Questions for FAQ on New Lymphedema Compression Treatment Items		
Topic	**Question**	**Reason for Inclusion**
DME Contracting for Measuring and Fitting Services	How can therapists privately contract with DME suppliers for garment measuring, fitting, and training services without invoking the Anti-Kickback Statute (AKS)?	There are concerns that by contracting with a specific DME supplier, it inherently promotes the use of one DME over others, in effect limiting or removing patient preference. Therapists would be incentivized to use only DMEs willing to pay for their services, instead of other DMEs that may offer wider or more clinically appropriate garment options.
	Are therapists expected to contract with DMEPOS suppliers annually, or on a case-by-case basis?	There are concerns that case-by-case contracting would be difficult to manage for therapists and could delay care for patients.
	Does a contract *shorter than* one year violate the Antikickback Statute or Stark Laws?	If therapists are offered a contract for services rendered for less than one year, they are concerned that the contract would violate the AKS or Stark Laws.
	If contracts are expected to be annual (or longer), is it appropriate for therapists to enter into the following types of agreements (the amounts and percentages are just hypothetical, assuming they are fair market value): • (a) For a flat percentage of the garment reimbursement for each garment? (e.g., 15% of the Medicare garment rate) • (b) For a flat rate of the garment reimbursement for each garment? (e.g., $40 for each garment). • (c) For a scaling percentage of the garment reimbursement for each garment, based on patient complexity? (e.g., 10% for stage 2, 15% for stage 3, 20% for stage 4)	It would be helpful for therapists to have some compliant concepts of what an appropriate contract for these services might look like.

	• (d) For a scaling rate of the garment reimbursement for each garment, based on patient complexity? (e.g., $40 for stage 2, $50 for stage 3, $60 for stage 4)	
	Is it appropriate for an arrangement to cover services rendered during or prior to the contract negotiations? Do either the Anti-kickback Statute or the Stark Law require that the services not have already been rendered?	There are concerns that, when contracting to receive payment for these services for the first time, therapists would need to delay measurement/care until an arrangement is made and the garment order initiated to receive payment. For example, we expect that measuring services would take place before the appropriate device is selected and an order is submitted with the DME supplier, during a therapy visit. This means that the therapist is not likely to have a contract with the DME supplier who has the correct garment, meaning that the therapist must either provide services without payment, or delay ordering until contract terms are agreed upon.
	Therapists work with a varying number of DMEPOS suppliers—is the expectation that to get paid consistently, they would have to enter into arrangements with each supplier?	Concerns have been raised on the significant administrative burden this causes with both the therapists and the DMEPOS suppliers.
	How can therapists with ownership interest in the DME contract without implicating the Stark Laws?	Some therapists have ownership in DMEs that they work with.
	Are there simple ways of determining fair market value (FMV)? How can therapists be sure their arrangements are designed with FMV for the services?	If compliance with the AKS/Stark is premised on FMV, therapists would have much better opportunity to contract with DMEs if they have access to resources that help them expediently determine whether the service pricing violates either of these laws.
	Are there geographic considerations in contracting that therapists should be concerned about? For instance, if an area has only two DME suppliers, would a contract with one, but not the other implicate the AKS if the therapist only refers to the DME they're contracted with? Would a permissible contract in one area potentially implicate the AKS in another?	We have been told that many DMEPOS suppliers do not intend to contract with therapists (even though they currently use therapists to perform measuring and fitting services), because the payment for the garment does not include enough reimbursement to pay for the garment and for the therapist's time. DMEPOS suppliers do not want to lose any of the reimbursement from the garment to other entities (such as therapists who are conducting the measuring and fitting for them). We are concerned that this limits which suppliers therapists will be able to refer

		their patients to for garments to only the ones who do agree to contract with the therapist, limiting patient access.
Billing & Coding	Do therapists and DMEPOS suppliers submitting the claims need to be concerned that MACs would rely on/apply a similar standard to the new LCD for pneumatic compression devices and thereby deny payment if the therapists and DMEPOS suppliers have contractual arrangements for measuring, fitting, and training services related to lymphedema compression garments? Will CMS be providing guidance to DME MACs to ensure this does not happen?	Under the new LCD for pneumatic compression devices, licensed/certified medical professionals (LCMPs), including therapists, cannot have a financial relationship with the DMEPOS supplier providing the device. We are concerned that DMEPOS MACs will utilize similar language in developing the LCDs/LCAs for this new benefit which would automatically invalidate being able to contract with the DMEPOS suppliers for measuring and fitting.
	How should therapists modify their current billing practices in response to the new benefit?	Therapists want to make sure that they can still provide services that they've been providing without worrying about claims denials.
	Will therapists be able to bill for time educating their patients on donning/doffing garments after the garment has been delivered by the DMEPOS supplier and the supplier has not provided education or additional education is required?	It is our understanding that in certain situations therapists can bill for education.
	Does the Lymphedema Treatment Act apply to Medicare Advantage plans as well as Traditional Medicare?	It is our understanding that MA plans must offer benefits that are covered under traditional Medicare, but early 2024 most MA plans do not provide coverage for lymphedema compression garments.
	When is it appropriate for a PT to order bandages, assuming the DME is providing the compression garment? Can they be ordered before and after the garment is purchased through the DME?	For clarification around potential double billing issues.
	When can a patient purchase a garment with cash, out-of-pocket? Is it only when the item is non-covered and has a compliant ABN?	For patients who cannot receive garments from a Medicare provider.

Oversight	How is CMS tracking information related to who is providing measuring and fitting services to inform future policymaking under the benefit?	In the final rule, CMS acknowledged the need to track who is performing measuring and fitting for future payment decisions, however, did not outline a mechanism with which to track that information. There are no modifiers, and no documentation requirements outlined that would identify whether the supplier is using outside therapists or internal, on the job trained measurers to do the measuring, fitting, and training. In a poll of almost 1,000 "fitters", it was determined that a therapist conducts the measuring and fitting more than 50% of the time, but the current payment structure only pays the DMEPOS supplier who conducts it less than 50% of the time. Without an ability to track for this data in the next year, how will CMS make determinations on future payment models for this service?
Education	Where can patients find out about their Medicare options for lymphedema garments?	Therapists seek guidance on the best resources to provide patients with to ensure they receive coverage for their garments.
Surgical Dressing Codes	Does CMS plan on creating new HCPCS codes for surgical dressings?	We have heard concerns from physicians who are concerned that certain lymphedema codes were moved from surgical dressing to the lymphedema category. If physicians order these for venous ulcers, they would no longer be able to bill these codes for non-lymphedema diagnoses. These physicians seek clarification on whether the code descriptions should be revised to say, "used as a surgical dressing," and CMS should create new lymphedema codes. We can provide a list of potentially affected codes if needed.