity, including employment,*…" (See FSOR, Addendum 1, Commenter #6, Comment #2a.) Therefore, the evaluation of medical necessity for O&P appliances will be broadened as specified in this revised definition. The example cited by the commenter would not be limited by "…the sole purpose of cosmetic restoration…" because the facial prosthesis in the example would be medically necessary.

Comment

4. 51315(c), 51315.1, 51315.2: Limiting authorization to individuals with a particular diagnosis. The reasonable standards provision of the Medicaid Act specifically prohibits states from limiting service provision to those with a particular diagnosis or condition. 42 U.S.C. Section 1396a(a)(17); 42 C.F.R. 440.230(c) ("The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service…solely because of the diagnosis, type of illness, or condition."); *see also Davis v. Shah,*2013 WL 6451176 at *18 (holding that where a state "is already providing orthopedic shoes and compression stockings to certain Medicaid recipients" it cannot deny other recipients access to the same orthopedic shoes and compression stockings "solely on the basis of diagnosis"). We commend DHCS for not including diagnosis-specific criteria for most of the appliances and services listed in this regulation. A few appliances and services do contain inappropriate limitations that should be removed or amended to include language stating that these appliances and services may be provided for individuals without the listed diagnoses when medically necessary. We recommend that all medical necessity criteria set out in the regulations be modeled after that for Legg Perthes Orthoses as defined by proposed section 51315.1(i)(2), which states that the orthoses is available to treat a specific condition or any "similar deformity or disease," and then goes on to describe a need defined in terms of what the orthoses actually address functionally. Similarly, the criteria for a knee orthoses as defined by proposed section 51315.1 (i)(3)(A) provides for the orthoses whenever "the patient has a deformity or injury of, or affecting the knee, such as one of the following," and then the last item on that is "any related medical condition affecting the knee." DHCS could start to address this issue by adding language in proposed section 51315(c), 51315.1, and 51315.2 that clearly indicates that orthoses and prostheses should

be authorized when they meet the particular criteria detailed in those sections, or for a functional equivalent of those criteria. In addition, we specifically recommend that DHCS amend the following definitions to remove condition-specific medical necessity criteria:

Response

The assumption is that these comments are in reference to Sections 51315.1(j)(3)(A) (related to Knee Orthoses) and 51315.1(j)(2) (related to Legg Perthes Orthoses).

The Department concurs with the need to not limit authorization of appliances to specific diseases or conditions. Section 51315.1(p) was amended to include "similar deformity or disease" through a 15-Day Public Availability, published on April 23, 2015.

This statement would not add clarity to the section; therefore, these sections were not amended based on comment.

Comment

4a. Section 51315.1(h)(3)(i)(1)(A)(2): tension based scoliosis orthosis is limited to children with adolescent idiopathic scoliosis.

Response

The assumption is that this comment is in reference to Section 51315.1(i)(1)(A)2.

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "or a similar deformity or disease."

See response to FSOR, Addendum 1, Commenter #6, Comment #4 for further response.

Comment

4b. Section 51315.1 (h)(9)(C)(7): reciprocating gait orthoses are limited to people with a diagnosis of paraplegia, spina bifida (dorsal region) or spina bifida (lumbar region).

Response

The assumption is that the comment is in reference to Section 51315.1(j)(9)(C)4. & 7.

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added a new subparagraph "d. Any related medical condition affecting the spine" so as not to limit medical conditions that may be appropriate for authorization and reimbursement of appliances to specific diseases or conditions.

See FSOR, Addendum 1, Commenter #6, Comment #4 for further response.

Comment

4c. Section 51315.1(p): trusses are limited to people with abdominal hernias.

Response

In consideration of this comment, and upon further review, this subsection was amended through a 15-Day Public Availability, published on April 23, 2015; the amendment added "or a similar deformity or disease" so as to not limit authorization of appliances to specific diseases or conditions.

See FSOR, Addendum 1, Commenter #6, Comment #4 for further response.

Comment

5. Section 51315.2: Facial Prostheses: We are concerned that this section omits any reference to Medi-Cal coverage of facial prostheses. Facial prostheses may be medically necessary for beneficiaries who have experienced congenital impairments, accidents, certain cancer surgeries. We recommend that DHCS amend this section to expressly allow for coverage of facial prostheses that will bring the beneficiary into the normal range of facial appearances when medically necessary.

Response

Facial prostheses are a benefit under the Medi-Cal program, but are not assigned a specific procedure code(s). Prosthetic appliances, including facial prostheses not assigned a specific procedure code(s), may be covered under a miscellaneous code as noted in Section 51315.2(g)(1).

Commenter Name, Title, Organization and Date of Comment(s)

7. Jodi Hicks, DiMare, Brown, Hicks & Kessler, LLC, Legislative & Regulatory Advocacy & Procurement, (Dated/Received November 13, 2014)

Comment

1. This is the question I received from one of our members yesterday: If you are able, please ask about DHCS 08-003, the new amendment of Orthotics & Prosthetics Appliances & Services (specifically in Section 51315 subsection (a)(2) – Orthopedic and Stock Conventional Shoes) that completely excludes podiatrists from prescribing orthopedic and stock conventional shoes (p 12), where we were included in the language of the pre-amended version (p 16, the first strikethrough paragraph).

Response

The omission of podiatrists from prescription authority for stock orthopedic and stock conventional shoes was not intentional and was added through a 15-Day Public Availability, published on April 23, 2015; the amendment added “or a licensed podiatrist” as recommended, to Section 51315(a)(2).

This amendment is included to provide specification of the provider types that may prescribe O&P appliances and services.