

Example of a patient's recently submitted email

(sections redacted to protect privacy)

August 16, 2023

To Novitas Medical Director Dr. Leslie Stevens:

I was shocked to learn that because of your new coverage policy “Skin Substitute Grafts/Cellular and or Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers” (policy# L35041/ A54117), I am no longer going to be able to continue using the product I am currently being treated with and that has been recommended by my doctor.

I have been under the care of Dr. [REDACTED] for many years at [REDACTED] in Washington, DC. I am currently receiving treatment for a non-healing diabetic foot ulcer and one of the products we are currently using is [REDACTED].

I understand that come September 17th, per your revised policy, I will not be able to continue treatment if I've already received the 4th application at that point in time and will need to disrupt the plan of care developed by me and my healthcare team. This is a drastic change in care plans with little warning to patients and providers.

I have many concerns. I cannot afford to pay for these treatments if Medicare does not cover them. Yet the risk of discontinued or interrupted treatment is amputation and so I am terrified. The current policy which is active until September 16th allowed for up to 9 applications, but now this plan of care for me will be disrupted. What medical studies show that only 4 applications are needed for healing my wound and to avoid an amputation?

I am concerned that policymakers sitting in an office who do not actually treat diabetic foot ulcers are telling my healthcare team that they know better about what treatments are right for me. As I understand it, the new Medicare policy will dictate what products can be used and for how long they can be used regardless of whether these skin substitutes are working for me in my situation and my wound is healing. I do not know how Medicare expects my provider to just switch products or for me to be okay with stopping mid-treatment. You have not even provided sufficient time for me and my provider to become more familiar with your more limited list of covered products so that we can transition my care in the most informed way. If the product that I am being treated with is working, why do we need to stop? It is wrong to move me to another product for which we will not know the potential results. How can you assure that this will be both cost effective and heal my wound?

As a patient facing these care challenges and facing the frightening potential of amputation if my wound healing is not successful, **I ask that you immediately withdraw the implementation of this Local Coverage Determination or at least delay the implementation** so that I (and other patients like me) can continue our current plan of care protocols without interruption. If my wound is not yet healed and I need stop my plan of treatment mid-way, I could potentially require an amputation. I can't imagine this is an outcome that Medicare wants. I most certainly don't!

I should not be faced with this when the treatment protocol established by my care team is working and my diabetic foot ulcer is showing signs of wound healing progression. Should I not be able to continue treatment and have a long-term non-healing wound that necessitates an amputation, data shows that a below knee amputation has up to 50% one-month mortality and up to a 66% mortality at one year. This is a gruesome and cruel fate so that Medicare can save money with this new coverage policy Will someone from Medicare explain this to me and my family? Policies should be about patients, not the pocketbook. Are you going to cover all of the costs associated with my amputation if it is needed? My prosthesis, my crutches, wheelchair or funeral?

This coming disruption to my care is preventable. I urge you to stop or delay implementation of these policies:

- Novitas [LCD \(L35041\)](#) and [LCA \(A54117\)](#)
- FCSO [LCD \(L36377\)](#) and [LCA \(A57680\)](#)
- CGS [LCD \(L36690\)](#) and [LCA \(A56696\)](#)

If you have specific questions about my care plan, please contact me and/or you have my permission to contact my health care provider listed above.

Sincerely,

[NAME/ADDRESS REDACTED]

Washington DC