**Appeal Denial for SoftWave TRT, LLC ESWT Treatment**

[Date]

[Address to MAC or other payer]

[Contact Name MAC or other Payer]

Regarding: Inquiry XXXX Medicare Beneficiary [Patient name] [number] Request Reconsideration of Payment

Dear [contact name]:

In reference to [appeal case number or ICN ] I am seeking payment for procedure code [insert unlisted code used] denied based on a decision of “investigational or unproven.”

My patient [ ] has been suffering with a non-healing wound for [XX weeks, months, or years]. My patient has underlying conditions of [diabetes, peripheral arterial disease, high blood pressure XX, venous insufficiency extending after treatment, history of chronic wounds, etc.]. After discussing the risks and benefits of ESWT, my patient was treated with [time, energy delivering a total of XX joules]. Evidence has confirmed ESWT treatments consistently induced faster and/or more complete wound healing and lower pain scores than placebo treatments or standard of care treatments. 1 2  My patient has experienced progression to healing evidence by [reduced: slough, exudate, wound size provide change, pain if they do not have peripheral neuropathy, with
an increase in healthy tissue re-epithelialization]. Due to the wound’s [each wound must be commented on separately if individually treated] improvement we plan on a series of treatments [XX times per week, for a total of XX treatments]. Progress notes are updated upon each patient evaluation and treatment. Please note the table included to summarize the progression to healing and treatment provided.



1 Larking, A. M., Duport, S., Clinton, M., Hardy, M., Andrews, K. (2010) Randomized control of extracorporeal shock wave therapy versus placebo for chronic decubitus ulceration. Clin Rehabil 24: 222–229.

2 Snyder, R., Galiano, R., Mayer, P., Rogers, L., C., Alvarez, O., Sanuwave Trial Investigators (2018) Diabetic foot ulcer
treatment with focused shockwave therapy: Two multicenter, prospective, controlled, double-blinded, randomized
Phase III clinical trials. J Wound Care 27: 822–836.



Clinical evidence in the peer reviewed published literature is abundant with clinical evidence of wounds
healing, therefore based on my patient’s signs, symptoms, pain, underlying conditions, and desire to bring
their wound(s) to closure [XX] was used. Clinical evidence in the U.S. and outside of the U.S. substantially confirms the evidence of ESWT benefit and reported positive results, including complete wound closure and reepithelialization, enhanced tissue granulation, reduced necrotic fibrin tissue, improved blood flow perfusion and angiogenesis, resulting a reduced time of closure in less than 12 weeks with less antibiotic use. It is my experience treating these patients to not offer ESWT DermaGold 100 would results in a worse outcome and not providing medically necessary care for this patient’s wound(s). 3

High quality scientific published studies includes 13 RCTs reporting patient monitoring, inclusion criteria, and followed to closure reported ESWT applied once or twice a week using low or medium energy, focused or defocused generator heads (energy range 0.03 to 0.25 mJ/mm2; usually 0.1 mJ/mm2) reported statistically significant differences in rates of wound closure when compared to a variety of standard of care (SOC) topical treatment modalities, sham ESWT treatment (user blinded), and hyperbaric oxygen therapy. My patient’s pain, inability to afford more complex wound treatments requested ESWT as a noninvasive, mostly painless, and safe option with evidence to bring their wound(s) to closure. 4

3 Snyder, R., Galiano, R., Mayer, P., Rogers, L., C., Alvarez, O., Sanuwave Trial Investigators (2018) Diabetic foot ulcer
treatment with focused shockwave therapy: Two multicenter, prospective, controlled, double-blinded, randomized Phase III clinical trials. J Wound Care 27: 822–836

4 Wang CJ. Extracorporeal shockwave therapy in musculoskeletal disorders. J Orthop Surg Res. 2012. doi:
10.1186/1749-799X-7-11.

Closure of the wound(s) is medically necessary and appropriate for [patient name]. My patient desired the most effective treatments to reduce their pain, suffering and inability to perform their activities of daily living (ADL). As clinicians we are required by Medicare policy to control pain limiting the use of opiates, and bring wounds to closure to reduced infection and the incidence of amputation. I used the least painful approach; enabling my patient to resume their ADL.

I am seeking $XXX as appropriate payment for my work and the technical expense of this new technology required to achieve improved wound closure with less pain for the treatment of recalcitrant wounds. Denying payment is unjustified due to my patients’ diagnosis, medical need, and the medical necessity of an accurate outcome which is cost effective to the insurer and importantly to my patient.

Based on the quality of the service provided, the medical necessity, and preponderance of clinical evidence, immediate accurate results, and improved patient outcome compels me to demand payment. As an
interventional radiologist I am providing medical care perfectly aligned with Medicare’s requirement for
reducing pain, reduce cost, enhance quality outcomes, and provide my patient with timely accurate clinical treatments. Payment is warranted.

Sincerely,

[Physician name, Title and Office]