American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

August 26, 2015

Stacey Brennan, M.D.
National Government Services
8115 Knue Rd
Indianapolis, IN 46250-
DMAC_Draft_LCD_Comments@anthem.com

Dear Dr. Brennan:

Thank you for giving us the opportunity to comment on the proposed Local Coverage Determination (LCD) on Lower Limb Prostheses. It is our understanding that all four DME MACs are putting forth identical LCDs on this topic, so although we will be using the NHIC proposed draft for comments, those comments would apply equally across all jurisdictions.

The American Academy of Physical Medicine and Rehabilitation (AAPM&R) is the national medical society representing physiatrists - physicians who are specialists in the field of physical medicine and rehabilitation and primarily focused on diagnosing and serving the needs of people with a wide range of disabilities and chronic conditions. Physiatrists treat adults and children with acute and chronic pain, persons who have experienced catastrophic events resulting in paraplegia, quadriplegia, traumatic brain injury, spinal cord injury, limb amputations, rheumatologic conditions, musculoskeletal injuries, and individuals with neurologic disorders or other disease processes that result in impairment and/or disability. With appropriate rehabilitation, many patients can regain significant function, live independently, and enjoy fulfilling lives.

Our initial concerns with the draft LCD focus on the statements that prostheses are complete and all-inclusive and there is no coverage for additional components or "add-on" codes. This appears to be a direct contradiction of the information in the current LCD, which says, for example, "When an initial below knee prosthesis (L5500) or a preparatory below knee prosthesis (L5510-L5530, L5540) is provided, prosthetic substitutions and/or additions of procedures and components ***are covered*** in accordance with the functional level assessment except for codes L5629, L5638, L5639, L5646, L5647, L5704, L5785, L5962, and L5980 which will be denied as not reasonable and necessary." (Emphasis added)

Contrast that language with the language in the draft LCD which says, for example, "Preparatory prostheses use basic prosthetic components, which

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. There is ***no coverage*** for any additional components, add-ons, upgrades, additions, adjustments, modifications, replacement etc. substitution of components, etc." (Emphasis added).

In describing preparatory prostheses, the current LCD is unequivocal in stating that prosthetic substitutions and/or additions of procedures and components are covered. The draft LCD under consideration states that HCPCS codes L5500-L5600 are all inclusive and there is no coverage for additional add-ons, components, etc. What has changed? The descriptors for the HCPCS codes appear the same in both policies, so how can the LCD change this very important part of their definition so drastically? Was the payment amount for the main prosthetic code raised in accordance with grouping all components under it?

If this sort of change in coverage is kept in place, it will negatively impact the patient's ability to obtain an appropriate prosthesis which meets the standard of care, as well as his or her ability to achieve optimal functioning.

In addition, certain sections in the draft LCD appear to put arbitrary limits on the timing of the process of assisting an amputee to become functional with a definitive prosthesis:

> "Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling….Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of a prosthesis, therefore a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis."

We are especially concerned about this 90 day bundling proposal. It will very likely adversely impact clinical care by potentially delaying or prohibiting the adjustment of prostheses and delaying the prescription of a more definitive prosthesis for a number of patients for an unnecessarily prolonged period of time. We ask that you reconsider the timeframe – 30 days might be more reasonable. 90 days is simply unacceptable.

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

Additionally, in the second sentence quoted above, you are equating provision of a wholly new and planned for definitive prosthesis with "additions, adjustments, modifications, replacement etc. to any components" of the preparatory prosthesis. The provision of the definitive prosthesis does not require any adjustment or modification of any components of the preparatory prosthetic. It is simply the next step in a prescribed series of steps for assisting a Medicare beneficiary to get back on his or her feet, so to speak. What is the point of requiring a 90 day waiting period when a patient is advancing from a preparatory to a definitive prosthesis?

Some of the requirements in the draft LCD appear overly restrictive. For instance, when describing the criteria for an initial definitive prosthesis, the phrase "The beneficiary is able to ambulate using the device at or above the identified functional level" is included as one of the criteria. What if the beneficiary cannot do so at the moment they receive a new prosthesis for a valid reason? For example, what if he or she has developed a pressure sore or requires formal training in order to adjust to the new prosthesis in order to achieve the identified functional level? What if he has the potential to ambulate at the identified level? Rehabilitation is focused on facilitating a patient's recovery with the goal of helping them achieve their maximum potential, which may require a finite period of time to do so; it is impractical to assume that every individual receiving a new prosthesis will immediately achieve the targeted functional status without a reasonable window of time to do so.

Along similar lines, under "Miscellaneous" there is a phrase that states, "If a prosthesis that exceeds the beneficiary's functional capabilities (K-level) is provided, it will be denied as not reasonable and necessary." This hardly seems fair, when the assessment of the patient's functional capability has to be done without access to the definitive prosthesis and the assessment is done on a person, not a widget. At most, shouldn't the penalty be that payment would be made only for the level of prosthesis for which his functional capability entitles him, rather than for no prosthesis at all? And again, what if he has the potential to reach that functional level with practice? There seems to be little or no consideration of the fact that a new amputee will undoubtedly gain more prowess as he becomes accustomed to his new prosthetic leg. The various criteria seem to assume that he is either at that level from the beginning or he will never attain that level.

There are also problematic statements under the levels of functional status on page 14. Under K1, there is a phrase that says, "Use of a walker or crutches while using a prosthesis results in a K1 classification." Under K2,

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

there is a sentence which states "Use of a cane while using a prosthesis results in a K2 classification." This is decidedly inappropriate– it means that a person who uses an assistive device will not qualify for better prostheses such as are available under K3 and K4. Many people use assistive devices, yet manage to get around their communities and accomplish their goals without any problem. Using such an assistive device as part of criteria to limit what kind of prosthesis a patient may qualify for, is directly counter to the principles on which rehabilitation is established. Too often, a person who has been in an accident or becomes ill is unable to return to their former way of doing things. Through rehabilitation, we assist such patients in developing new ways to accomplish the functional tasks that are important to them; it does not matter if he or she needs an assistive device, whether it be a cane for safety or forearm crutches for added stability, as long as the assistive device makes it easier or even possible to achieve functional goals they were previously unable to do.

Some specific additional examples of areas in need of clarification or revision include:

- Page 3 has the following two statements:
  - A new amputation is defined as … a revision to the original amputation site...
  - A revised amputation is defined as additional surgery to an existing amputation site.

  How do these two definitions differ from each other?

- Page 3 - the definition of a Licensed or Certified Medical Professional (LCMP) is stated as "…a Physician (MD/DO), Physician Assistant (PA), Nurse Practitioner (NP), or Physical Therapist (PT) with training, experience, and whose scope of practice permits the comprehensive functional assessment of beneficiaries with amputations." On page 6, the LCMP is defined as "a physical therapist (PT) or occupational therapist (OT), or physician with training and expertise in the functional evaluation of beneficiaries with amputations." This second definition leaves out two positions that were part of the first definition (Physician Assistant (PA), Nurse Practitioner (NP)) and adds in a position that is not in the first definition (occupational therapist (OT).) It is not clear how you came to select these particular positions as being capable of conducting a "comprehensive functional assessment of beneficiaries with amputations." As it currently works in practice, it is often the prosthetist who, as part of the rehabilitation team, assists in completing the comprehensive functional assessment.

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

- It is also not clear what exactly an LCMP can be considered qualified to perform; or to put it in another way, what exactly is meant by the phrase "comprehensive functional assessment." Can an LCMP really do all of the in-person functional assessment as it is defined in this draft LCD? Or is the LCD meant to say that an LCMP can do the functional assessment only, not an "Independent Medical Examination" including the "beneficiary's overall health status at the time of the examination." It is confusing because the title of the section is "Independent Medical Examination," which implies an examination by a physician or a qualified non-physician practitioner, but the body of the paragraph does not use this phrasing. Rather, it states "the treating physician must conduct an in-person examination documenting the overall functional abilities and limitations of the beneficiary" and goes on to say that the physician may refer the patient to an LCMP to perform "all or part of the in-person functional assessment examination." A full medical examination would be beyond the scope of physical and occupational therapists so it would be helpful to clarify whether or not the requirement is for an "independent medical examination" or an "in-person functional assessment examination," and which components may be performed by an LCMP.

- On page 4, when discussing "immediate prostheses", there is a statement that, "If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary." This may be logical for the definitive prosthesis and perhaps even for the preparatory prosthesis at a particular point in time (remember, the patient may have the "potential" to come around and be able and willing to use a prosthesis at a later time); but how can it be accurate for an immediate prosthesis? Even if the patient has no potential to use a final prosthesis, he would still benefit from some of the effects of the initial prosthesis. For example, on page 3, an immediate prosthesis is defined as follows: "An immediate prosthesis, also referred to as a post-operative prosthesis, is applied in the operating room immediately following amputation. It helps control initial swelling, reduce pain, protect the amputation site by enveloping the residual limb in a rigid dressing, and allows for immediate, although light, ambulatory rehabilitation..." Other than light ambulatory rehabilitation, the patient would need and benefit from the other effects of an immediate prosthesis. Perhaps it might be better to leave "immediate prostheses" off of the LCD.

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

- Page 13 – The criteria cited for a rehabilitation program are overly restrictive and don't correlate with the K-levels. They would seem to only justify a prosthesis at levels K-3 and K-4. Why does the patient need to don and doff the prosthesis without assistance? How does one judge whether he or she has the tolerance to use the prosthesis for a "normal day's activities"? What if the patient has the potential to do more, given the right set of circumstances? Some patients need extra time to get to the predicted level, or they may always need some minimal assistance, but that should not preclude them receiving an appropriate prosthesis. Another point in need of clarification – if the LCD requires the patient to undergo a rehab program with their preparatory prosthesis, will Medicare still cover rehabilitation after the patient receives his or her definitive prosthesis?

- Page 13 - Functional Status (K-Level) – The definitions under the minimal requirements are subject to dispute – What is "sufficient" trunk control? "Adequate" posture? Who judges whether the patient has "the appearance of a natural gait"? Will there be occasions where the patient, physician, and prosthetist are perfectly happy with the prosthesis but a medical reviewer decides, for example, that the patient's posture could use improvement and therefore the prosthesis, which has already been put into use, is not covered?

- Page 13 – there is a phrase that says "An in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary must be performed by a licensed/certified medical professional with expertise in the treatment of amputees prior to the provision of ***any prosthesis***." (Emphasis added) Please clarify what you mean by "any" prosthesis. Does it include preparatory prostheses? Immediate prostheses? Or is it only pertinent to definitive prostheses? If it does include an immediate prosthesis, how is an "in-person, comprehensive medical assessment" supposed to be done if, for instance, the patient is brought in by ambulance after a motorcycle accident and needs immediate surgery, including amputation of one of his lower limbs? Since the immediate prosthesis will be applied immediately after surgery, obviously there cannot have been any comprehensive medical assessment of his functional capabilities.

- Page 15 – Please clarify the information under "Dispensing Orders." On the one hand, it sounds like every piece of equipment must have

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

a dispensing order, on the other hand, it excludes items that require a written order prior to delivery. Is this the same as the "detailed written order" or is a second written order required to dispense the item?

There also needs to be clarification about documentation in support of medical necessity for lower limb prostheses. As the draft LCD notes on page 16, "Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes." It goes on to say that "Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs" and "Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient ***by themselves*** for the purpose of determining that an item is reasonable and necessary." (Emphasis added)

There is an argument to be made that the prosthetists' notes should be considered part of the medical record. In fact, a bill was introduced in the House of Representatives on March 23, 2015 (HR 1530) to ensure that this is the understanding. The Medicare Orthotics and Prosthetics Improvement Act of 2015 contains a provision that says, "Documentation created by an orthotist or prosthetist is considered part of the patient's medical record." The bill was referred to the House Energy and Commerce Subcommittee on Health on March 27, 2015. A related bill in the Senate, S829, has been referred to the Committee on Finance.

In a section of the Program Integrity Manual (PIM) "titled "Documentation in the Patient's Medical Record," CMS lists the following information that should be part of the medical record:

> "For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc." IOM 100-8 Program Integrity Manual, Chapter 5, section 5.7

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

Although most of this information will be supplied by the physician, the prosthetist's notes will inform parts of the physician's decision making, and therefore should be part of the medical record.

The LCD itself affirms that, "The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient ***by themselves*** for the purpose of determining that an item is reasonable and necessary. (Emphasis added) It does not say that they should be excluded from the medical records.

The reason this is important is because it has been noted to influence what Medicare reviewers will use in determining whether medical necessity requirements are met for a particular claim. Oftentimes, they will only consider information that is in the medical record, despite the following from the Program Integrity Manual:

> "The MACs, CERT, Recovery Auditors, and ZPICs shall review ***any information necessary*** to make a prepayment and/or postpayment claim determination, unless otherwise directed in this manual. This includes reviewing any documentation submitted with the claim and any other documentation subsequently requested from the provider or other entity when necessary. Reviewers also have the discretion to consider billing history or other information obtained from the Common Working File (in limited circumstances), outcome assessment and information set (OASIS), or the minimum data set (MDS), among others. (Emphasis added)
>
> For Medicare to consider coverage and payment for any item or service, the ***information submitted by the supplier*** or provider ***must corroborate*** the documentation in the beneficiary's medical documentation and confirm that Medicare coverage criteria have been met." (Emphasis added) IOM 100-8 Program Integrity Manual, Chapter 3, section 3.3.2.1
>
> "Certificates of Medical Necessity (CMN), DME Information Forms (DIF), ***supplier-prepared statements,*** and physician attestations ***by themselves*** do NOT provide sufficient documentation of medical necessity, even if signed by the ordering physician." (Emphasis added)

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

These statements correlate nicely with the information in the draft LCD. Neither the draft LCD nor the PIM states that only the medical record can be used to obtain information to help verify medical necessity. However, in our experience, as mentioned above, this is often a requirement from the medical reviewers. Somehow, the phrase "Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes," is taken to mean that "supplier-produced records cannot be used in determining medical necessity."

To add insult to injury, even if the prosthetist's notes were not considered part of the medical record, they should at least be considered in making a determination of medical necessity under the requirements in the PIM. However, experience tells us that will not happen.

In addition to information in the medical record, a lower limb prosthesis requires that a detailed written order be created prior to any billing for the prosthesis. The PIM states that:

> "The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number." IOM 100-8 Program Integrity Manual, Chapter 5, section 5.2.3

It also states that:

> "Someone other than the physician may complete the detailed description of the item. However, the treating physician must review the detailed description and personally sign and date the order to indicate agreement."

There is similar language in the draft policy, which states "Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document."

If someone other than the physician may complete the detailed description of the item on the order as long as the physician signs it, why can't a prosthetist's notes and descriptions be provided to the physician by the prosthetist and, the physician having received and approved the recommendations, why can't the notes be made a part of the medical record by the physician, much as a lab report or radiology report is?

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

It is unrealistic to ask an ordering physician to know all the codes and descriptions for all of the possible parts of a prosthetic, much less to document all the possible options considered, when that is something prosthetists specialize in. Prosthetists are generally either licensed by their state or, if the state does not provide for such licensure, they are certified by one of the major O&P certification boards. Such licensure or certification could be made a requirement to guard against unscrupulous suppliers, as was recommended by the OIG, and as required under the proposed bill mentioned previously (The Medicare Orthotics and Prosthetics Improvement Act of 2015). Prosthetists provide a service in the care of people with amputations, and it is not clear why their documentation cannot be considered a part of or, at a minimum, used in conjunction with the medical record. Prosthetists don't just deliver a product – they participate in or perform many of the tasks needed to determine the best prosthetic for a patient and, as such, their documentation should be treated with the same respect as any other professional. Refusing to use their notes in reviewing the medical necessity of a claim is both insulting to the prosthetist and wastes the physician's limited time.

Finally, there appear to be some instances in which information that is not applicable to lower limb prostheses is included in the LCD. This can be confusing; therefore we request that you consider removing instructions that are not relevant. For example:

- On page 15 continuing to page 16, there is information about "items provided on a periodic basis, including drugs." It talks about dosage, quantity, number of refills, etc., none of which appear applicable to lower limb prostheses.

- On page 16, under the heading MEDICAL RECORD INFORMATION, there are two sections which do not appear relevant to lower limb prostheses – one on documenting continued medical need and one on documenting continued use. Both appear to be applicable to supplies, rental items, or drugs.

- On page 19, the section entitled "Equipment Retained from a Prior Payer" states that:

  "Even if there is no change in the beneficiary's medical condition, the beneficiary must meet all coverage, coding and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim."

American Academy of Physical Medicine and Rehabilitation

aaPM&R

9700 W. Bryn Mawr Ave., Suite 200
Rosemont, Illinois 60018
www.aapmr.org

phone 847/737.6000
fax 847/754.4368
info@aapmr.org

Further down, the section appears to be talking about rental items, but in the first part it is not clear on what is included. Would the section pertain to lower limb prostheses if the beneficiary received the prosthesis while covered under an employer-based insurance policy and is now transitioning to Medicare? It not, the section should be removed or at least clarified. For one thing it requires Proof of Delivery even though the patient may have received the prosthesis long ago. For another, it states that, "the first day of the first rental month in which Medicare payments are made for the item (i.e., date of service) serves as the start date of the reasonable useful lifetime and period of continuous use. If the section is not intended to be only about rental items, what would be the start date for reasonable lifetime usage for non-rental items? If it is considered to be the date on which a first claim is made to Medicare related to the prosthesis, it could end up preventing the patient from obtaining a replacement for a prosthesis that may be several years old, but whose "useful life" is considered to be just beginning.

- At the bottom of page 22, reference is made to Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs). I saw no mention that either of those forms is required for Lower Limb Prostheses, yet their specific identification in the LCD makes one wonder if they are applicable and, if so, where additional information on them would be found.

Once again, thank you for the opportunity to comment on this proposed LCD. The Academy takes its responsibilities to our patients very seriously and appreciates the opportunity to advocate for services which are most definitely needed, but are not perhaps so understandable to a person without the clinical experience of working with people with disabilities. If you have any questions or would like additional information, please don't hesitate to contact our Health Policy Manager, Kate Stinneford, at 847-373-6022 or kstinneford@aapmr.org.

Respectfully,

Phillip R. Bryant, DO
Chair, Reimbursement and Policy Review Committee