Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Educational Webinar

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Draft Local Coverage Determinations (LCDs)

Collaborative Policy CGS, NGS, Palmetto, Noridian, Novitas, First Coast and WPS

- L39756 Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD - Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (L39756)

- A59618 Billing and Coding: Skin Substitutes Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Article - Billing and Coding: Skin Substitutes Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (A59618)

- A55941 Response to Comments: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Article - Response to Comments: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (A59941)

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Covered Indications

- **If the patient meets all criteria as outlined in this LCD, application of a skin substitute graft or CTP in the treatment of DFU and VLU is considered reasonable and necessary for the following conditions:**
- The presence of a chronic, non-infected DFU or VLU having failed to respond to documented standard of care (SOC) treatment (outlined below) for a minimum of 4 weeks with documented compliance.
- ICD-10-CM codes to support the diagnosis are listed in the Billing and Coding Article.

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Documentation requirements

- The skin substitute graft/CTP is applied to an ulcer that has failed to heal or stalled in response to documented standard of care treatment.
- Documentation of response requires:
  - Measurements of the initial ulcer, pre- and post-completion of at least 4 weeks of SOC, with additional measurements at initial placement and each subsequent placement of the skin substitute graft/CTP.
  - Standard of care measures without measurable signs of healing must have preceded the application for a minimum of 4 weeks and must continue for the course of therapy.
  - Continuous compression therapy for VLU must be documented for the episode of care.

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Covered Indications

- Comprehensive patient assessment (history, exam, vascular assessment)and diagnostic tests as indicated) in an implemented treatment plan.
  - For patients with a DFU: assessment of Type 1 or Type 2 diabetes and management history with attention to certain comorbidities (e.g., vascular disease, neuropathy, osteomyelitis), review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion), and assessment of off-loading device or use of appropriate footwear.
  - For patients with a VLU: assessment of clinical history (that includes prior ulcers, higher body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, higher number of pregnancies, and physical inactivity), physical exam (edema, skin changes and vascular competence), evaluation of superficial or deep venous reflux, perforator incompetence, and chronic (or acute) venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressings is an essential component of SOC for venous stasis.
  - *Documentation that modifiable risk factors, such as diabetes optimization, are being addressed to improve likelihood of healing. For venous leg ulcers, it is expected that appropriate management and consultation, if indicated, be obtained for the diagnosis and stabilization of any venous related disease.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Covered Indications & Documentation Requirements

An implemented treatment plan demonstrating all the following:

- Debridement as appropriate to a clean granular base.
  - *An **operative note** must support the procedure (e.g., application of skin substitute graft/CTPs to legs) for the relevant date of service (first application starts the 12-to 16-week episode of care) and include the reason for the procedure and a complete description of the procedure including product used (with identifying package label in the chart), and relevant findings.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Covered Indications & Documentation Requirements

- Documented evidence of offloading for DFU and some form of sustained compression dressings for VLU.
- Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling (if applicable).
  - *Documentation that **modifiable risk factors**, such as diabetes optimization**, are being addressed to improve likelihood of healing**. For venous leg ulcers, it is expected that appropriate management and consultation, if indicated, be obtained for the diagnosis and stabilization of any venous related disease.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Covered Indications & Documentation Requirements

- Placement of skin substitute graft/CTP on infected, ischemic, or necrotic wound bed is non-covered.
- Coverage requirements include:
  - Infection control with removal of foreign body or nidus of infection.
  - Management of exudate with maintenance of a moist environment (moist saline gauze, other classic dressings, bioactive dressing, etc.).
  - *Description of the ulcer(s) must be documented at baseline (prior to beginning standard of care treatment) relative to size, location, stage, duration, and* ***presence of infection****, in addition to the type of standard of care treatment given and the response.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Provider types & training

- Patients receiving skin replacement surgery with a skin substitute graft/CTP should be under the care of a qualified physician/non-physician practitioner (NPP) for the treatment of a systemic disease process (e.g., diabetes mellitus, chronic venous insufficiency, or peripheral vascular disease). It is imperative that systemic disease be monitored and treated to ensure adequate healing of the ulcer and documented in the medical record.
- Services provided within the LCD coverage indications will be considered reasonable and necessary when all aspects of care are within the scope of practice of the provider's professional licensure.
- All procedures must be performed by appropriately trained providers in the appropriate setting.

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Coverage Requirements & Coding

To qualify as skin substitute graft/CTP the product must be:

1. A non-autologous human cellular or tissue product (e.g., dermal or epidermal, cellular and acellular, homograft **OR** allograft), **OR** non-human cellular and tissue product (i.e., xenograft), **OR** biological product (synthetic or xenogeneic) which applied as a sheet, allowing the scaffolding for skin growth and is intended to remain on the recipient and grow in place or allow recipient's cells to grow into the implanted graft material

Do not report non-graft wound dressings or injected skin substitute HCPCS codes with skin substitute graft/cellular and/or tissue-based products (CTP) and HCPCS application codes as this would be considered incorrect coding. Such products are bundled into other standard management procedures if medically necessary and are not separately payable.

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Coverage Requirements & Coding

2. Have quality supporting evidence to demonstrate the product's safety, effectiveness, and positive clinical outcomes in the function as a graft for DFU and/or VLU. Predicate products are not sufficient evidence for an individual product.

The products Group 2 have met coverage requirements for DFU and the products in Group 3 have met requirements for VLU

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Application Limits

- The maximum number of applications of skin substitute graft/CTP within the episode of skin replacement therapy (defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP) is 8 applications.
  - The mean number of applications associated with complete wound healing is 4; however, with documentation of progression of wound closure under the current treatment plan and medical necessity for additional applications, up to 8 applications may be allowed.
  - Use of greater than 4 applications require an attestation from the provider showing that the requirements specified in the LCD have been met and the additional applications are medically necessary. In absence of this attestation, denial of the additional applications will occur.
- Greater than 8 applications of a skin substitute graft/CTP within an episode of care (up to 16 weeks) is not reasonable & necessary and will be denied.

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Application Limits

Attestation is accomplished by applying Modifier –KX

- Modifier -KX must be used as an attestation by the practitioner and/or provider of the service that documentation is on file verifying that the patient meets the requirements for additional applications of skin substitute grafts/CTP.
- Consistent with the LCD more than 4 applications of a skin substitute grafts/CTP in a 12–16-week period must be appended with a -KX modifier.
- Failure to apply the -KX modifier for applications greater then 4 will result in return of claim or claim denial. Aberrant use of the -KX modifier may trigger focused medical review.

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Application Limits

- The usual episode of care for skin substitute graft/CTP is 12 weeks; however, some wounds may take longer to heal. An additional 4 weeks will be allowed, totaling 16 weeks from initial application.
  - *Documentation must include an assessment outlining the plan for skin replacement therapy and the choice of skin substitute grafts/CTP for the 12-to-16-week period as well as any anticipated repeat applications within the 12-to-16-week period.*
  - *Graphic evidence of ulcer size, depth, and characteristics of the ulcer or photo documentation of the ulcer at baseline and follow-up with measurements of wound including size and depth should be part of the medical record.*
  - *The reason(s) for any repeat application/ extended time should be specifically addressed in the medical record, including whether the current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Repeat Applications

- Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure) is not covered.
  - *The **reason(s) for any repeat application** should be specifically addressed in the medical record, including whether the current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan.*
  - *Documentation should include estimated time for extended treatment and number of additional applications anticipated and plan of care if healing is not achieved as planned.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Documentation Requirements Wastage

- The skin substitute graft/CTP must be used in an efficient manner utilizing the most appropriate size product available at the time of treatment. Excessive wastage (discarded amount) should be avoided by utilization of size appropriate packaging of the product consistent with wound size. The graft must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin substitute graft/CTP.
  - *Any amount of **wasted skin substitute graft/CTP must be clearly documented in the procedure note** with ALL the following information (at a minimum): Date, time and location of ulcer(s) treated; Name of skin substitute graft/CTP and package size: Approximate amount of product unit used; Approximate amount of product unit discarded; Reason for the wastage (including the reason for using a package size larger than was necessary for the size of the ulcer, if applicable); Manufacturer's serial/lot/batch or other unit identification number of graft/CTP material. When the manufacturer does not supply unit identification, the record must document such. The amount billed as wastage cannot exceed the price of the package.*

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Documentation Requirements Wastage

JW and JZ Modifiers

- When billing for Part B drugs and biologicals (except those provided under a competitive acquisition program [CAP]), the use of the **JW modifier** to identify unused drugs or biologicals from single use vials or single use packages that are appropriately discarded is required. The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded drug or biological in the patient's medical record.
- Any amount wasted must be clearly documented in the medical record and should include the date and time, amount of medication wasted, and the reason for the wastage. The use of the **JZ modifier** (attesting that there were no discarded amounts) is required on claims to report there are no discarded amounts of unused drugs or biologicals from single use vials or single use packages.
- Claims for drugs separately payable under Medicare Part B from single-dose containers are required to report either the JW or JZ modifier to identify any discarded amounts or to attest that there are no discarded amounts, respectively. Part B claims for these products submitted without the JW or JZ modifier appended will be rejected.
- The JW and JZ modifier policy does not apply for drugs that are not separately payable, such as packaged OPPS or ASC drugs, or drugs administered in the FQHC or RHC setting.
- The JW and JZ modifiers do not apply to drugs assigned status indicator N (Items and Services Packaged into APC Rates) under the OPPS. Similarly, the JW and JZ modifiers do not apply to drugs assigned payment indicator "N1" (ASC).

Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers: Multiple Wounds

- To determine the surface area for application of skin substitute graft codes for multiple wounds, all wound areas within the same anatomic site, as described by the skin application code descriptors, should be added.
- If the skin substitute graft is applied to wounds on a different anatomic site, they should bill the corresponding application code for the anatomical site for each date of service (DOS)
- Do not code modifier 59 on skin substitute, graft application, or skin substitute product codes. Skin substitute graft application codes are appropriately coded based upon total surface area of anatomical locations and not by number of ulcers.
- Modifier -50 and modifiers -LT and -RT are not appropriately appended to skin substitute codes. Coding for skin substitute graft application is based upon total surface area of the ulcers; therefore, Modifiers -50, -LT, and -RT are not required for proper claim adjudication.

Q&A

Q: What about the use of skin substitute graft and CTP for indications other than DFU/VLU?

A: This LCD address the use of skin substitute graft and CTP for diabetic foot and venous leg ulcers. Ulcers for other indications are not addressed in this LCD and coverage determination is based on individual MAC discretion. As required to be R&N services must be supported by evidence and demonstrate improved health care outcomes. For how evidence is evaluated see the article Principles of Study Design.

Q&A

Q: If a product is classified or approved by FDA, is it covered?

A: FDA classification and indication are not the sole determinants of designation as a skin substitute graft/CTP or provide the reasonable and necessary threshold for coverage. Coverage is based on evidence for the product's effectiveness and ability to improve health outcomes as required for Medicare coverage.

- For coverage under the Medicare program an item or service must be Reasonable and Necessary. For further information see:
  - CMS IOM Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 5.4 Reasonable and Necessary Provision in an LCD

Q&A

Q: What about patients who are currently receiving a non-covered product for care?

A: In order to ensure no disruption to patient care during treatment the notice period of the policy was extended from the usual 45 days to 90 days to allow treatment to be completed without disrupting care. During this time providers can transition to covered products to avoid disruption of care after the policy effective date of 02/12/25.

Q&A

Q: What if the provider feels the patient needs >8 applications or longer than 16 weeks of treatment?

A: There are few circumstances in which extension beyond 16 weeks or >8 applications is clinically indicated based on current evidence. In a retrospective review (cited in LCD) that collected frequency data there was minimal change in wound size after 7 applications and 16 weeks supporting these parameters. If the patient is not healing at this point evaluation to ensure optimization of underlying medical conditions or other treatment options is recommended.

Q&A

Q: Will this be part of the prior authorization program?

A: The services selected from prior authorization are not determined by the MACs. Currently, it is not part of Medicare's prior authorization program.

Q&A

Q: What is the maximum number of applications in a year?

A: The limitation is based on the maximum applications for an ulcer during that episode of care. If the ulcer does not progress or heal within 16 weeks continued use of the product is non-covered. If a new ulcer develops during this time that begins a new time cycle for that ulcer. All ulcers must meet the requirements of the LCD and documentation requirements products to be covered.

Aberrant use, such as frequent applications, in the same patient may be subject to medical review.

Q&A

Q: Is there a minimum duration for which a DFU or VLU must be present before considering the application of skin substitute grafts?

A: The requirement is the presence of a chronic, non-infected DFU having failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment for a minimum of 4 weeks with documented compliance.

Q&A

Q: The ulcer should be how much in size for it to be considered medically necessary for grafting? There is no explicitly stated minimum ulcer size for grafting in this LCD.

A: A minimum is not stated as there are multiple factors that play a role in this decision and there was not evidence to support a specific size however, ulcers <1cm rarely need grafting. To qualify for grafting it must be non-healing with SOC for minimum of 4 weeks and meet all requirements for coverage in the LCD.

Q&A

Q: Does the LCD require controlled diabetes for patients with venous leg ulcers (VLUs)? Upon reviewing the section on controlling comorbidities, there is no mention of diabetes management as a specific requirement for VLU treatment.

A: If diabetic yes- the policy states treatment of the systemic disease process(es) etiologic for the condition and the condition and treatment plan must be part of the documentation.

Q&A

Q: The patient's nutritional status must be addressed in the medical documentation as part of the standard of care. What objective data would be sufficient to meet this requirement?

A: This may be individualized based on patients' conditions so there is no set requirement but should be included as part of the comprehensive evaluation of the patient.

Q&A

Q: The following situation is deemed not reasonable or necessary: repeating skin substitute graft applications when prior attempts have failed. Failure is defined as an ulcer showing increased size or depth, no measurable change from baseline, or no signs of improvement, such as granulation, epithelialization, or progress toward closure. At what point should this determination be made? After how many applications should this be assessed?

A: Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure) and is not covered- this should be accessed prior to any re-application regardless of time interval or number of applications.

Q&A

Q: In the previous LCD, it was specified that a patient who smokes must abstain from smoking for at least four weeks before the first SSG application. This proposed LCD does not state anything regarding this point. What is the guideline related to it?

A: Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling, if applicable.

Q&A

Q: The LCD specifies that standard of care (SOC) requires the patient to be under the management of a qualified provider for the systemic diseases, with this documented in the medical record. Does this mean that in the medical record, the identity of the provider responsible for this concurrent medical management should be documented?

A: Yes.

Q&A

Q: Coverage criteria #1 says DFU with at least 50% ulcer area reduction and failed SOC management for 4 weeks may qualify- does this mean any wound that does not achieved at least 50% reduction qualifies?

A: No, to qualify an ulcer must meet all coverage criteria (6/6) and in #4 the ulcer must be have failed to heal or stalled response despite SOC measures must have preceded the application for a minimum of 4 weeks and established SOC treatment must continue for the course of therapy.

Failed response: Increased size or depth, no change in baseline size or depth, or no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing

Stalled Wound: An ulcer that has entered a nonhealing or intransigent phase.

Q&A

Q: Is the 12-month restriction for use of the products in a recurrent ulcer gone? I read this in the comments but did not see mention in the body of the LCD. Could you confirm that these products can now be used again in the same patient on the same wound within the same 12-month period?

A: The limitation is based on the maximum applications for an ulcer during that episode of care. If the ulcer does not progress or heal within 16 weeks continued use of the product is non-covered. If a new ulcer develops during this time that begins a new time cycle for that ulcer. All ulcers must meet the requirements of the LCD and documentation requirements products to be covered. Aberrant use, such as frequent applications, in the same patient may be subject to medical review.

Q&A

Q: If a provider wishes to use a non-covered skin substitute that has historically demonstrated excellent wound healing outcomes, can they appeal for coverage of this non-covered product? What specific documentation or clinical evidence would be required to support the appeal for coverage under Medicare's guidelines?

A: It is not appropriate to bill Medicare for services that are not covered (as described by the entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier (GA, GX, GY, or GZ). If an appeal is made documentation of care and supporting literature should accompany the appeal.

Q&A

Q: Are the edits subjecting claims beyond the 4th application to require a KX modifier linked to the 15271-15278 procedure codes, or will they only be induced when the procedure code is billed in conjunction with the group 1 or 2 diagnosis codes?

Will the edit limiting coverage to group 4 CPT codes only restrict coverage when group 4 CPT codes are billed in combination with a group 1 or 2 diagnosis code?

A: Coverage adjudications are limited to the policy as written.

Q&A

Q: Can CMS confirm that Critical Access Hospitals must use the JW / JZ modifiers, even for products with an assigned status indicator of N or N1**?**

A: The modifiers do apply to CAH hospitals, however, they apply only to separately payable drugs, so they would not apply to packaged drugs. There are separately payable drugs that are used in a CAH and the modifiers would apply there. See #7 at:

- Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions

Q&A

Q: Will the “progress towards closure” documentation anticipated to support applications 5, 6, 7, and 8 allow for reporting on improvements beyond wound size, depth, and granulation tissue, such as pain reduction, drainage, and wound bed oxygen levels?

A: Repeat applications of skin substitute graft/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer, no measurable change from baseline, and no sign of significant improvement or indication that significant improvement is likely (such as granulation, epithelialization, or progress towards closure).

Q&A

Q: How does the new CMS LCD skin subs impact the coverage and reimbursement guidelines for Medi-Cal, particularly for VLU and DFU wound care treatments involving amniotic tissues? Will Medicare Advantage Plans be required to follow these Medicare guidelines?

A:"In the United States, according to federal law, Part C providers must provide their beneficiaries with all services and supplies that Original Medicare Parts A and B cover. They must also provide any additional benefits proclaimed in their Part C policy. Medicare Advantage policies can provide additional benefits that are approved by the Centers for Medicare & Medicaid Services (CMS)"

Reference:

- Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections sections 90 – 90.6 https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c04.pdf
- Do Medicare Advantage Plans Follow CMS Guidelines? | Medicare & Medicare Advantage Info, Help and Enrollment

Q&A

Q: Can CMS provide evidence that supports every single and subsequent application of a CAMP will result in a measurable decrease in the size or a favorable change from baseline? This is particularly relevant given that it may take several applications of a CAMP to allow for the development of an environment in the wound bed under the CAMP barrier that diminishes the underlying inflammation, which can inhibit progression toward closure, thus allowing processes like granulation tissue proliferation and epithelial cell migration to resume.

A: If the wound is not healing other treatment modalities can be considered. Several products have evidence of healing with single application or one repeat supporting not all wounds need multiple applications.

Q&A

Q: The change to extend coverage to 8 applications is helpful, but the use of KX modifier will limit patient access if it becomes a *de facto* 4-application limitation. Will the MACs conduct reviews on any provider that submits a claim over 4 applications, or will the MACs review providers that always file claims over 4 applications?

A: This is not a limitation but an attestation of medical necessity- reviews would be determined by MAC discretion.

Q&A

Q: Is the KX modifier meant to be applied to the group 1 codes? It is referenced in the text of the billing and coding article, but not in any of the coding information to reference which groups it applies to. I would also like to clarify that the KX modifier is to be applied to the CPT code or the product code?

A: The KY modifier is applied to the CPT code.

Q&A Reconsideration Process

- **LCD reconsideration request**
  - An informal meeting may be requested prior to submission.
  - Request should be submitted to all MACs. This can be accomplished in a single request addressed to all MACs.
  - Request will be reviewed and determined in valid or invalid within 60 days.
  - Request should be submitted with peer reviewed published literature to support the request.
  - MAC will follow the process outlined in Medical Program Integrity Manual Chapter 13.
  - Any literature published after the notice period began (11/14/24) needs to go through the reconsideration process.
  - Request can be received once the policy is effective (02/12/25).

Q&A Reconsideration Process

- **Timeline**
  - MACs have committed to review the LCD every 12 months. This is not a requirement of the PIM but a decision the MACs made to provide guidance to stakeholder on the process. The 12 months begins when the LCD becomes effective (02/12/25).
  - The MACs can review sooner if there are valid request as determined by MACs capacity to conduct reviews earlier.
  - In effort to expediate the process the LCD may be open to comments on the new/changed sections only.
  - MACs will coordinate the reviews, open meeting and comment period to expediate the process.

Q&A Reconsideration Process

- **Other Q&A's**
  - MACs cannot move the codes to the billing and coding article as all coverage changes must go through the entire process per the PIM.
  - MACs do not design study or provide clinical endpoint guidelines. There are multiple resources listed in the LCD and RTC article to provide support to investigators.
  - MACs did not change the approach to how evidence was evaluated between the proposed and final LCD. At the request of stakeholder additional details of the process were added to the LCD. The intention of the MACs is to review future products using these standards and that future evidence seeks to address knowledge gaps that are highlighted throughout the LCD and RTC Article.

Q&A Reconsideration Process

- **Other Q&A's**
  - How do you address limitations in current research? We acknowledge there are limitations in research and hope future study designs can better address these limitations. The covered products all have demonstrated effectiveness and improved outcomes in a controlled manner and supported by additional published clinical evidence. The LCD offers a transparent review of all studies reviewed and utilized established tools to access quality of evidence (risk of bias assessment) to ensure studies have equal consideration regardless of funding source.
  - Why RoB2 tool? RoB2 was selected as this is the tool used in GRADE and since essential all studies were funded by manufacturers and RoB2 does not automatically associate industry funding with a higher risk of bias. Instead, it meticulously examines the study's design to pinpoint any potential biases, ensuring that well-conducted research, irrespective of funding sources, is recognized for its contribution to evidence-based medicine it was determined to be most appropriate for this analysis. This tool was used and referenced in both the proposed and final drafts.

Q&A

Q: Why is this not an NCD?

A: NCDs are developed by CMS. The MACs are responsible for developing local coverage policy to address needs the needs of their jurisdiction. Since the MACs all identified needs to address in their regions, they worked together to develop a local coverage policy to meet their needs. There are no restrictions on collaboration among MACs and improves consistency of care across jurisdictions.

MACs do not have ability to do coverage with evidence development.