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Recorded Webinar: Lower Limb Prostheses

Contract	DME MAC Jurisdictions B & C
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Welcome to the Lower Limb Prostheses webinar. My name is Judie Roan with the Outreach and Education Department at CGS.

We do have disclaimers in all our presentations and this information is current as of this moment.

It is important to note that attendees cannot record presentations for any reason; however, CGS can record webinars for future presentation purposes.

We have a rather short agenda today, but we are going to review coverage criteria and documentation requirements of lower limb prostheses. We'll talk about repairs and replacement, coding and billing, prior authorization process, and I'll be providing resources as well.

The first topic on our agenda is coverage criteria and documentation requirements.

A lower limb prosthesis is considered for coverage when the beneficiary will reach or maintain a defined functional state within a reasonable period, and they are motivated to ambulate.

The Local Coverage Determination (LCD) as well as the Policy Article have coverage criteria, billing information, and detailed information about the coverage of lower limb prostheses.

Now a beneficiary's potential functional ability: this information is determined by the medical records from the prosthetist and treating practitioner. It considers factors such as: beneficiary's history; beneficiary's current condition; status of the residual limb; the nature of their other medical problems; and, of course, that desire to ambulate.

So, these are the functional levels. You'll see level 0 through level 4, identified by the modifiers K0 through K4. From the lowest level, which is K0, that means the beneficiary does not have the ability or the potential to ambulate or transfer with or without assistance and a prosthesis will not enhance their quality of life or mobility.

All the way up to the K4 level, which is the ability or potential for prosthetic ambulation that exceeds basic ambulation skills exhibiting high impact stress or energy levels. Now, this K4 or level 4 is typical of the prosthetic demands of a child, active adult, or an athlete.

So, the documentation of the functional level. The medical records must document the beneficiary's current functional capabilities as well as any expected functional potential, including an explanation for the difference.

For example, the beneficiary was ambulating at a K3 level prior to amputation. They are currently ambulating at a K2 level, but they are in physical therapy.

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They are progressing nicely in physical therapy. It's highly likely their potential functional ability will be a K3 within an a decent period of time.

But if that's their potential -- that they will ambulate at a K 3 level — they have the potential to ambulate at that level. But they're currently a K2, we're looking for the difference in the medical record.

It is recognized that within that functional classification hierarchy that a bilateral amputee often cannot be strictly bound by those functional level classifications. If you have a beneficiary who is bilateral, in that scenario, we are looking for documentation to substantiate why, say, they need a C-leg or why you are providing a K3 prosthetic to that beneficiary.

And again, the expectation of their functional ability must be clearly documented and retained in the prosthetist's records; the simple entry of a K modifier by itself is not sufficient. There has to be information about their history and current condition which supports that designation of the functional level by the prosthetist.

So, we don't expect that the medical record from the ordering physician or practitioner is going to actually formally list this beneficiary as a K3 unless the beneficiary is going to a physiologist. We are aware that the average physician is not familiar with functional levels and that is a responsibility or within the scope of practice of the prosthetist.

However, the medical record itself must substantiate whatever information is provided by the prosthetists.

Here's a good example: The beneficiary is morbidly obese. They have severe COPD. When a claim is reviewed, or documentation is audited, if you're billing for a K4 level for that beneficiary, that would be highly unlikely, and I know that's a very extreme example. But it just identifies what we'd be looking for in the medical record.

So again, we're going to look at the beneficiary's overall condition in addition to the classification of a particular functional level.

The treating practitioner documentation. What we'd be looking for in that beneficiary's medical record would be documentation to substantiate the medical necessity for that particular item and the quantity ordered. Again, if the beneficiary is lateral or bilateral, documentation from the physician should include but is not limited to their diagnosis, the duration of their conditions, any clinical courses of treatment, any functional limitations, their prognosis and experiences with related items. Any supplier-prepared statements or an attestation by itself is not sufficient documentation of medical necessity, even if it's signed by the treating/ordering practitioner.

We'd be looking for documentation from the actual medical record to substantiate the need for the item provided.

Now, the prosthetist's records. They are considered as part of the whole medical record and are considered in the context of the documentation made by the physician or other healthcare practitioners.

The prosthetist's records provide additional details to demonstrate that the prosthetic or an orthotic that was billed to Medicare was reasonable and necessary. It is expected that that the prosthetist's records will corroborate and provide details consistent with the physician or practitioner's records. If there is a conflict between the physician's notes and the supplier's record, this could result in a denial.

It is important to keep in mind that payment may not be provided solely based on the orthotist and prosthetist documentation. We will be looking for documentation in the medical record from the treating or ordering practitioner to substantiate need.

Now for any item that is billed to Medicare, there must be an order. So, for any lower limb prosthetic, a standard written order must be communicated to the supplier prior to claim submission.

If you are utilizing any templates for your orders, you must confirm that it meets all of the bullets listed on this slide. We see far too many claims denied because a standard written order was missing a technical component.

The standard written order must have the beneficiary's name or MBI Medicare beneficiary identifier, the order date, a general description of the item and that can either be that general description. It could be the HCPCS, a HCPCS code narrative, or a brand name/model number.

All separately billed components must also be listed on that standard written order, quantity to be dispensed if applicable. This would really only apply if you are providing more than one item or if the beneficiary is a bilateral amputee.

The treating practitioners name or national provider identifier and the treating practitioner signature.

We do have some examples there at the bottom of the slide that show general descriptions with quantity. You'll see a left AK or above knee socket, two socket inserts, a bilateral sach foot, etc.

A new order can be completed by someone other than the ordering physician. However, they must be signed by the treating practitioner.

So, say you receive a verbal order or a prescription pad that's not a valid standard written order. It's missing elements. You can send that template based on that phone order or based on the prescription pad order to the physician, fill it out, everything of course except for the signature, then send it over to the physician to be signed.

If a correction is needed to an order, use a single line strike through so that original content is still readable or legible and the prescriber must sign and date that revision. It could be the signature or initials are also acceptable. That correction must be completed including the signature and date on the order prior to claim submission.

Amendments or delayed entries to paper records must be clearly signed and dated upon entry into the record. If there's an amendment needed to the medical record, they must be signed and dated, and we must be able to read what was there originally.

New orders are required for all initial claims if there's a change in the order. This policy does not require an order on a regular basis, but there is a new order requirement when an item is replaced, and if there is a change in the supplier and the new supplier is unable to obtain a copy of the order from the transferring supplier. This would happen when the beneficiary initially goes to a different prosthetist, they start making a limb for that beneficiary, and for whatever reason they leave that particular supplier and come to you.

In that scenario, you have to have an order. If you can't obtain an order from the other supplier, then you would just want to get a new order from the physician.

Continued medical need. For any item, the initial justification for the medical need is established around the time the item is first ordered.

The medical records demonstrating that the item is reasonable or necessary are created just prior to or at the time of that initial prescription. Once an initial medical need is established, unless continued coverage requirements are specified in the LCD, the ongoing need for a lower limb prosthesis is assumed to be met.

For continued medical need for lower limb prosthesis, there is no requirement for further documentation of continued medical need as long as the beneficiary continues to meet the criteria.

Moving into proof of delivery, this is another common error that we see particularly with Comprehensive Error Rate Testing or the CERT contractor.

Only method one would be acceptable for lower limb prosthetics. Because, of course, the providing the item directly to the beneficiary, if you're utilizing a template for your proof of delivery, please ensure it has all of the elements listed on the slide.

Your proof of delivery must include the beneficiary's name; the delivery address; the date delivered; the quantity delivered, and this is required regardless of if it is one or numerous of a particular item; and the description of the item being delivered. So, again, that can still be that narrative, the HCPCS code, the long description of the HCPCS code or the brand name and model number. The beneficiary's signature, or a beneficiary designee signature. And, in this particular scenario, the date of service is your date of delivery.

So, the date of service is not when the beneficiary comes in for an initial evaluation or a fitting. It is when the beneficiary actually leaves with that prosthetic device. That is your date of service.

Just a few reminders on date-to-service requirements. There are exceptions to quite a few Medicare rules, but for date of service, the beneficiary is being discharged from a hospital or nursing facility. The supplier can deliver to that facility up to 2 days prior to discharge for fitting or training purposes or can also deliver to the beneficiary's home within 2 days prior to discharge

from a hospital or skill nursing facility. The item must be for use in the beneficiary's home, and, in this scenario, the supplier would submit the date of discharge as the date of service and if the beneficiary is being discharged to their home, the place of service would be twelve.

Moving into repairs, adjustments, and replacements. Adjustments for repairs of processes of a prosthesis and a prosthetic component are considered for coverage under the original order for the device as long as there's been no change to the beneficiary's medical necessity. Adjustments that are required by wear or by a change in the beneficiary's condition are covered under the initial order for the prosthesis for the life of that prosthesis. However, if you are providing a replacement of that item you would need to get a new order.

A repair is considered for coverage if it is necessary to make the prosthesis functional. If the expense of repairs exceeds the estimated expense of purchasing another prosthesis, no payments will be made for the amount of the excess and any maintenance which is necessitated by a manufacturer's recommendation or construction of that item and if it is performed by the prosthetists, it is considered for coverage as a repair.

What is considered as non-covered is any routine periodic servicing such as cleaning, testing, and checking of the prosthesis.

Now, the supplier must maintain detailed documentation describing the need for and the nature of all repairs. In the documentation, if the claim were audited, we would be looking for the specific adjustments and repairs performed, and a detailed explanation of the justification for any component or parts that were replaced and justification of the labor time that was used to restore the item to its functionality.

Now, replacement of a prosthesis or a prosthetic component are covered if the treating practitioner orders a replacement device or part because any of the following listed on your slide. There's a change in the physiological condition of the beneficiary, irreparable wear of the device or a part of the device, or the condition of that device or the part requires repairs, and the cost of those repairs would be more than 60% of the cost of replacement.

Payment is made without regard to continuous use or a reasonable useful lifetime restriction, if the treating practitioner determines replacement is reasonable and necessary.

So, what that means is that a law was passed in, I believe it was in 2000, that the reasonable useful lifetime guidelines that apply to other items does not apply to lower limb prosthetics.

So that payment is made without regards to the reasonable useful lifetime as long as the physician determines replacement is reasonable and necessary. This includes liners and inserts that are replaced due to an irreparable wear.

One of the top reasons that we see for CERT denials for lower limb prosthetics is replacement and there is no documentation of the reason for replacement. So, claims involving replacement of a prosthesis must be supported by a new order, as I stated earlier, and documentation that supports the reason for replacement.

That reason for replacement must be documented by the treating practitioner and it can either be in the medical record or on the order. This is the only place that we accept documentation on an order. So that reason for replacement must follow under one of those three that we mentioned earlier. I'll go through them again. But again, that can be on the order.

If replacement is needed, it can come from the actual order and they are a change in the physiological condition of the beneficiaries that results in the need for a replacement such as changes to the beneficiary's residual limb, the functional need changes, an irreparable change to the condition of the device or in part of the device that results in the need for replacement or again the condition of the device or part. Require repairs and the cost of those repairs are more than 60% of the cost of replacement.

For documentation of replacement, the prosthetist must retain the documentation of the prosthesis, or the component replaced. If it is a part, a description of the labor involved, regardless of the time since the prosthesis was provided to the beneficiary. This must be available upon request.

The reason for replacement changes in the residual limb, their functional need changes or those irreparable damage or wear and tear due to excessive beneficiary weight or the prosthetic demands of a very active amputee.

Now for replacement due to loss or irreparable damage.

These may be reimbursed without an order if it is determined that the prosthesis as originally ordered still fills the beneficiary's needs.

If there is no change in condition, there must be documentation to support irreparable damage, such as the item is no longer usable due to a house fire, a flood, a car accident, and we'd be looking for that documentation. In this scenario, you would append the RA modifier to the claim which identifies replacement and include a narrative on the claim as well in the NTE 2300 or 2400 or the notes field on your electronic claim, if the item is lost, stolen or irreparably damaged.

Here is an example of valid documentation of replacement from the treating practitioner. So, you'll see that this is an old order because it's called a detailed written order and they went away in 2020. But it's a standard written order and medical necessity, you'll see that the physician documented the reason for replacement. The reason for replacement was that that beneficiary lost a hundred pounds. So, they went from 250 to 150 pounds in 6 months.

Their current prosthesis no longer fits. So that would be considered valid documentation of replacement from the treating practitioner documented on the order, signed, and dated.

We do have a separate lower limb prostheses prior authorization session coming up within the next few months, which will dive into some additional detail, but today we'll be providing a summary of prior authorization.

These codes are all functional Level 3, and there are six codes listed that are subject to required prior authorization. So prior authorization must be submitted prior to providing these items to the beneficiary for Medicare.

A quick outline of the prior authorization process.

The supplier receives an order and medical records for an item on that required prior authorization list. They then submit the prior authorization request and documentation as well as the order to the DME MAC for medical review. And we then send a decision letter with a unique tracking number, also known as a UTN to the supplier.

If the supplier receives a provisional affirmative PA decision, which means an approved or affirmative or approved prior auth decision, the item must be delivered within 120 days. Then the claim is submitted and be sure to include that UTN or unique tracking number on that claim or the claim will be denied.

If the supplier receives a denial or non-affirmative PA decision, you can continue to resubmit prior authorization requests as often as necessary.

You can obtain additional documentation and resubmit the request or submit the claim for denial, including that non-affirmative UTN on the claim.

If you obtain an Advanced Beneficiary Notice of Non-coverage, append the GA modifier. If you just want to go through the appeals process, submit the claim, and appeal rights are available after the claim denial.

Just to be clear, prior authorization does not have appeal rights. Claims have appeal rights.

The prior authorization can be corrected and resubmitted or additional documentation can be submitted. After the claim is processed and denied, you can go through all five levels of the appeals process on the claim.

How do we submit a prior authorization request? The quickest, easiest way is to utilize the myCGS web portal.

They were taking 3 days to show status. That was prior to, I think, two updates ago to my CGS, but now it is, relatively instantaneous. So, you can immediately see that we have received your prior auth request.

To submit a prior auth, all you have to do is complete the required fields on the prior authorization request form on the Form and Submission screen, select your documentation to upload with those forms, and then check the status of your submission.

You can always fax or mail as well. You would complete the prior authorization submission form and submit all of your documentation to CGS either through fax or mail.

Then there is ESMD or Electronic Submission of Medical Documentation. That is a system that is available to an electronic system when you submit that, you do have to indicate the document or content type of 8.4.

And again, submit the form and all required documentation. If you would like additional information on ESMD, it is available on CMS's website so you can absolutely obtain it there.

This is just a copy of the coversheet, and it shows you the myCGS portal and all the information we'd be looking for and how to upload those files.

Now the documentation that's required for that request includes all of the documentation without proof of delivery that would be looking for in an audit: a standard written order; medical records from the treating practitioner; potential functional level classification; treating practitioners' medical records; and the prosthetist's records.

So, for prosthetics, prior authorization does not create any new documentation requirements. Prior authorization is just looking for that documentation to be submitted earlier in the claims process.

Moving into decision letters, we will send that decision letter with the UTN to the submitter through fax, mail, or myCGS, or it can also be received through ESMD.

Your provisional affirmative decision. That is a preliminary finding that a future claim submitted to Medicare for the item likely meets the Medicare coverage coding and payment requirement. It is not a guarantee of payment.

Maybe you'll leave off a K modifier or an RTLT modifier. The beneficiary may have a Medicare Advantage plan. There are many reasons that your claim could still be denied. That's why checking eligibility in my CGS is so beneficial.

For a non-affirmative decision again, a preliminary finding that if a future claim is submitted for those items likely does not meet Medicare's coverage coding and payment requirements. Now for letters that are mailed, they will be mailed to the address on file with the NPE contractors. Keep in mind if you have numerous locations, your correspondence address with the national provider enrollment contractors may not be your location.

That's why my CGS is even more beneficial.

The timeframe for an initial request Medicare will send a decision with that UTN within ten business days same for your resubmitted requests. You can submit an expedited request that is incredibly rare for a lower limb prosthetic.

However, we will attempt to review and communicate a decision within two business days. And there must be documentation and justification where a delay in a review and response could jeopardize the life or the health of that beneficiary. Needles to say, that is why we don't receive many for prosthetics.

You do have to provide that item to the beneficiary within 120 calendar days following that provisional affirmative decision. If it is not provided within those 120 days, a new prior authorization request does need to be submitted to restart that time frame.

The top non-affirmation reasons are listed on the slide. And one of the issues that we see in prior authorization are consistently the same issues that we would see in an audit.

- The medical record does not clearly identify an original content of the amendment correction or delayed entry, which I mentioned earlier.
- The signature isn't valid. It doesn't comply with the CMS signature requirements and guidelines.
- It only has an attestation statement or an order, or a supplier-prepared statement. Again, you want to be sure to include medical records from the physician when the medical record isn't signed and that can be handwritten or wet or an electronic signature.

There were various other issues that are not listed.

I mentioned that even if you received a prior authorization request, you could still get a denial once the claim submitted if you neglected to add the UTN or an RTLT modifier.

So those RT right or LT left modifiers are required if you are providing bilateral items. If the same code for a prosthesis socket or component is billed on the same date of service, each item must

be billed on a separate claim line utilizing one unit of service and RT on one LT on the other. Do not use the RTLT modifiers on the same claim and bill with two units of service.

Now there are certain items that do require that functional level that we talked about earlier. It's a K0 through K4 modifiers they are required for knee, foot, ankle, and hip component HCPCS codes.

We do have those codes listed on the slide for you. So, if any of those codes are submitted without the K0 through the K4 modifier, they claim will be denied automatically on the front end as missing a modifier.

Now in addition to that, some items are only covered for specific functional levels. We'd always refer to the LCD in the policy article for the particular code that you're providing.

An easy way to find those codes is Control F once you're in the actual LCD or policy article. Enter the HCPCS code and you can go through and just see the criteria for that particular item.

Billing for repairs or adjustments, the L7510 is used for any minor pieces/parts for those without a specific HCPCS code to achieve an adjustment or repair.

The L7520 is used to bill for labor associated with adjustments and repairs that either do not involve replacement parts or involve replacement parts that are billed with that L7510 for the minor parts strapping, screws, bolts, those types of things that don't have individual HCPCS.

One unit of service of the L7520 equals 15 minutes of labor. The time reported must only be actual repair time. And the sub bullets listed on the bottom of your slide must not be billed using that L7520 such as: evaluation to determine the need for a repair adjustment or a follow-up assessment; evaluation of problems regarding the fit or function of the prosthesis: any general beneficiary education or gait instruction; and any programming of electronic componentry. The L7520 should not be used for any of those items.

I mentioned that UTN for prior authorization. It goes on item 23 for the very few suppliers who still submit paper claims. For electronic claims, it would go in the claim information loop is the 2300 fields or the 2400 service line loop in the prior authorization segment. The qualifier G1 in the REF01 and the UTN would be REF02.

Some additional information regarding inpatient hospital or skilled nursing facilities. If a prosthesis is provided to a beneficiary during an inpatient hospital stay prior to the date of discharge and is used for inpatient treatment and/or rehabilitation, the claim is not submitted to the DME MAC.

If a lower limb prosthesis code is provided to the beneficiary in Part A prior to the date of discharge and again used for inpatient treatment or rehabilitation, it cannot be submitted to the DME MAC.

Major Category 3 HCPCS codes that are provided to a beneficiary during a part A-covered SNF stay can be billed to the DME MACs.

Any lower limb prosthetic that is provided in a skilled nursing facility when the stay is not a Part A covered stay can be submitted to the DME MAC.

And if the item is delivered within 2 days prior to discharge, from a hospital or a skilled nursing facility and it is not needed for inpatient treatment or rehabilitation, but it's left in the room for the beneficiary to take home, then that can also be submitted to the DME MAC.

Going to move through some resources. We have a lower limb prosthesis checklist. We strongly suggest utilizing that checklist either periodically to do self-audits or always prior to submitting either your prior authorization request or responding to a CERT audit or any other auditing contractor.

To assist with physician documentation, we have also created a "Dear Physician" letter.

I mentioned the Local Coverage Determinations and Policy Articles and the Standard Documentation Requirements for All Claims Submitted to the DME MACs. We do have an entire page of information dedicated to lower limb prosthesis and prior authorization and that is available on our website.

Jurisdiction B resources. This includes our IVR, customer service, phone reopenings, paper claim submission, redetermination reopenings, EFT forms, and written inquiries address, overpayment appeals and for those of you that submit PWK segments.

This is all for Jurisdiction C. Same information, but for Jurisdiction C. It's important to always be sure to respond to the correct jurisdiction that initially processed the claim. If you've received an

overpayment request from Jurisdiction B, please be sure to respond to Jurisdiction B so there's no delays in our ability to process that request.

Additional other contractor resources include the PDAC or Pricing Data Analysis and Coding contractor, if you ever have a question about which HCPCS code to bill for a specific item you're providing.

Then there is CEDI or Common Electronic Data Interchange and that is the front end of the Medicare Claims processing system. If you receive a rejection, they could reject for an invalid HCPCS code, an invalid Medicare number. When you submit an electronic claim, first it goes to CEDI, then it gets sent off to the applicable jurisdiction for processing.

Also, if you still submit paper claims for those of you that can. If you are interested in submitting electronic claims, CEDI does offer a free software.

Then there are the NPE contractors, formerly known as the National Supplier Clearinghouse, now known as the National Provider Enrollment Contractors, there are two. NPE East is Novitas Solutions and that is for supplier locations east of the Mississippi River and NPE West is Palmetto GBA and of course that's for supplier locations west of the Mississippi River.

If you have questions about your enrollment, your hours of operation, supplier standards, licensure requirements, surety bonds, all of those types of questions would not come to the DME MAC, they will need to be referred to the NPE contractors.

CGS does have a mailing list, so hopefully those of you that are on today are signed up and get our emails on a regular basis. You will receive the most recent information, changes to the Medicare program, when we are doing workshops, upcoming webinars. It is very easy to sign up.

And if you're not utilizing myCGS or not utilizing it to the best of its ability, you can save time and money by submitting your redetermination, reopening, prior authorization requests all through the myCGS portal.

If you already have my CGS, but you're not using it using it to the best of its ability, you can refer to the myCGS User Guide. If you are not currently signed up to myCGS, you can; the process has become much easier than it used to be. Refer to the myCGS Registration Guide. Keep in mind if you have myCGS but perhaps don't have access to certain functions that is probably within your organization and your lead for myCGS or the designated approver. So, if you can't submit prior auth requests, but you have myCGS definitely talk to your designated approver.

Just wanted to provide a quick update. This does not apply to lower limb prostheses because they're not subject to competitive bidding. However, a lot of suppliers also provide off-the-shelf orthosis. So just wanted to let everyone know that effective January first of next year, there will be a temporary gap in competitive bidding. During that temporary gap, any Medicare-enrolled supplier can provide competitive bid items to those beneficiaries. There are special payment rules, with adjusted fees and former competitive bid areas. They're based on 100% of the SPA or Single Payment Amount for a competitive bid area. There are specific fees you can find at the address on our slides, specific to certain off-the-shelf spinal and knee orthosis.

There will be a temporary gap. We do not know what's going to happen after the gap as of yet; stay tuned.

All right, I'd like to thank you so much for listening.