SoftWave

Tissue Regeneration Technologies

REIMBURSEMENT GUIDE

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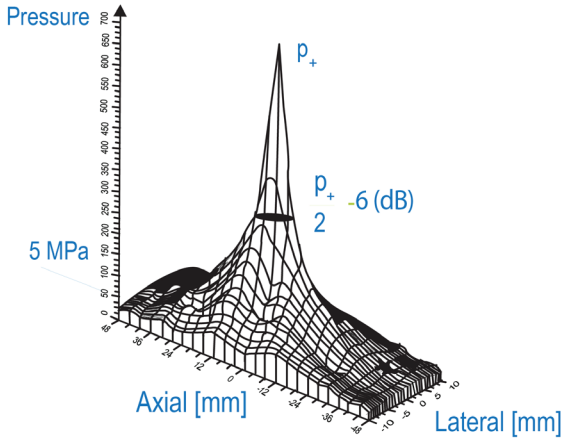

SoftWave
Tissue Regeneration Technologies

SoftWave Tissue Regeneration Technologies, LLC gathers reimbursement information from third-party sources and presents this information for illustrative purposes only. This information does not constitute reimbursement or legal advice and does not guarantee that this information is accurate, complete, without errors, or that use of any of the codes provided will ensure coverage or payment at any particular level. Medicare may implement policies differently in various parts of the country. Physicians and hospitals should confirm with a particular payer or coding authority, such as the American Medical Association or medical specialty society, which codes or combinations of codes are appropriate for a particular procedure or combination of procedures. Reimbursement for a product or procedure can be different depending upon the setting in which the product is used. Coverage and payment policies also change over time and SoftWave Tissue Regeneration Technologies, LLC assumes no obligation to update the information provided herein.

OrthoGold100®/DermaGold100®

FDA Device Class

1. Class I, K182682 Therapeutic massager
2. Class II, K191961 Extracorporeal Shock Wave Device for Treatment of Chronic Wounds
3. Class II, K200926 Extracorporeal Shock Wave Device for Treatment of Chronic Wounds

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Intended Use

1. The OrthoGold 100®/DermaGold 100® is intended for the activation of connective tissue.
2. The OrthoGold 100®/DermaGold 100® is indicated to provide acoustic pressure shock waves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OrthoGold 100®/DermaGold 100® is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.
3. The OrthoGold 100®/DermaGold 100® is indicated to provide acoustic pressure shock waves in the treatment of superficial partial thickness second degree burns in adults (22 years or older). The OrthoGold 100®/DermaGold 100® is indicated for use in conjunction with standard of care burn treatment(s).

SoftWave
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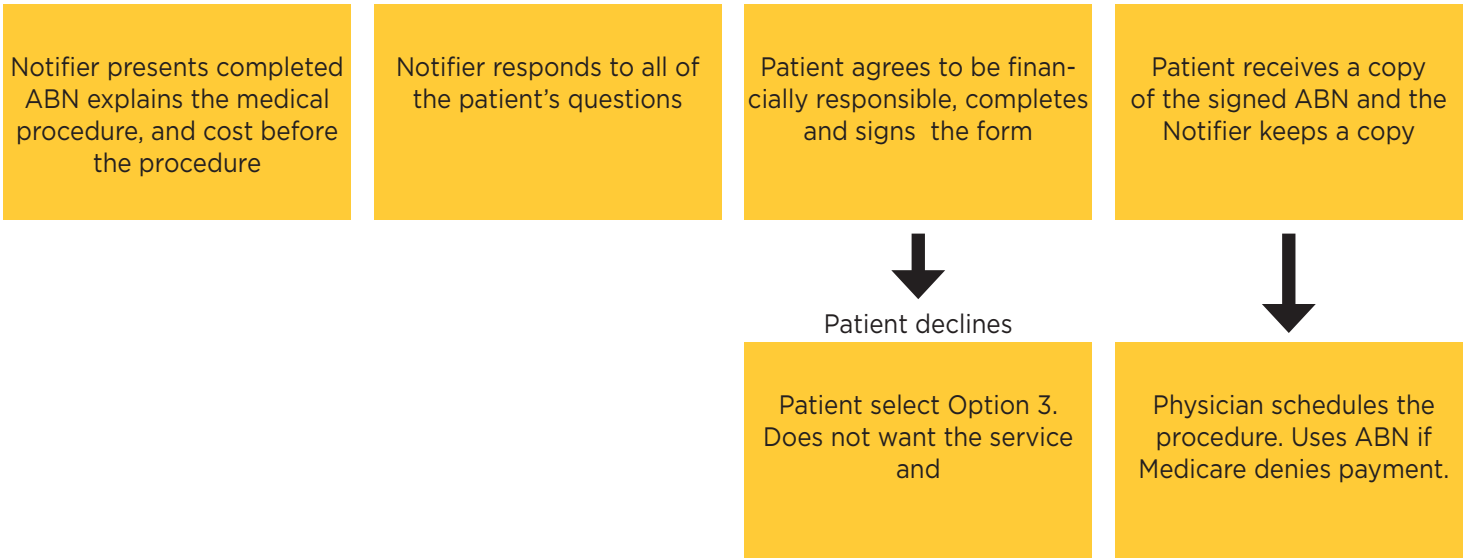
Advanced Beneficiary Notice

A. ABN is for patients meeting medical necessity criteria a malady that may benefit from the Softwave® DermaGold®, OrthoGold 100®, OrthoGold 280®, CardioGold® and UroGold® Therapy.
B. Notifier is the physician, or their qualified assigned staff.
C. Patient, or their assigned representative must be informed of the medical need prior to the procedure Medicare's is believed to deny. (Patient is synonymous with assigned representative).



1. Notifier: Physician or their staff: Answer all of the patient's questions before the patient or their representative completes the form and makes their selection. raised during that review must be answered before it is signed.
2. Notifier: must present the ABN far enough in advance that the beneficiary or representative has time to consider the options and make an informed choice.
3. Notifier: inform the patient of their financial liability, likely cost, and if there is a series of services the likely total cost.
4. Once all blanks are completed and the form is signed, a copy is given to the beneficiary or representative and the notifier retains a copy of the patient's ABN.
5. The ABN may also be used to provide notification of financial liability for items or services that Medicare never covers. When the ABN is used in this way, it is not necessary for the beneficiary to choose an option box or s ign the notice.
6. **Exceptions** ABNs are never required in emergency or urgent care situations.

The Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, is issued by providers physicians, practitioners, and suppliers to Fee for Service Medicare beneficiaries in situations where Medicare **payment is expected to be denied**. The ABN is issued in order to transfer potential financial liability to the Medicare beneficiary in certain instances. Guidelines for issuing the ABN can be found beginning in Section 50 in the **Medicare Claims Processing Manual, 100-4, Chapter 30**.

FAQ Advanced Beneficiary Notice (ABN)

The following information is being provided to aid communication for Softwave® Tissue Regeneration Technologies, LLC (TRT) representatives with healthcare providers or their customers when explaining the use of Advanced Beneficiary Notice (ABN) for their patients. The ABN forms provided are to be used for physician charges or hospital outpatient services not for hospital inpatient admissions.

1. Can SoftWave present an ABN to a healthcare provider customer?
Response: The ABN is a legal billing document intended to be presented to patients by healthcare professionals when informing the patient of a medically necessary procedure and the related costs. As part of shared decision making, the patient is to be informed to aid their decision to give their consent to allow specific clinical solution related to their medical care. The healthcare provider has sole responsibility on the use of this document with their patients. The presentation of the ABN is intended only as a means for the physician or hospital billing personnel or their assignee to inform the patient **in advance of the procedure of the medical necessity, the clinical rationale, the patient's financial responsibility, and it's associated costs**.

It is expected the physician or their assigned healthcare support staff will discuss the medical necessity of the new clinical solution to patients. Cost estimate information will also be shared with the patient. The patient will then respond to the questions by marking one of the box options on the official CMS R-131 ABN form.

Dual eligible patients, those with Medicare and Medicaid coverage must check Box 1. In addition the provider must mark through the language as provided.

❒ **OPTION 1.** I want the (D) listed above, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN.

These edits are required because the provider cannot bill the dual eligible beneficiary when the ABN is furnished. Providers must refrain from billing the beneficiary pending adjudication by both Medicare and Medicaid in light of federal law affecting coverage and billing of dual eligible beneficiaries.

Customers may choose to use an ABN as a fair means of informing their patients that there could be an additional charge over that which their insurance company may not pay. The discussion pertaining to the use of an ABN and use of a new clinical solution should only be between license healthcare providers or their assigned representatives and their patients. SoftWave TRT, LLC **representatives are prohibited to participate in any role in those conversations**.

2. Precisely what role can a SoftWave representative participate regarding use of an ABN with our providers/customers?
Response: There are ways an ABN may be processed-or used for Medicare patients or commercial patients. The directions provided are for Medicare patients, yet may aid with commercial patients. The commercial version provides an example document informing the patient of a medical service or treatment their physician may recommend is medically necessary, but the patient's insurer may not cover for its use. This is a process of informing the patient, yet the SoftWave representative should only advise the medical staff about the document. The SoftWave representative should ***only hand off the document*** to the physician, their staff, or to key members of the hospital responsible for billing or providing informed consent to their patients. SoftWave, LLC representatives are **prohibited** to participate in any direct patient care role of its use.

Providers can present the ABN to their commercial patients. It is recommended they verify the patient's specific payer does not warn against the use of the ABN. Some restrictive Health Maintenance Organization insurance plans do not allow the provider to present an ABN. These tend to be in the minority.

Advanced Beneficiary Notice

3. Can a SoftWave representative refer a customer (healthcare provider) to The Institute for Quality Resource Management (IQRM) if they have further questions regarding use of ABN?
Response: The IQRM does not represent SoftWave Tissue Regeneration Technologies, LLC technologies, nor does it have any invested interest in its technology market use. IQRM's role is to provide healthcare economic-billing guidance and respond to coding and billing questions from healthcare providers. Should SoftWave representatives have any healthcare provider customers who have questions regarding use of ABN, billing, coding, payment perspectives, and pricing based on similar relative value units, you may refer these providers directly to IQRM for assistance. To aid the providers understanding, IQRM will provide appropriate clinical information as needed or coding regulations to aid their understanding in ABN and their appropriate use.

Institute for Quality Resource Management (Phone) (877-997-3360 (leahamir@vantageview.com Email)

4. When presenting an ABN form to customers for use, can SoftWave representatives assist in any discussion(s) concerning ABN pricing?
Response: The only price a SoftWave representative can discuss is with their healthcare provider customers is the pricing schedule negotiated for the SoftWave Tissue Regeneration Technologies, LLC devices or their system disposables. That may include hospital purchasing department, perhaps the physician user, and/or the physician's or hospital financial staff. For example the SoftWave representative can disclose the selling price and the benefits of the system. They can train the physician, or the physician's staff on the use of the device. SoftWave representatives are prohibited to discuss the price of the SoftWave Tissue Regeneration Technologies, LLC device or system disposables directly with patients; even if a patient asks.

If a SoftWave representative is asked by a healthcare provider what are others charging?…". An appropriate response may include you have no evidence of that data. If pressed for information the SoftWave representative may say it would be logical to charge in a manner similar to how your practice or facility would routinely charge for similar procedures having comparable physician work.

Disclaimer Softwave® Tissue Regeneration Technologies, LLC gathers reimbursement information from third-party sources and presents this information for illustrative purposes only. This information does not constitute reimbursement or legal advice and does not guarantee that this information is accurate, complete, without errors, or that use of any of the codes provided will ensure coverage or payment at any particular level. Medicare may implement policies differently in various parts of the country. Physicians and hospitals should confirm with a particular payer or coding authority, such as the American Medical Association or medical specialty society, which codes or combinations of codes are appropriate for a particular procedure or combination of procedures. Reimbursement for a product or procedure can be different depending upon the setting in which the product is used. Coverage and payment policies also change over time and Softwave® Tissue Regeneration Technologies, LLC assumes no obligation to update the information provided herein.

Information to Aid Use of the ABN

Institute for Quality Resource Management

1. Only use the CMS approved ABN version 6/30/2023. This is the ONLY recognized ABN form recognized by CMS.
2. Do not make any changes to the document. Information pertaining to the specific procedure that may result in nonpayment has been provided.
3. Only the physician or their assigned staff can use the ABN to inform the patient and obtain their consent.
4. The intent is for the physician or their assigned staff to inform the patient of the possibility of nonpayment by Medicare. To complete the blank to describe the procedure, I have inserted language of the procedure. The physician or their assigned representative should include the anatomical area(s) and note the diagnosis necessitating the ESWT.
5. The amount to be charged to the patient must be included at the time of informing the patient. I have provided an example amount in field F.
6. IT IS CRITICALLY IMPORTANT THE ABN IS PRESENTED TO THE PATIENT **BEFORE THE PROCEDURE**.
7. If the ABN is provided after the procedure, after denial has been realized by the patient or healthcare provider, the ABN is determined to not have been provided and is in no way relevant for the procedure relative to obtaining reimbursement from the patient or their insurers.

A. Notifier:

B. Patient Name: **C. Identification Number:**

Advance Beneficiary Notice of Non-coverage (ABN)

NOTE: If Medicare doesn't pay for **D.** Extracorporeal shockwave therapy (anatomic site) below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** Targeted exact insertion of needle for organ specific procedures below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost
Extracorporeal shockwave therapy (anatomic site)	Not medically necessary unproven technology and procedure	$250.00

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** Extracorporeal shockwave therapy (anatomic site) listed above.

  Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **D.** Extracorporeal shockwave therapy (anatomic site) listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D.** Extracorporeal shockwave therapy (anatomic site) listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. I cannot appeal if Medicare is not billed.

☐ **OPTION 3.** I don't want the **D.** Extracorporeal shockwave therapy (anatomic site) listed above. I understand with this choice I am **not** responsible for payment, and I cannot appeal to see if Medicare would pay.

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048).

Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:

CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: AltFormatRequest@cms.hhs.gov.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

SoftWave
Tissue Regeneration Technologies

2020 Coding Options

Provided by Institute for Quality Resource Management

CPT Code[1]	Description	Non Facility Physician	Facility Physician	APC [3]/SI	APC Payment	ASC [4]	ASC Payment
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	C	C	5113/J1	$2,830.40	G2	$1,328.25
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle	C	C	5113/J1	$2,830.40	G2	$1,328.25
0512T (2018)	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	C	C	5051/S	$179.55	R2	$90.73
0513T (2018)	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)	C	C	N		N1	
28890 (2006)	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia	$321.02	$221.92	5112/J1	$1,392.35	P3	$191.21
20999 (2017)	For extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy, use 20999) Unlisted procedure, musculoskeletal system, general	C	C	5111/T	$206.19		
50590[1]	Lithotripsy, extracorporeal shock wave	$765.56	$580.27	5374/J1	$3,076.34	G2	$1,395.10
55899[2]	Unlisted procedure, male genital system] [when specified as ESWT (for example for ED or Peyronie's disease)	C	C	5371/T	$266.14		
C	Physician payment is determined by Medicare Administrative Contractor (MAC)						
APC SI	Ambulatory Payment Classification payment status indicator (SI) T- 50% reduction of billed with S, T, JI, J2. S=paid 100% significant procedure. J1=packaged payment when billed with S, T. Complexity adjustments may exist for some code combinations.						
ASC G2	Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.						
ASC P3	Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS non-facility PE RVUs; payment based on MPFS non-facility PE RVUs.						
ASC R2	Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS non-facility PE RVUs; payment based on OPPS relative payment weight.						

[1] 2020 AMA CPT All Rights Reserved.
[2] 2021 Proposed Rule CMS 1734 Addendum B. Physician RVU
[3] 2021 CMS Proposed Rule OPPS Addendum B.
[4] 2021 CMS Proposed Rule ASC Addendum AA

SoftWave
Tissue Regeneration Technologies

2020 Coding Options

Provided by Institute for Quality Resource Management

CPT	Description	SoftWave TRT Products	Evidence for Code Application
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy	OrthoGold 100® OrthoGold 280®	Treatment involving musculoskeletal system with shock waves at greater than 0.20 mJ/mm^2
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle	OrthoGold 100® OrthoGold 280®	Treatment with shock waves at greater than 0.20 mJ/mm^2 involving lateral humeral epicondyle and patient sedation
0512T (2018)	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound	DermaGold 100®	Treatment with shock waves at greater than 0.20 mJ/mm^2 involving integumentary system
0513T (2018)	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)	DermaGold 100®	Treatment with shock waves at greater than 0.20 mJ/mm^2 involving integumentary system
28890 (2006)	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia	OrthoGold 100® OrthoGold 280®	Treatment with shock waves at greater than 0.20 mJ/mm^2 involving plantar fascia and patient sedation
20999 (2017)	For extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy, use 20999) Unlisted procedure, musculoskeletal system, general	OrthoGold 100® OrthoGold 280® CardioGold® UroGold®	Treatment with shock waves at less than 0.10 mJ/mm2 involving cardiac muscle or other part of musculoskeletal system
50590[1]	Lithotripsy, extracorporeal shock wave	LithoGold®	Treatment with shock waves to break up kidney stones
55899[2]	Unlisted procedure, male genital system [when specified as ESWT (for example for ED or Peyronie's disease)]	UroGold®	Treatment with shock waves involving male genital system

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Sample Letter of Medical Necessity

Print on Physician Letterhead

[Date]
[Insurance Company]
[Address]
[City, State, Zip Code]
Re: [Patient Name]
Policy Number: [xxxxxx]
Group Number [xxxxxx]

To Whom It May Concern:

Enclosed for your review are clinical articles documenting the effective use of [SoftWave's DermaGold 100®].

The attached Statement of Medical Necessity and information pertaining to [Patient Name]'s clinical history and diagnosis clearly demonstrate that [SoftWave's DermaGold 100®] is the appropriate treatment of choice.

Please send me written verification of coverage and payment for the procedure noted for [Patient Name] as soon as possible. If you have any questions pertaining to the clinical history or my treatment plan, please call me directly at: [Office Phone Number].

Thank you for your immediate attention to this matter.

Sincerely,
[Physician Name]

Enclosure: Statement of Medical Necessity

CC: Estimate of Professional and Facility Charges Patient Records
[Patient Name]
Medical Record File
[Facility billing contract]

Appeal Denial for SoftWave TRT, LLC ESWT Treatment

Print on Physician Letterhead

[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.

Feature	Wound 1	Change	Wound 1	Change
Date	3/4/2021	3 days	3/7/2021	3 days
Location	LL LT leg calf		LL LT leg calf	
Size	10.5x3.5 cm		8.2 x 2.8 cm	13.79 cm less
Slough	heavy		heavy	moderate
Exudate	heavy		heavy	moderate
Pain	5		5	4
Treatment	Non sharp debridement cleanse, ESWT SoftWave		Cleanse, ESWT SoftWave dressing	Return 3 days, ESWT Tx
TX Plan	Return 3 days SoftWave ESWT			

[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.

Feature	Wound 2	Change	Wound 2	Change
Date				
Location				
Size				
Slough				
Exudate				
Pain				
Treatment				
TX Plan				

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/mm^2; usually 0.1 mJ/mm^2) 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.

Appeal Denial for SoftWave TRT, LLC ESWT Treatment

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]

Prior-Authorization Denial Appeal Sample Letter

Providers, please note: *Despite the filing of a prior-authorization request, certain commercial health plans may still elect not to cover or grant prior-authorization for this procedure without further information and clinical evidence supporting its use. Should prior-authorization be denied, the physician requesting coverage should immediately file a written appeal with the health plan and request reconsideration of the coverage decision. When requesting a prior-authorization appeal it is important to remember that payors may require all elements of a procedure to be prior-authorized per their payor guidelines. To assist you, the following example is offered as a starting point for your prior-authorization denial appeal and reconsideration request.*

[SITE LETTERHEAD]
[DATE]
[NAME OF INSURANCE COMPANY] [ATTN:]
[FAX#:]

Regarding: [PRIMARY CPT CODE:]
[INSURANCE IDENTIFICATION NUMBER]
[REFERENCE #:]
[PRIMARY CPT CODE:]
[PRIMARY DX CODE:]

Dear Utilization Review Manager:

Please accept this letter on behalf of [PATIENT NAME], as an appeal to [INSURANCE COMPANY]'s decision to deny coverage for the recommended [PROCEDURE]. It is my understanding, per [INSURANCE COMPANY]'s denial letter dated [INSERT DENIAL LETTER DATE], that this procedure has been denied because [REASON FOR DENIAL].

I respectfully request that [INSURANCE COMPANY] reconsider its denial and provide authorization for this treatment option. I believe this denial was made in error. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for [SoftWave Treatment]

Description of Procedure: [PHYSICIAN MAY INSERT DETAILED PROCEDURE DESCRIPTION FOR SPECIFIC TECHNOLOGY/ ANATOMY INCLUDING THE USE OF [SoftWave Treatment, CHOOSE ONE BELOW]

SoftWave is a non-invasive, extracorporeal shock wave procedure using patented technology to initiate the body's immune system. It has FDA clearance for the treatment of superficial, partial-thickness, second-degree burns in adults and for the treatment of Diabetic Foot Ulcers (DFU's).

Relevant Clinical Evidence for Procedure Modality: [PHYSICIAN MAY INSERT RELEVANT CLINICAL EVIDENCE FOR SPECIFIC TECHNOLOGY/ANATOMY, CHOOSE FROM OPTIONS ON PAGE BELOW].

Patient's Clinical Need for SoftWave Procedure: [PATIENT NAME] is a [AGE] [GENDER] who presented to me with [DESCRIBE SYMPTOMS WITH SPECIFICITY]. Prior treatments have included [DESCRIBE CONSERVATIVE CARE, USE OF MEDICATIONS, PRIOR TREATMENTS, and PHYSICAL AIDS].

To assist in your reconsideration of this patient's clinical need for the intended procedure, a copy of the relevant clinical notes that support use of [SoftWave] is enclosed to support you with your decision to overturn your initial denial of coverage for these services. It is my sincere hope that [INSURANCE COMPANY] will respond with a positive decision so that [PATIENT NAME] can benefit from the results of this procedure. Should you have further questions or concerns, please do not hesitate to call me at [INSERT PHYSICIAN TELEPHONE NUMBER]. Thank you for your immediate attention and reconsideration.

Sincerely,
[PHYSICIAN NAME], [DEGREE]
[PRACTICE NAME]