Executive Summary of Key Issues in the Proposed DME MAC Changes to the Local Coverage Determination Relating to Reimbursement for Lower Limb Prosthetics

- Creates clear definitions and distinctions between immediate, preparatory, and definitive prostheses, and also raises question as to whether addition codes maybe billed as part of a preparatory prosthesis. Note: Restricting delivery of a definitive prosthesis until after completion of a rehabilitation program may not in the best interest of the beneficiary nor is it cost effective.

- For immediate, preparatory , and definitive prostheses, there is language that states that they are all inclusive and that separate components billed with prosthetic base codes will be denied as either not medically necessary or as unbundling, which is likely to adversely impact patient care for Medicare beneficiaries. Historically, the L Code system has recognized that the use of addition codes is not unbundling.

- All additions, adjustments, modifications, replacements, etc. for the first 90 days after delivery of the prosthesis are included in the Medicare payment for the prosthesis. Proposed policy does not allow for socket changes or component changes on preparatory prostheses for 90 days following delivery of the preparatory prosthesis.

- Requirements that patients must have a healed incision site and must be starting a rehabilitation program will create additional documentation hurdles for prosthetic providers which also may further delay patient's care.

- The new policy contains requirements that in order for the initial definitive prosthesis to be covered, the patient must have successfully completed a rehabilitation program. The policy also requires an in-person medical evaluation with the ordering physician or a licensed certified medical professional (LCMP) with no financial interest in payment of the claim to be designated by the ordering physician.

- The draft LCD indicates that socket inserts represented by L5673, L5679, L5681, and L5683 represent custom fabricated socket inserts and will only be covered when non-custom socket interfaces do not provide an adequate interface between the socket and the residual limb.

- Suction suspension systems will be considered not medically necessary for functional level 1 patients. Note: CMS and/or the DME MACs do not have the authority to determine the safety and effectiveness of prosthetic services. This responsibility lies exclusively with the Food and Drug Administration (FDA).

- The consolidation of HCPCS codes L5976, L5980, L5981, and L5987 to a temporary code (KXXX1) and L5982, L5984, and L5986 to a temporary code (KXXX2) will severely impact the patient's choice of prosthetic feet and ankles that best meet their individual clinical needs—resulting in a Medicare standardized approach to re-bundling and reducing codes arbitrarily translating into lower quality care for Medicare amputees, and so lesser mobility and reduced independence.

- While not a new policy, the draft LCD includes language that states that prosthetic skins are only covered in situations where a patient may be exposed to unusually harsh environmental conditions and provides protection beyond what is inherently provided by prosthetic covers.

- Draft policy does not provide coverage for amputees that did not participate in a rehabilitation program immediately following their amputation but are now candidates for prosthetic intervention.

- The requirement that the prosthesis must provide the patient with "the appearance of a natural gait" should not preclude coverage of a prosthesis that is otherwise functional (the truth is that for some patients who can attain excellent mobility, natural gait is not possible, and again this approach simply creates another audit complication, where CMS contractors (RACs and others) can claim that since the patient did not attain the "appearance of a natural gait", the cost of the entire prosthesis can be reversed as not medically necessary. The requirement that the functional level assessment ***must include documentation that the patient has sufficient cognitive, cardio-pulmonary, and neuro-muscular control to ambulate effectively at the determined functional level*** is extremely discriminatory to patients who may be compromised in these areas without bearing on their ability to efficiently ambulate with a prosthesis. The elimination of patient potential from the revised functional level categories may significantly limit access to higher functional level componentry for patients who are progressing adequately through the rehab process.

- If the patient utilizes, or if the patient's records show that Medicare has paid for, any form of mobility aid (cane, crutches, walker, etc.) access to higher quality prosthetic components will be severely limited, regardless of your functional capabilities. The use of a walker, crutches, or a cane e.g., for nighttime bathroom access, or periodic situation of soreness or skin irritation from greater than normal activity) should not, in and of itself, limit a patient to a specific functional level classification.

- The draft LCD reiterates two troublesome policies which have caused significant headaches and financial losses to O&P professionals. First, the document restates that the prosthetist's note will not be considered as part of the patient's medical record for purposes of establishing medical necessity, which relies on the physician records (prosthetist notes may be used only in corroborating things stated in those physician records). Second, the document also reiterates the new proof of delivery polices insofar as the HCPCS coding descriptor, no matter how specific it is, is not considered sufficient to describe the device—any device without a serial number, part number or model number is at severe risk of not being reimbursed for absence of a sufficiently extensive description.

Major Issues in Draft Lower Limb Prosthesis LCD/Policy Article

Local Coverage Determination (LCD)

1. **Creates clear definitions and distinctions between immediate, preparatory, and definitive prostheses.**

   Potential Impact: Clear definitions may make justification for the provision of immediate and preparatory prostheses easier to obtain. May drive providers away from providing definitive prostheses as soon as possible following amputation and back to the more traditional model of provision of an immediate prosthesis, followed by a preparatory prosthesis and then a definitive prosthesis. Immediate prostheses remain covered as part of an inpatient episode (Part A) as by definition they are applied in the operating room immediately following the amputation. The draft LCD and Policy Article state that there is no functional level requirement for coverage of immediate or preparatory prostheses. This leads to the question as to whether addition codes will be permitted to be billed to describe components that are provided as part of a preparatory prosthesis that exceed the basic component that is inherent in the base code (e.g. SACH foot, single axis knee, etc.)

   Pathway to Improvement: The LCD should allow for the provision of definitive prosthetic componentry as soon as clinically appropriate for amputees who may benefit from the use of definitive components throughout the rehabilitation process. Restricting delivery of a definitive prosthesis until after completion of a rehabilitation program is not in the best interest of the beneficiary nor is it cost effective. Forcing every patient to utilize a preparatory prosthesis, followed by a completely new definitive prosthesis rather than allowing them to be fit with a definitive prosthesis and allowing for socket changes as the residual limb matures may actually cost the Medicare program more money. The LCD and Policy Article should also clearly indicate that appropriate additions to preparatory prosthesis, in line with the patient's functional level assessment are permitted.

2. **Language regarding "All Inclusive" nature of prosthetic base codes**

   Potential Impact: For immediate, preparatory , and definitive prostheses, there is language that states that they are all inclusive and that separate components billed with prosthetic base codes will be denied as either not medically necessary or as unbundling. This statement goes against the nature of the prosthetic add on system which uses a combination of base codes and relative addition codes to describe the endless combination of components that make up a complete prosthesis, and the resulting cookie-cutter approach is bound to adversely impact patient care for Medicare beneficiaries. The statement regarding the all inclusive nature of prosthetic base

codes is also contradicted later in the draft LCD when appropriate addition codes for knees, feet, etc. are discussed.

Pathway to Improvement: The LCD and Policy article must recognize the unique nature of the L Code system which is designed to use a single base code and multiple addition codes to accurately describe the complete prosthesis that best meets the clinical needs of the patient. Historically, the L Code system has recognized that the use of addition codes is not unbundling. Far from it, rather it is essential to assuring that the custom device fabricated for each patient best fits the specific needs of that patient. Contrary to the proposed LCD's impetus to severely restrict addition codes, the L Code system was specifically designed to use addition codes to report the provision of clinically appropriate prosthetic components and features.

3. **All additions, adjustments, modifications, replacements, etc. for the first 90 days after delivery of the prosthesis are included in the Medicare payment for the prosthesis**

Potential Impact: This policy statement no longer allows for reimbursement for adjustments, repairs, modifications, etc. caused by loss, irreparable damage, or a change in the patient's condition within the 90 days following delivery of the completed prosthesis. Under existing policy, these are covered even when they occur within the first 90 days after delivery. Restricting coverage for all adjustments, repairs, or replacements to those that are required more than 90 days after deliver y will result in the delay of medically necessary adjustments that patients need in order for their prosthesis to fit and function properly.

Pathway to Improvement: The LCD and Policy Article must allow reimbursement for adjustments, repairs, and component replacement within 90 days of delivery of the prosthesis in situations where there is a documented change in patient condition or the device is lost, stolen, or irreparably damaged. Failure to provide reimbursement for these situations will lead to delays in medically necessary services, including the likelihood of delays until after the 90 day period has expired.

4. **Requirements for provision of a preparatory prosthesis**

Potential Impact: Requirements that patients must have a healed incision site and must be starting a rehabilitation program will create additional documentation hurdles for prosthetic providers. Providers must also obtain documentation that the residual limb is still in the process of reshaping and maturing. The policy statement that preparatory prostheses are "all inclusive" creates concern about the ability to use appropriate addition codes for specific components that best meet the clinical needs of the individual patient. Proposed policy does not allow for socket changes or component changes on preparatory prostheses for 90 days following delivery of the preparatory prosthesis. This creates concern regarding replacements needed due to a documented change in patient condition.

Pathway to Improvement: The LCD and Policy Article must not rely on arbitrary events such as a healed incision site, or active participation in a rehabilitation program as prerequisites for coverage of a preparatory prosthesis. Patients should be eligible for coverage for a preparatory prosthesis as soon as they can benefit from the use of a prosthesis. While rehabilitation is an

important part of the overall process, it should not be absolute requirement for coverage as patients may be able to benefit from prosthetic intervention prior to beginning the formal rehabilitation process.

5. **Requirements for provision of a definitive prosthesis**

Potential Impact: The new policy contains requirements that in order for the initial definitive prosthesis to be covered, the patient must have successfully completed a rehabilitation program. This appears to indicate that the patient must first be provided with a preparatory prosthesis that is used during a rehabilitation program and cannot receive a definitive prosthesis until the rehab program is completed The policy also requires an in-person medical evaluation with the ordering physician or a licensed certified medical professional (LCMP) designated by the ordering physician with no financial interest in payment of the claim. The LCD and Policy Article state that the LCPM must have "experience and training in the functional assessment of beneficiaries with amputations." There is no discussion in the LCD or Policy Article regarding how to determine that the designated LCMP has the necessary expertise and training required to evaluate the patient. The LCD indicates that definitive prosthesis codes are "all inclusive" and creates concern about the ability to use appropriate addition codes for specific components that best meet the clinical needs of the individual patient. Proposed LCD does not allow for socket changes or component changes on definitive prostheses for 90 days following delivery of the prosthesis. This creates concern regarding replacements needed due to a documented change in patient condition.

Pathway to Improvement: The LCD and Policy article should not restrict coverage of a definitive prosthesis to those patients who have completed a rehabilitation program or those that have been first fit with a preparatory prosthesis. Many patients will benefit from definitive componentry early in the rehabilitation process. While the residual limb may not be fully "mature" the provision of definitive components early in the rehab process may allow patients to move through the rehab process using consistent componentry that best meets their clinical needs. Replacing the prosthetic socket as the limb matures, without replacing the remainder of the definitive components may be more cost effective for the Medicare program. The LCD and Policy Article must also provide a mechanism to verify that the LCMP is qualified to perform the beneficiary evaluation on behalf of the physician.

6. **Acrylic lamination and total contact are considered inherent in the design of the prosthetic socket**

Potential Impact: Acrylic lamination and total contact socket design have been acceptable addition codes that were reimbursed separately since the implementation of the LCode system. Policy that states that they are inherent in the design of prosthetic sockets and therefore are included in the base code reimbursement will have an immediate effect on overall reimbursement for a prosthesis. This represents an attempt to create a new all-inclusive bundle without recognizing the economic realities. The result, sadly, is likely to be a 'race-to-the-bottom' where there is a lower standard for Medicare beneficiaries who will receive only the "stripped down" prosthetic device which, in truth, is all that the Medicare program is willing to

pay for. There must be an appropriate increase to the Medicare allowed amount for prosthetic base codes to account for these features.

Pathway to Improvement: The LCD and Policy Article must continue to allow for the addition of total contact socket design and the use of acrylic resin lamination as separately reimbursed features of the definitive prosthesis. These additions are not inherent in the description of the base prosthesis codes. While they have become common additions, reimbursement for these features was not included in the fee for the base code. If CMS believes that they are inherent in the base procedures, the Medicare allowable for the base procedures must be adjusted to account for these features.

7. Serious misinterpretation of socket insert codes

Potential Impact: The draft LCD indicates that socket inserts represented by L5673, L5679, L5681, and L5683 represent custom fabricated socket inserts and will only be covered when non-custom socket interfaces do not provide an adequate interface between the socket and the residual limb. This approach simply creates another audit quagmire, where CMS contractors (RACs and others) can deny a claim based on their interpretation that the patient could be fit with a less costly liner, resulting in no reimbursement for what was provided. L5673 and L5679 actually represent both prefabricated roll on style liners as well as custom liners fabricated from an existing model of the patient's residual limb. The policy statement that roll on style liners will only be considered for coverage if the patient cannot be fit with a non-custom fabricated liner (e.g. pelite,plastazote, etc) is misguided and incorrect.

Pathway to Improvement: The LCD and Policy Article must recognize that roll on style prosthetic liners described by L5673 and L5679 are not always custom fabricated or custom fitted to a model of the patient's residual limb. They are often purchased in predetermined thicknesses based on the clinical needs of the patient. The proposed policy that requires documentation of the need for a custom liner is flawed due to the complete misunderstanding of the types of products represented by L5673 and L5679. Forcing patients to use antiquated socket insert technology such as pelite and plastazote will result in poor outcomes for patients.

8. Distinction between mechanical suspension and suction suspension

Potential Impact: No significant change regarding non-medical necessity for both mechanical and suction suspension on the same prosthesis. Suction suspension systems will be considered not medically necessary for functional level 1 patients. Elimination of coverage (lack of clinical evidence) for volume management systems described by L5781 and L5782 will impact patients who can benefit from limb volume management and moisture evacuation systems. The policy statement that says, "Some prostheses are complete or all inclusive systems. Separate billing for a suspension system with these items will be denied as unbundling" is arbitrary and provides no additional clarification. The only prosthetic base codes that include suspension are those that describe immediate post surgical prostheses. All other base codes do not inherently include suspension of any type in their descriptor.

Pathway to Improvement: There is no clinical reason why K1 functional level patients cannot benefit from suction suspension and coverage for suction suspension should not be restricted due to a patient's functional level assessment. Functional level assessment is only used to determine the clinically appropriate hip, knee, ankle, and feet that an amputee may receive. There must be coverage for limb volume management systems for patients who have a demonstrated clinical need for this feature. CMS and/or the DME MACs do not have the authority to determine the safety and effectiveness of prosthetic services. This responsibility lies exclusively with the Food and Drug Administration (FDA). The LCD and Policy article must clarify that only immediate post-surgical base codes inherently include suspension in their descriptor.

9. Consolidation of foot and ankle codes

Potential Impact: The consolidation of HCPCS codes L5976, L5980, L5981, and L5987 to a temporary code (KXXX1) and L5982, L5984, and L5986 to a temporary code (KXXX2) will severely impact the patient's choice of prosthetic feet and ankles that best meet their individual clinical needs—resulting in a Medicare cookie-cutter approach to re-bundling and reducing codes arbitrarily translating into lower quality care for Medicare amputees, and so lesser mobility and reduced independence. The vast reimbursement range of the consolidated codes will have significant impact on provider reimbursement for specific prosthetic feet and ankles. The classification of L5968 as only eligible for K3 or K4 patients seems counterintuitive to the function of products described by the code. An active dorsiflexion feature provides adequate ground clearance of the prosthetic foot during swing phase of the gait cycle which serves to prevent the toes of the prosthetic foot from "catching" and causing trips and falls. This feature is more clinically appropriate for K1 and K2 amputees than those with higher functional capabilities.

Pathway for Improvement: The LCD and Policy Article must continue to allow the use of established HCPCS codes, recognized as part of the HIPAA designated HCPCS code set, that most accurately describe the function of specific prosthetic feet. The consolidation of multiple codes that describe prosthetic feet with very unique function into a single generic code will severely limit and restrict the ability of patients to receive the prosthetic foot or feet that best meet their specific clinical need.

10. Prosthetic knee coverage

Potential Impact: There is little significant change to coverage of prosthetic knees from previous iterations of policy with the exception that a quick change, self aligning unit (L5617) will no longer be considered medically necessary. The existing policy that highlights six criteria, all of which must be met, in order for coverage of L5859 to be considered appears to be overly restrictive and will limit coverage to beneficiaries who meet some of the criteria or have a documented medical need for a power assisted knee that is not included in the six criteria incorporated into policy.

Pathway for Improvement: The LCD and Policy Article should not limit coverage for L5859 for only those patients that meet all of the six criteria included in the current LCD and Policy Article. In cases where there is a documented medical need for the power assist function described by L5859, coverage should be available.

11. Inconsistency between coverage for ultralight material codes in the LCD and Policy Article

Potential Impact: The LCD indicates that the ultralight material codes will be considered for coverage when a prosthetic component is individually made using ultralight materials but the Policy Article indicates that ultralight material codes may only be billed when used to describe ultralight materials used in the fabrication of the prosthetic socket and that they may not be used to describe components that are made from ultralight materials. The LCD and Policy Article are in direct conflict with each other regarding coverage of ultralight materials.

Pathway for Improvement: The LCD and Policy article must be consistent regarding the proper use of the ultralight material code(s). They should be used to describe ultralight materials used in the fabrication of the prosthetic socket as well as to describe prosthetic components that are manufactured using ultralight material.

12. Coverage of prosthetic outer surface coverings (skins)

Potential Impact: While not a new policy, the draft LCD includes language that states that prosthetic skins are only covered in situations where a patient may be exposed to unusually harsh environmental conditions and provides protection beyond what is inherently provided by prosthetic covers. AOPA has addressed its concern regarding this narrow coverage definition in the past but the draft LCD and Policy Article provide another opportunity to do so. AOPA has previously communicated its concern regarding this policy statement to both the DME MACs and CMS directly on several occasions. A link to AOPA's past correspondence on this issue may be found by clicking on the following link: http://www.aopanet.org/wp-content/uploads/2015/07/ProstheticCoversLetterandResponse.pdf

Pathway to Improvement: Coverage for protective outer surface coverings should be restored when there is a medical need to protect the internal components of the prosthesis from elemental or environmental conditions for which a traditional prosthetic cover does not offer protection. Outer protective covering systems protect prosthetic components from exposure to moisture and other conditions that may cause the components to physically degrade and ultimately fail, resulting in potential patient injury. The policy requirement that protective outer covering systems are only eligible for coverage when there is exposure to extremely harsh environmental conditions is unnecessarily restrictive as traditional covers offer little to no protection from exposure to moisture such as rain, urine in incontinent patients or other common environmental conditions.

13. Requirement for rehabilitation program

Potential Impact: Draft policy does not provide coverage for amputees that did not participate in a rehabilitation program immediately following their amputation but are now candidates for

prosthetic intervention. Policy does allow for prosthetic replacement without participation in a rehabilitation program for amputees who are currently utilizing a prosthesis.

Pathway for Improvement: Coverage for a prosthesis should not be limited to amputees who have participated or will participate in a rehabilitation program. While rehabilitation is an important part of the recovery period for an amputee, it should not be a prerequisite for prosthetic coverage. This policy would severely restrict the provision of a prosthesis for a patient who may not have been able to participate in a rehabilitation process immediately following surgery, but is now interested in receiving a prosthesis.

14. Functional level status

Potential Impact: The requirement for an in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary prior to provision of any prosthesis may result in significant delays in the delivery of medically necessary prosthetic care. The requirement that the prosthesis must provide the patient with "the appearance of a natural gait" should not preclude coverage of a prosthesis that is otherwise functional (the truth is that for some patients who can attain excellent mobility, natural gait is not possible, and again this approach simply creates another audit quagmire, where CMS contraxctors (RACs and others) can claim that since the patient did not attain the "appearance of a natural gait", the cost of the entire prosthesis can be reversed as not medically necessary. The requirement that the functional level assessment must include documentation that the patient has sufficient cognitive, cardio-pulmonary, and neuro-muscular control to ambulate effectively at the determined functional level is extremely discriminatory to patients who may be compromised in these areas without bearing on their ability to efficiently ambulate with a prosthesis. The elimination of patient potential from the revised functional level categories may significantly limit access to higher functional level componentry for patients who are progressing adequately through the rehab process. The use of a walker, crutches, or a cane (or CMS identifying that the patient's Medicare charges include provision of such an assistive device, e.g., for nighttime bathroom access, or periodic situation of soreness or skin irritation from greater than normal activity) should not, in and of itself, limit a patient to a specific functional level classification. The revised LCD and Policy Article make no consideration for bilateral amputees who may benefit clinically from higher functional level components.

Pathway for Improvement: The reliance on functional level assessment to determine what prosthetic components best meet the clinical needs of the individual patient must be reconsidered. There is comprehensive research available that show that patients with lower functional capabilities actually benefit more from microprocessor controlled prosthetic knees as the knee provides greater stability and "stumble control" during the gait cycle. This results in fewer falls, which ultimately reduces Medicare costs associated with treatment for fall related injuries. In addition, research and Medicare's own data, shows that patients who receive prosthetic components that are above their established functional level have less overall total health care cost, even though they may have a higher cost for their prosthesis, for a variety of reasons, likely including greater mobility, lower fall and injury rates, reduced co-morbid conditions such as obesity, risk of diabetes, or vascular disease in the other limb(s) as compared

to patients who receive components that match their (K2) functional level. Functional level assessment should not be the only factor considered when determing the prosthetic components that best meet the clinical needs of the patient. The use of an assistive aid during walking with a prosthesis should not have any impact on the functional assessment of the patient. In addition, cognitive, cardio-pulmonary, or neuro-muscular co-morbidities that are not related to the patient's ability to effectively ambulate while wearing a prosthesis should not be used to justify denial of coverage or to effectively reduce the patient's functional level status.

15. **Requirement for an independent medical examination**

Potential Impact: The requirement for an in-person examination by the treating physician prior to delivery of a definitive prosthesis will result in significant delays in the delivery of medically necessary prostheses. The ability of the treating physician to refer the patient to a licensed /certified medical professional to perform all or part of the in-person examination is a positive development as it will allow professionals with proper knowledge and training in the functional assessment of amputees to perform the evaluation, except that the additional step is added for a second physician review of the LCMP's report, and potential follow-up second face-to-face patient visit. The exception to the requirement that the evaluation is performed by an LCMP with no financial interest in payment of the claim for hospital owned suppliers should be extended to include physicians who may work for the hospital system which owns the supplier as well. The extensive documentation regarding the functional assessment of the patient will continue to be a major hurdle to suppliers who face tremendous difficulty obtaining basic clinical documentation from physicians and other health care professionals today. If the LCMP is considered a healthcare professional for purposes of medical records, there should be no physician "sign off" required in order for claims to be paid.

Pathway to Improvement: The in person evaluation by the physician should not be required prior to the physician writing the order for a prosthesis. This requirement will result in significant delays in providing medically necessary care. When a physician refers the patient to a LCMP for purposes of completing the in person evaluation, the physician should not have to sign off on the findings of the LCMP and/or should not have to conduct a second in person evaluation to confirm the report of the LCMP. There must be further clarification that extends the "hospital owned" exception to physicians as well as LCMPs.

Policy Article

16. **Adjustments, repairs, and component replacement within 90 days of delivery are no longer separately reimbursable when required due to a change in patient condition**

Potential Impact: Current policy allows separate reimbursement for adjustments, repairs, and replacement when caused by a change in patient condition regardless of the amount of time that has passed since delivery of the device. This simply reflects the reality that all patients are not the same, and that some patient's residual limb healing may proceed with abherrations and anomalies, just like every patient healing situation. This is especially relevant for socket changes that may be required shortly after delivery as a result of volume changes to the patient's

residual limb. Failure to provide reimbursement in this scenario will lead to financial hardship to providers and potential delays in medically necessary patient care, to the detriment of Medicare amputee beneficiaries.

Pathway to Improvement: The LCD and Policy Article must allow reimbursement for adjustments, repairs, and component replacement within 90 days of delivery of the prosthesis is situations where there is a documented change in patient condition or the device is lost, stolen, or irreparably damaged. Failure to provide reimbursement for these situations will lead to delays in medically necessary services.

17. Non-coverage of L5990-Adjustable heel height

Potential Impact: L5990 is identified as a convenience item and is therefore categorized as statutorily non-covered, no benefit. There are several vocational and clinical situations that require a patient to be able to adjust the heel height of their prosthetic foot. AOPA addressed this issue several years ago and the DME MACs changed the status of L5990 **f**rom non-covered, no benefit to not medically necessary. This allowed providers and patients the opportunity to appeal denials for this code based on individual situations where medical necessity of this feature was documented. The return to non-covered, no benefit status no longer allows for appeals in limited circumstances.

Pathway for Improvement: Coverage for L5990 in situations where there is a clinical need for the patient to adjust the heel height of their prosthetic foot must be reinstated. While coverage for reasons due to convenience or patient desire may be restricted as not medically necessary, the complete elimination of this feature as a potential benefit will result in negative outcomes for patients.

18. Definition of a custom fabricated socket insert (L5673, L5679, L5681, and L5683)

Potential Impact: The policy article includes prosthetic liners described by L5673 and L5679 in the definition of custom fabricated socket inserts. While products described by these codes include liners that are either custom fabricated or custom fitted over an existing positive model of the patient's residual limb, they also included prefabricated liners that are sold in specific thicknesses according to the clinical needs of the patient. There should not be a requirement that in order for coverage, L5673 and L5679 must be custom fabricated or custom fitted over a positive model of the patient's limb.

Pathway to Improvement: The LCD and Policy Article must recognize that roll on style prosthetic liners described by L5673 and L5679 are not always custom fabricated or custom fitted to a model of the patient's residual limb. They are often purchased in predetermined thicknesses based on the clinical needs of the patient. The proposed policy that requires documentation of the need for a custom liner is flawed due to the complete misunderstanding of the types of products represented by L5673 and L5679. Forcing patients to use antiquated socket insert technology such as pelite and plastazote will result in poor outcomes for patients.

19. (Re)programming of microprocessor based components is considered a non-covered service

Potential Impact: The policy articles specifically adds (re)programming as a non-covered, routine periodic adjustment. This is not listed in the current policy and is eligible for separate reimbursement.

Pathway for Improvement: Regular (re)programming of microprocessor based components is clinically necessary to ensure the proper function of these components. These adjustments require expertise in order to be completed properly and should be considered as reimbursable adjustments, similar to physical adjustments that are required for the proper functioning of a prosthesis.

20. Foot/Ankle coding changes (Same issue as number 9)

Potential Impact: The consolidation of HCPCS codes L5976, L5980, L5981, and L5987 to a temporary code (KXXX1) and L5982, L5984, and L5986 to a temporary code (KXXX2) will severely impact the patient's choice of prosthetic feet and ankles that best meet their individual clinical needs. The vast reimbursement range of the consolidated codes will have significant impact on provider reimbursement for specific prosthetic feet and ankles. The classification of L5968 as only eligible for K3 or K4 patients seems counterintuitive to the function of products described by the code. An active dorsiflexion feature provides adequate ground clearance of the prosthetic foot during swing phase of the gait cycle which serves to prevent the toes of the prosthetic foot from "catching" and causing trips and falls. This feature is more clinically appropriate for K1 and K2 amputees than those with higher functional capabilities.

Pathway for Improvement: The LCD and Policy Article must continue to allow the use of established HCPCS codes, recognized as part of the HIPAA designated HCPCS code set, that most accurately describe the function of specific prosthetic feet. The consolidation of multiple codes that describe prosthetic feet with very unique function into a single generic code will severely limit and restrict the ability of patients to receive the prosthetic foot or feet that best meet their specific clinical need.

21. Non –Coverage of L5969

Potential Impact: Existing and proposed policy for this code indicates that claims will be denied as not medically necessary because it does not meet the medical evidence requirement outlined in the Medicare Program Integrity Manual. The FDA has acknowledged that products described by L5969 as safe and effective and therefore should be covered by Medicare when medically necessary for a specific patient.

Pathway for Improvement: Coverage for L5969 should be available for patients who may benefit clinically from the features that products described by L5969 provide. CMS and/or the DME MACs do not have the authority to determine the safety and effectiveness of prosthetic services. This responsibility lies exclusively with the Food and Drug Administration (FDA), which has confirmed the safety and efficacy of these products.

22. Proof of delivery and failure to recognize the validity of prosthetist's notes

Potential Impact: The draft policy reiterates two troublesome policies which have caused significant headaches and financial losses to O&P professionals. First, the document restates that the prosthetist's note will not be considered as part of the patient's medical record for purposes of establishing medical necessity, which relies on the physician records (prosthetist notes may be used only in corroborating) things stated in those physician records. Second, the document also reiterates the new proof of delivery polices insofar as the HCPCS coding descriptor, no matter how specific it is, is not considered sufficient to describe the device—any device without a serial number, part number or model number is at severe risk of not be reimbursed for absence of a sufficiently extensive description.

Pathway for Improvement: The policy must recognize the role of the prosthetist as a qualified member of the rehabilitation team and recognize their clinical expertise as part of the medical record. In addition, proof of delivery requirements must allow for a consistent process that allows providers to properly document the services that were delivered to the patient, especially those that are custom in nature and therefore do not have an inherent brand name, model number, or serial number.