



Written Testimony
Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition
Patient-Focused Drug Development for Nonhealing Chronic Wounds
FDA-2026-N-5057

October 12, 2026

The Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition appreciates the opportunity to submit this written testimony regarding nonhealing chronic wounds and the critical need to advance prevention, treatment, and management of these complex conditions. The ITEM Coalition urges the Food and Drug Administration (“FDA”) to work closely with the Centers for Medicare and Medicaid Services (“CMS”) to recognize the significant and multifaceted impact that chronic nonhealing wounds have on patients and to support a comprehensive, patient-centered approach to the development and evaluation of treatments and technologies for these conditions.

The ITEM Coalition is a national consumer- and clinician-led coalition comprised of 103 national organizations advocating for access to and coverage of assistive devices, technologies, and related services for people with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including limb loss and limb difference, multiple sclerosis, spinal cord injury, brain injury, stroke, paralysis, cerebral palsy, spina bifida, hearing, speech, and visual impairments, myositis, and other life-altering conditions.

Chronic, nonhealing wounds can have profound and lasting consequences for patients. They are frequently associated with underlying diseases and complex health conditions and can affect virtually every aspect of an individual’s daily life. Patients may experience persistent pain, drainage and odor from the wound site, impaired mobility, sleep disruption, caregiver burden, social isolation, loss of independence, infection, hospitalization, surgery, and amputation as a result of a nonhealing chronic wound. The consequences extend well beyond the physical wound itself.

For this reason, chronic wound management must extend beyond wound closure.

Chronic Wound Care Is About More Than Closing the Wound

Wound closure is critically important and should remain a fundamental measure of treatment success. However, for patients living with chronic wounds, closure is not the endpoint of the patient journey, nor should it be the sole measure by which a treatment’s value is determined. A wound that closes but subsequently reopens leaves a patient with significant pain, impaired mobility, recurrent breakdown, substantial treatment burden, loss of function, and interruption of the healing trajectory, all of which are poor outcomes for patients.

Successful wound healing includes whether the patient can return to living his or her life with less pain, greater independence, and a reduced risk of serious complications. Patients want to know:

- Will I be able to walk, sleep, work, and participate in daily activities?
- Will I be able to manage pain, drainage, and odor?
- Can I avoid infection, hospitalization, surgery, or amputation?
- Can I maintain my independence?
- Can I reduce the amount of assistance I require from family members or caregivers?
- Will my wound remain healed?
- Can I return to the activities and quality of life I had before the wound developed?

These are not secondary considerations. For patients living with chronic wounds, they often define whether treatment has actually improved their lives.

Chronic wounds can cause persistent pain and drainage, interfere with sleep and daily activities, limit mobility, and impose substantial burdens on patients and caregivers. Failure to achieve durable healing can expose patients to recurrence, infection, hospitalization, surgery, and potential amputation, while also contributing to psychological harms such as depression and social isolation. A treatment that improves one aspect of wound healing while leaving these broader consequences unaddressed may therefore provide only a partial solution to the patient's needs.

Durability also matters. A wound that closes temporarily but subsequently breaks down is fundamentally different from a wound that heals and remains healed. Preventing recurrence can be particularly important for patients whose underlying risk factors, such as impaired mobility, pressure, sensory loss, or other chronic conditions, remain present after closure. The goal should be not simply to achieve closure, but to support durable healing and reduce the likelihood of recurrent wounds and intensive treatment.

The ITEM Coalition therefore encourages the FDA to work with CMS to adopt and promote a broader, patient-centered understanding of meaningful treatment success in the development and evaluation of chronic wound therapies. Wound healing and closure should remain critical endpoints, but should be considered alongside durability of healing, symptom improvement, functional recovery, mobility, independence, treatment burden, quality of life, and the prevention of serious complications.

Clinical research should, to the extent possible, capture these outcomes so that FDA, CMS, and other stakeholders can better understand the full clinical value of new therapies and technologies. Patient-reported outcomes and measures of physical functioning should complement traditional clinical measures, while infection, hospitalization, surgery, amputation, and wound recurrence should be considered where appropriate.

Chronic Wound Management Requires Multiple Interventions

Chronic wound care is rarely a matter of a single intervention. Patients with chronic wounds frequently require multiple therapies throughout the course of their care, with different

interventions addressing different aspects of the wound, the underlying condition, and the patient's functional needs. The clinical priorities may also change over time as the wound evolves, the patient responds to treatment, and new complications or barriers to healing emerge.

For example, one intervention may be necessary to prepare the wound bed, while another manages exudate or protects surrounding tissue. A different therapy may be needed to promote granulation or epithelialization, manage pain or other symptoms, prevent infection or other complications, or reduce the mechanical forces contributing to wound development or recurrence. At the same time, mobility, positioning, offloading, and the use of assistive technologies may be necessary to allow the patient to remain functional while minimizing further tissue injury. These interventions may be sequential, concurrent, or repeated over the course of treatment.

The ITEM Coalition stresses to FDA that chronic wound care is an integrated care journey, not a series of separate treatment categories. The need for multiple interventions should not be interpreted as evidence that any one modality is unnecessary or duplicative; rather, it reflects the complexity of chronic wounds and the multiple barriers that can prevent healing.

This distinction is particularly important for patients with complex or nonhealing wounds. A chronic wound may persist because of multiple interacting factors, including impaired circulation, pressure or shear forces at the wound site, impaired sensation, infection, inflammation, inadequate wound-bed preparation, excessive exudate, limited mobility, or other underlying health conditions. Addressing only one of these factors may be insufficient to achieve durable healing. A comprehensive treatment plan must be responsive to the individual patient's clinical circumstances and may require multiple therapies working together over an extended period.

Wound-bed preparation provides an important illustration of why chronic wound treatment should not be viewed through a single-intervention or wound-closure lens. Many patients cannot progress toward healing until nonvisible tissue is removed and the wound environment is appropriately managed. Debridement and other wound-bed preparation strategies may therefore be necessary before, during, or alongside interventions intended to promote healing. Therapies that facilitate or support wound-bed preparation can play an essential role in the overall treatment pathway even though their contribution may not be reflected by the final wound-closure endpoint.

Similarly, an intervention may provide an important clinical benefit without independently producing wound closure. A technology that reduces pressure on vulnerable tissue, manages exudate, protects the periwound area, reduces treatment burden, or allows a patient to remain safely mobile may be essential to creating the conditions in which healing can occur. Likewise, an intervention that reduces the risk of recurrence after closure may provide substantial value even though its primary benefit occurs after the wound has technically healed.

The ITEM Coalition therefore urges FDA to recognize the interdependent and complementary nature of chronic wound therapies when considering the development and evaluation of new treatments and technologies. Clinical research and regulatory decision-making should account for the fact that patients may receive multiple therapies as part of routine care and that the

effectiveness of one intervention may depend, in part, on other components of the patient's treatment plan.

A more complete understanding of chronic wound treatment should ask not simply, "Did this intervention close the wound?" but also, "What role did this intervention play in helping the patient heal, remain healed, avoid complications, maintain function, and return to daily life?"

Medical Devices and Assistive Technologies Are Essential to Chronic Wound Care

Medical devices and assistive technologies play an essential role throughout the continuum of chronic wound prevention, management, healing, and recovery. For many individuals, particularly those with complex medical conditions, mobility impairment, neurological conditions, diabetes, vascular disease, or a history of pressure injuries, these technologies are not simply adjuncts to treatment. They can be fundamental to preventing wounds from developing, protecting vulnerable tissue, managing an existing wound, facilitating healing, preventing recurrence, and preserving mobility and independence.

The range of technologies involved in chronic wound care is broad. Standing systems integrated into power wheelchairs, for instance, provide an important example of how assistive technology can contribute to pressure management and wound prevention and care. For individuals who rely on power wheelchairs for mobility and spend extended periods in a seated position, the ability to transition safely from a seated to a standing position can facilitate weight shifting and redistribution of pressure away from areas that may be particularly vulnerable to pressure injury. This capability can be especially important for individuals who cannot independently stand or reposition themselves and who otherwise may have limited opportunities to relieve pressure during the day. For these patients, a standing system can be an important component of a broader strategy to protect skin integrity, facilitate wound healing, and reduce the risk of recurrent pressure injuries.

The importance of access to these technologies also underscores the need for timely action by CMS on coverage of standing systems in Group 3 power wheelchairs. The ITEM Coalition has long advocated for Medicare coverage of these systems for beneficiaries for whom standing and weight shifting are clinically appropriate. The continued delay in addressing the pending national coverage reconsideration request for standing systems in power wheelchairs—which has been under consideration at CMS for six years—leaves beneficiaries who could benefit from this technology without a clear and consistent path to coverage. As FDA and other stakeholders consider the role of innovative technologies in managing chronic wounds, it is important to recognize that the development of effective technologies alone is not sufficient if patients cannot obtain them. ***The ITEM Coalition therefore urges continued attention to the clinical value of standing systems and calls on FDA to work with CMS to act expeditiously on the pending coverage request so that Medicare beneficiaries can have meaningful access to this potentially important wound-prevention and wound-management technology.***

Similarly, diabetic shoes and other offloading therapeutic footwear and orthotic technologies can play a critical role in preventing and managing diabetic foot wounds, which too often lead to limb amputation. Diabetes can increase the risk of foot ulceration through a combination of factors, including loss of protective sensation and changes in the biomechanics and distribution

of pressure across the foot. Properly designed therapeutic footwear can help accommodate the patient's foot, redistribute pressure away from vulnerable areas, reduce friction and shear, and protect the foot from additional injury. For individuals who have previously experienced a diabetic foot ulcer, these technologies can also be important in reducing the risk of recurrence. Unfortunately, CMS restrictive coverage policy and reimbursement levels under the diabetic shoe and insert benefit limit access to care. Currently, it is estimated that only about one percent of Medicare beneficiaries in need of diabetic shoes and inserts have access to them. In this context, appropriate footwear can be an important component of a comprehensive wound-prevention and wound-management strategy.

Negative pressure wound therapy ("NPWT") provides another example of how medical device innovation can directly support chronic wound management and healing while reducing treatment burden. Medicare recognizes qualifying NPWT equipment under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") benefit for certain chronic wounds, including Stage 3 and 4 pressure ulcers and qualifying neuropathic, venous, arterial, and mixed-etiology ulcers. Innovation in NPWT has produced increasingly portable and patient-centered systems that can deliver active therapy while allowing patients greater mobility and the ability to continue many daily activities.

These technologies can be critical to preventing pressure from interrupting the healing process (e.g., ambulating on an artificial limb while a wound is healing, sitting in a wheelchair while nursing a pressure ulcer on one's buttocks) while also redistributing weight, protecting vulnerable tissue, facilitating appropriate positioning, and enabling safe mobility. Other technologies can support wound assessment, monitoring, and clinical decision-making through imaging, digital wound measurement, tissue assessment, remote monitoring, and other digital health tools.

In practice, a patient may require a pressure-redistribution surface, an offloading device, therapeutic footwear, NPWT, and mobility or positioning equipment at different stages of care. These interventions may be necessary in combination with drugs or biologics and may address distinct barriers to healing or recurrence.

The ITEM Coalition therefore urges FDA to recognize medical devices, assistive technologies, and other wound-care technologies as integral components of the broader chronic wound treatment ecosystem. Regulatory and clinical development approaches should account for the different roles these technologies can play, from prevention and pressure redistribution, to wound-bed management and exudate control, to healing, monitoring, recurrence prevention, mobility, and functional recovery.

Patients should not have to choose between innovative drugs or biologics and innovative devices or technologies. They may need both, and the appropriate combination will depend on the patient's wound, underlying conditions, functional status, environment, and stage of treatment.

The ITEM Coalition encourages FDA to support an innovation environment that allows developers to pursue new approaches across this continuum and evaluates technologies not only by their ability to facilitate wound closure, but also by their ability to prevent recurrence,

reduce complications and treatment burden, preserve mobility and independence, and improve the patient's overall quality of life.

Clinical Research Should Reflect Real-World Chronic Wound Care

The ITEM Coalition encourages FDA and CMS to support clinical research approaches that reflect the realities of treating patients with chronic nonhealing wounds, and the open meeting held in August certainly signals FDA is pursuing this approach. Chronic wounds are complex, dynamic conditions, and the patients who experience them often differ substantially in their underlying health conditions, functional status, wound characteristics, and treatment needs. Clinical research should account for this complexity to the greatest extent scientifically and ethically appropriate.

Patients with chronic wounds frequently have multiple underlying health conditions and may receive several interventions simultaneously. Clinical trials that evaluate an intervention in isolation may therefore provide an incomplete picture of how that intervention will perform when incorporated into actual clinical practice.

Clinical studies should, to the extent scientifically and ethically appropriate, include patients who resemble those who will ultimately receive the therapy in the real world. This includes appropriate consideration of patients with relevant comorbidities, varying degrees of wound severity and chronicity, functional limitations, and other disability-related characteristics that may influence treatment response. While appropriate study populations and eligibility criteria are essential to generating scientifically valid evidence, overly restrictive criteria can limit the applicability of study findings to the patients with the greatest need for new treatment options.

Research should also recognize that chronic wound care is multimodal and longitudinal, rather than a single intervention followed by a simple binary determination of success or failure. Patients may receive different treatments sequentially or concurrently, and the clinical objective may change over time, from protecting vulnerable tissue and preparing the wound bed, to promoting healing and ultimately preventing recurrence and restoring function.

At the same time, clinical trial participation should not impose unnecessary burdens on individuals who are already coping with a highly burdensome condition. Patients with chronic wounds may face pain, impaired mobility, frequent wound-care appointments, transportation challenges, and other physical, psychological, and logistical demands. Requiring excessive visits, duplicative assessments, or unnecessary complex study procedures can make participation difficult or impossible for the patients whose experiences are most important to understanding a therapy's potential benefit.

The ITEM Coalition therefore encourages FDA, CMS, and other stakeholders to pursue pragmatic, patient-centered clinical research approaches that balance scientific rigor with real-world applicability. Clinical trials should generate robust evidence while minimizing unnecessary burdens on participants, incorporate outcomes that matter to patients, and reflect the patients and care environments in which new therapies will ultimately be used.

The ITEM Coalition therefore encourages FDA to use its work in this area to advance a comprehensive, patient-centered framework that recognizes the complexity of chronic wounds, supports innovation across therapeutic modalities, and evaluates success according to the outcomes that matter most to patients. Such an approach will help ensure that advances in chronic wound treatment translate into meaningful and durable improvements in the lives of those living with these challenging conditions.

Thank you for your consideration of these comments. The ITEM Coalition looks forward to continued engagement with FDA and other stakeholders to advance meaningful innovation and improve outcomes for individuals living with chronic nonhealing wounds. Should you have any further questions, please contact the ITEM Coalition Co-Coordination at Peter.Thomas@PowersLaw.com and Michael.Barnett@PowersLaw.com or by calling 202-466-6550.

Sincerely,

The Undersigned Members of the ITEM Coalition

Access Ready, Inc.

ACCSES

All Wheels Up

Alliance of Wound Care Stakeholders

ALS Association*

American Association for Homecare

American Association on Health and Disability

American Congress of Rehabilitation Medicine (ACRM)

American Macular Degeneration Foundation (AMDF)

Amputee Coalition*

Association of Rehabilitation Nurses

Autistic Women & Nonbinary Network

Center on Aging and DIS-Ability Policy

Christopher & Dana Reeve Foundation*

CureLGMD2i

Institute for Matching Person and Technology

International Registry of Rehabilitation Technology Suppliers (iNRRTS)

Lakeshore Foundation

Long Island Center for Independent Living, Inc. (LICIL)

National Association for the Advancement of Orthotics and Prosthetics (NAAOP)

National Clinician Task Force

National Disability Rights Network (NDRN)

NCART

Paralyzed Veterans of America

RESNA

Spina Bifida Association*

Unite 2 Fight Paralysis (U2FP)

United Spinal Association*
VisionServe Alliance

****Indicates ITEM Coalition Steering Committee Member***