Clinical Practice Guideline: **Wound Care**

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GUIDELINES

Wound Debridement

Wound care is defined as the care of wounds that are refractory to healing or have complicated healing cycles either because of the nature of the wound itself or because of complicating metabolic and/or physiological factors. This definition excludes management of acute wounds, the care of wounds that normally heal by primary intention such as clean, incised traumatic wounds, surgical wounds that are closed primarily and other postoperative wound care not separately payable during the surgical global period.

American Specialty Health – Specialty (ASH) would expect that wound care may be medically necessary for the following types of wounds as indicated by appropriate documentation in support of medical necessity:

- Second- and third-degree burn wounds
- Surgical wounds that must be left open to heal by secondary intention
- Infected open wounds induced by trauma or surgery
- Wounds associated with complicating autoimmune, metabolic, vascular or pressure factors
- Open or closed wounds complicated by necrotic tissue and eschar

Documentation to support selective debridement (CPT® Codes 97597 and 97598) must include the following to support medical necessity:

- Clear description of instruments used for debridement (e.g., high-pressure waterjet, scissors, scalpel, forceps)
- Thorough objective assessment of the wound including drainage, color, texture, temperature, vascularity, condition of surrounding tissue, and size of the area to be targeted for debridement
- Description of adjunctive measures to support debridement procedures, if indicated (e.g., management of pressure (e.g., off-loading, padding, appropriate footwear), infection, vascular insufficiency, metabolic disorder, and/or nutritional deficiency)
- Documentation of complexity of skills required by treating practitioner indicated in medical record

Documentation to support non-selective debridement (CPT® 97602) must include the following to support medical necessity:

- Type of technique utilized (i.e., wet-to-moist, enzymatic, abrasion)
- Thorough objective assessment of the wound including drainage, color, texture, temperature, vascularity, condition of surrounding tissue, and size of the area to be targeted for debridement
- Description of adjunctive measures to support debridement procedures, if indicated (i.e., management of pressure (i.e., off-loading, padding, appropriate footwear), infection, vascular insufficiency, metabolic disorder, and/or nutritional deficiency)
- Documentation of complexity of skills required by treating practitioner indicated in medical record

If there is no documented evidence (e.g., objective measurements) of ongoing significant benefit, then the medical record documentation must provide other clear evidence of medical necessity for treatments. Physicians and qualified non-physician practitioners, licensed physical therapists and licensed occupational therapists acting within their scope of practice and licensure may provide debridement services and use the Physical Medicine and Rehabilitation codes including CPT® 97597, 97598 and 97602. Removal of non-tissue integrated fibrin exudates, crusts, biofilms, or other materials from a wound without removal of tissue does not meet the definition of any debridement code and may not be reported as such.

Debridement of the wound(s) when indicated must be performed discriminately and at appropriate intervals. Prolonged, repetitive debridement services require adequate documentation of complicating circumstances that reasonably necessitated additional services. ASH expects that with appropriate care, wound volume or surface dimension should decrease by at least 10 percent per month or wounds will demonstrate margin advancement of no less than 1 mm/week. ASH expects the wound-care treatment plan to be modified in the event that appropriate healing is not achieved.

Medically necessary chronic wound care must be performed in accordance with accepted standards for medical and surgical treatment of wounds. Eventual wound closure with or without grafts, skin replacements or other surgery (such as amputation, wound excision, etc.) should be the goal of most chronic wound care. Isolated wound care, when other adjunctive measures are indicated, is not considered to be medically necessary. With appropriate management, it is expected that, in most cases, a wound will reach a state at which its care should be performed primarily by the patient and/or the patient's caregiver with periodic physician assessment and supervision. Wound care that can be performed by the patient or the patient's caregiver will be considered to be maintenance care and not medically necessary.

ASH considers CPT® code 17250 (Chemical cauterization of granulation tissue (proud flesh, sinus, or fistula)) an integral service as part of a health care provider's medical or surgical care and not separately billable with debridement CPT® codes in the table below.

Evaluation/Re-assessment

Other than an initial evaluation, wound assessment is an integral part of all wound care service codes and, as such, these assessments are not separately billable.

- Initial wound assessments that are medically necessary may be reimbursable as a separately identifiable Evaluation and Management (E/M) service or i.e., physical therapy evaluation CPT® 97161-97163.
- Re-assessments/re-evaluations of a wound (which may be completed with a dressing change) are considered to be a non-covered routine service. An exception would require documentation clearly supporting that there had been a significant improvement, decline, or change in the patient's condition or functional status that was not anticipated in the plan of care and required further evaluation.

CPT® Codes and Descriptions

CPT® Code	CPT® Code Description
97597	Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instructions (s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less
97598	Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session
17250	Chemical cauterization of granulation tissue (i.e. proud flesh)

Wound Care Modalities

A. Whirlpool

- If the patient uses whirlpool for treatment of a wound prior to receiving selective debridement services for the wound during the same visit, then the whirlpool is not separately reimbursable and should not be billed with modifier 59 unless two separate wounds are treated with different modalities.
- If the patient uses whirlpool for treatment of a wound prior to receiving non-selective debridement services for the wound during the same visit, then the whirlpool is separately reimbursable and may be billed with modifier 59.
- Whirlpool can also be completed during the same visit for non-wound care-related purposes. It is appropriate to separately bill CPT® 97022 when the whirlpool is used for other purposes not involving wound care, e.g., facilitation of range of motion activities.

B. Electrical Stimulation Therapy

Care of chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and/or venous stasis ulcers through use of Electrical Stimulation (ES) (electrical current via electrodes placed directly on the skin in close proximity to the ulcer; CPT®/HCPCS codes G0281, 97014, 97032) may be covered as medically necessary when the following criteria are met:

- Patient is a Medicare beneficiary; AND
- Failure to demonstrate measurable signs of healing (e.g., signs of epithelialization and reduction in ulcer size) with a 30-day trial of conventional wound management, including optimization of nutritional status, moist dressings, and debridement. ES would not be medically necessary as an initial treatment modality.

Other considerations:

- If after 30 days of ES therapy no measurable signs of healing (e.g., decrease in wound size/surface or volume, decrease in amount of exudates and decrease in amount of necrotic tissue) are demonstrated, ES should be discontinued.
- ES treatment sessions are not medically necessary beyond one hour. Prolonged treatments using ES do not provide additional benefit.
- ES also must be discontinued when the wound demonstrates a 100 percent epithelialized wound bed.
- ASH considers ES therapy for chronic ulcers unproven when these criteria are not met (e.g., not a Medicare beneficiary).

- Additionally, comprehensive wound treatments must include optimization of nutritional status, debridement to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary care to resolve any infection that may be present. Specific wound care based on type of wound includes frequent repositioning of a member with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers and the use of a compression system for members with venous ulcers.

C. Electromagnetic Therapy

Care of chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and/or venous stasis ulcers through use of Electromagnetic (EM) therapy (pulsed magnetic field to induce current) may be covered as medically necessary when the following criteria are met:

- Patient is a Medicare beneficiary; AND
- Failure to demonstrate measurable signs of healing (e.g., signs of epithelialization and reduction in ulcer size) with a 30-day trial of conventional wound management, including optimization of nutritional status, moist dressings, and debridement. EM would not be medically necessary as an initial treatment modality.

Other considerations:

- If after 30 days of EM therapy no measurable signs of healing (e.g., decrease in wound size/surface or volume, decrease in amount of exudates and decrease in amount of necrotic tissue) are demonstrated, EM should be discontinued.
- EM treatment sessions are not medically necessary beyond one hour. Prolonged treatments using EM do not provide additional benefit.
- EM also must be discontinued when the wound demonstrates a 100 percent epithelialized wound bed.
- ASH considers EM therapy for chronic ulcers unproven when these criteria are not met (e.g., not a Medicare beneficiary).
- Additionally, comprehensive wound treatments must include optimization of nutritional status, debridement to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary care to resolve any infection that may be present. Specific wound care based on type of wound includes frequent repositioning of a member with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers and the use of a compression system for members with venous ulcers.

D. Ultraviolet (UV) Light

ASH considers the treatment of decubitus ulcers with CPT® code 97028 – UV light NOT medically necessary, except in the following circumstance where it may be reasonable and necessary:

- For Medicare beneficiaries requiring the application of a drying heat, such as for the treatment of severe psoriasis where there is limited range of motion.
    - Supportive Documentation Requirements (required at least every 10 visits)
        - Area(s) being treated
        - Objective clinical findings/measurements to support the need for ultraviolet
        - Minimal erythema dosage

E. Low-Frequency, Non-Contact, Non-Thermal Ultrasound

CPT® code 97610 [low frequency, non-contact, non-thermal ultrasound, including topical application(s) when performed, wound assessment, and instruction(s) for ongoing care, per day] describes a system that uses continuous low-frequency ultrasonic energy to produce and propel a mist of liquid and deliver continuous low-frequency ultrasound to the wound bed. This modality is often referred to as 'MIST Therapy.'

Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) may be covered as medically necessary wound therapy for Medicare beneficiaries for any of the following clinical conditions:

- Wounds, burns and ulcers meeting ASH medical necessity criteria for debridement, but which are too painful for sharp or excisional debridement and described in the medical record
- Wounds, burns and ulcers meeting ASH medical necessity criteria for debridement but with documented contraindications to sharp or excisional debridement
- Wounds, burns and ulcers meeting ASH medical necessity criteria for debridement but with documented evidence of no signs of improvement after 30 days of standard wound care

Other considerations:

- Low-frequency, non-contact, non-thermal ultrasound (MIST Therapy) must be provided 2 to 3 times per week to be considered medically necessary
    - The length of individual treatments will vary per wound size

- Observable, documented improvements in the wound(s) should be evident after 6 treatments. Improvements include documented reduction in pain, necrotic tissue, or wound size or improved granulation tissue
    - Continuing treatments are not covered for wounds demonstrating no improvement after 6 treatments
- MIST therapy is considered unproven and not a covered service for non-Medicare patients

F. Ultrasound

ASH considers care of chronic wounds through use of therapeutic Ultrasound; CPT® code 97035) medically necessary based on the following criteria:

- Failure to demonstrate measurable signs of healing (e.g., signs of epithelialization and reduction in ulcer size) with a 30-day trial of conventional wound management, including optimization of nutritional status, moist dressings, and debridement. Ultrasound would not be medically necessary as an initial treatment modality.

G. Low Level Laser Therapy

ASH considers Low Level Laser Therapy unproven for treatment of chronic wounds. There is insufficient evidence to support its use.

Dressing Use and Change

Application of wound dressing continues to be the standard of care for wound treatment; however, the literature is inconclusive as it relates to standardized topical preparations and types of dressings. Documentation must support the use of the type of dressing for bandage. Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 in. greater than the dimensions of the wound. For example, a 5 cm x 5 cm (2 in. x 2 in.) wound requires a 4 in. x 4 in. pad size.

The quantity and type of dressings dispensed at any one time must consider the status of the wound(s), the likelihood of change, and the recent use of dressings. Dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds. Suppliers are also expected to have a mechanism for determining the quantity of dressings that the patient is using and to adjust their provision of dressings accordingly. No more than a one month's supply of dressings may be provided at one time unless there is documentation to support the necessity of greater quantities in the home setting in an individual case. An even smaller quantity may be appropriate in the situations described above.

Surgical dressings must be tailored to the specific needs of an individual patient. When surgical dressings are provided in kits, only those components of the kit that meet the definition of a surgical dressing, that are ordered by the physician, and that are medically

necessary are covered. Most compression bandages are reusable. Usual frequency of replacement would be no more than one per week unless they are part of a multi-layer compression bandage system.

Multi-layered, sustained, graduated, high compression bandage systems are used primarily to treat lymphedema and venous or stasis leg ulcers. Several graduated, high-compression bandage systems products have been developed, including Profore®, Dyna-Flex®, Surepress®, Setopress®, and other similar product systems.

HCPCS/ CPT® Code	HCPCS/ CPT® Code Description
A6448	Light compression bandage, elastic, knitted/woven, width less than 3 inches, per yard
A6449	Light compression bandage, elastic, knitted/woven, width greater than or equal to 3 inches and less than 5 inches, per yard
A6450	Light compression bandage, elastic, knitted/woven, width greater than or equal to 5 inches, per yard
29581	Application of multi-layer compression system; leg (below knee), including ankle and foot

A dressing change may not be billed as either a debridement or other wound care service under any circumstance (e.g., CPT® 97597, 97598, 97602).

- Medicare does not separately reimburse for dressing changes or patient/caregiver training in the care of the wound. These services are reimbursed as part of a billable E/M or procedure code that, commonly but not necessarily, occurs on the same date of service as the dressing change. If not included in another service, the costs associated with dressing changes may be reported as not separately payable.
- All topical applications (e.g., medications, ointments, and dressings) are included in the payment for the procedure codes.

Surgical Debridement

Debridement, Subcutaneous Tissue, Muscle and/or Fascia

ASH considers services consisting of CPT® Codes 11042, 11043, 11045, and 11046 to be medically necessary for the debridement of muscle and/or subcutaneous tissue upon meeting **ALL of** the following criteria (1, 2, and 3) below:

1. Conditions that may require debridement include at least one of the following:

ICD-10 Code	ICD-10 Code Description
I70.232, I70.242	Atherosclerosis of native arteries of leg with ulceration of calf
I70.233, I70.243	Atherosclerosis of native arteries of leg with ulceration of ankle
I70.234, I70.244	Atherosclerosis of native arteries of leg with ulceration of heel and midfoot
I70.235, I70.245	Atherosclerosis of native arteries of leg with ulceration of other part of foot
I70.238 - I70.239, I70.248 - I70.249	Atherosclerosis of native arteries of leg with ulceration of other part of lower leg or unspecified site
I70.25	Atherosclerosis of native arteries of other extremities with ulceration
I70.332, I70.342, I70.432, I70.442, I70.532, I70.542, I70.632, I70.642, I70.732, I70.742	Atherosclerosis of bypass graft(s) of the leg with ulceration of calf
I70.333, I70.343, I70.433, I70.443, I70.533, I70.543, I70.633, I70.643, I70.733, I70.743	Atherosclerosis of bypass graft(s) of the leg with ulceration of ankle
I70.334, I70.344, I70.434, I70.444, I70.534, I70.544, I70.634, I70.644, I70.734, I70.744	Atherosclerosis of bypass graft(s) of the leg with ulceration of heel and midfoot
I70.335, I70.345, I70.435, I70.445, I70.535, I70.545, I70.635, I70.645, I70.735, I70.745	Atherosclerosis of bypass graft(s) of the leg with ulceration of other part of foot

ICD-10 Code	ICD-10 Code Description
I70.338 - I70.339, I70.348 - I70.349, I70.438 - I70.439, I70.448 - I70.449, I70.538 - I70.539, I70.548 - I70.549, I70.638 - I70.639, I70.648 - I70.649, I70.738 - I70.739, I70.748 - I70.749	Atherosclerosis of bypass graft(s) of the leg with ulceration of other part of lower leg or unspecified site
I70.35, I70.45, I70.55, I70.65, I70.75	Atherosclerosis of bypass graft(s) of other extremity with ulceration
L02.415 - L02.419, L03.115 - L03.119, L03.125 - L03.129	Cutaneous abscess, cellulitis, and acute lymphangitis of lower and unspecified part of limb
L02.611 - L02.619	Cutaneous abscess of foot
L08.81, L08.89	Pyoderma vegetans - Other specified local infections of the skin and subcutaneous tissue
L08.9	Local infection of the skin and subcutaneous tissue, unspecified
L89.200, L89.210, L89.220, L89.300, L89.310, L89.320, L89.500, L89.510, L89.520, L89.600, L89.610, L89.620, L89.890, L89.95	Pressure ulcer of hip, buttock, ankle, heel, other site, and unspecified site; unstageable
L89.204, L89.214, L89.224, L89.304, L89.314, L89.324, L89.504, L89.514, L89.524, L89.604, L89.614, L89.624, L89.894, L89.94	Pressure ulcer of hip, buttock, ankle, heel, other site, and unspecified site; stage 4

ICD-10 Code	ICD-10 Code Description
L89.209, L89.219, L89.229, L89.309, L89.319, L89.329, L89.509, L89.519, L89.529, L89.609, L89.619, L89.629, L89.899, L89.90	Pressure ulcer of hip, buttock, ankle, heel, other site, and unspecified site; unspecified stage
L89.500 - L89.529	Pressure ulcer of ankle
L89.600 - L89.629	Pressure ulcer of heel
L89.890 - L89.899	Pressure ulcer of other site
L89.90 - L89.95	Pressure ulcer of unspecified site
L97.201 - L97.229	Non-pressure chronic ulcer of calf
L97.301 - L97.329	Non-pressure chronic ulcer of ankle
L97.401 - L97.429	Non-pressure chronic ulcer of heel and midfoot
L97.501 - L97.529	Non-pressure chronic ulcer of other part of foot
L97.801 - L97.829	Non-pressure chronic ulcer of other part of lower leg
L97.901 - L97.929	Non-pressure chronic ulcer of unspecified part of lower leg
L98.411 - L98.419	Non-pressure chronic ulcer of buttock
L98.491 - L98.499	Non-pressure chronic ulcer of skin of other sites
M72.6	Necrotizing fasciitis

2. All significant relevant comorbid conditions are addressed that could interfere with optimal wound healing.
3. If there is no necrotic, devitalized, fibrotic, or other tissue or foreign matter present that would interfere with wound healing, the debridement service is not medically necessary. The presence or absence of such tissue or foreign matter must be documented in the medical record.

The number of debridement services required is variable and depends on numerous intrinsic and extrinsic factors. Debridement of the wound(s) when indicated must be performed discriminately and at appropriate intervals. ASH expects fewer than 5 debridement sessions involving removal of muscle to be required for management of most

wounds. Prolonged, repetitive debridement services require adequate documentation of complicating circumstances that reasonably necessitated additional services.

Local infiltration, metacarpal/digital block or topical anesthesia are included in the reimbursement for debridement services and are not separately payable. Anesthesia administered by or incident to the provider performing the debridement procedure is not separately payable.

Exclusion criteria: CPT® codes 11042, 11043, 11045, and 11046 are **NOT** appropriate for the following conditions:

- Skin breakdown under a dorsal corn is not considered an ulcer and generally does not require debridement. These lesions typically heal without significant surgical intervention beyond removal of the corn and shoe modification.
- Removing a collar of callus (hyperkeratotic tissue) around an ulcer is not debridement of skin or necrotic tissue.

It is expected that, with appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should decrease over time. It is also expected the wound care treatment plan is modified in the event that appropriate healing is not achieved. It is expected that co-morbid conditions that may interfere with normal wound healing have been addressed; the etiology of the wound has been determined and addressed as well as addressing patient compliance issues. This may include, for example, evaluation of pulses, ABI and/or possible consultation with a vascular surgeon.

Debridement, Bone

ASH considers services consisting of CPT® Codes 11044 and 11047 to be medically necessary for the debridement of bone upon meeting **ALL of** the following criteria (1, 2, and 3) below:

1. Conditions that may require debridement include at least one of the following:

ICD-10 Code	ICD-10 Code Description
A18.03	Tuberculosis of other bones
M86.00, M86.10, M86.20	Acute hematogenous, other acute, and subacute osteomyelitis; unspecified site
M86.061 - M86.069, M86.161 - M86.169, M86.261 - M86.269	Acute hematogenous, other acute, and subacute osteomyelitis; tibia and fibula
M86.071 - M86.079, M86.171 - M86.179, M86.271 - M86.279	Acute hematogenous, other acute, and subacute osteomyelitis; ankle and foot

ICD-10 Code	ICD-10 Code Description
M86.08, M86.18, M86.28	Acute hematogenous, other acute, and subacute osteomyelitis; other site
M86.09, M86.19, M86.29	Acute hematogenous, other acute, and subacute osteomyelitis; multiple sites
M86.30, M86.40, M86.50, M86.60	Chronic multifocal, with draining sinus, other chronic hematogenous, and other chronic osteomyelitis; unspecified site
M86.361 - M86.369, M86.461 - M86.469, M86.561 - M86.569, M86.661 - M86.669	Chronic multifocal, with draining sinus, other chronic hematogenous, and other chronic osteomyelitis; tibia and fibula
M86.371 - M86.379, M86.471 - M86.479, M86.571 - M86.579, M86.671 - M86.679,	Chronic multifocal, with draining sinus, other chronic hematogenous, and other chronic osteomyelitis; ankle and foot
M86.38, M86.48, M86.58, M86.68	Chronic multifocal, with draining sinus, other chronic hematogenous, and other chronic osteomyelitis; other site
M86.39, M86.49, M86.59, M86.69	Chronic multifocal, with draining sinus, other chronic hematogenous, and other chronic osteomyelitis; multiple sites
M86.8X0, M86.8X6, M86.8X7, M86.8X8, M86.8X9	Other osteomyelitis; unspecified sites, lower leg, ankle and foot, other site, and multiple sites
M86.9	Osteomyelitis, unspecified
M90.861 - M90.869	Osteopathy in diseases classified elsewhere, lower leg
M90.871 - M90.879	Osteopathy in diseases classified elsewhere, ankle and foot
M90.88	Osteopathy in diseases classified elsewhere, other site
M90.89	Osteopathy in diseases classified elsewhere, multiple sites

2. All significant relevant comorbid conditions are addressed that could interfere with optimal wound healing.
3. If there is no necrotic, devitalized, fibrotic, or other tissue or foreign matter present that would interfere with wound healing, the debridement service is not medically necessary. The presence or absence of such tissue or foreign matter must be documented in the medical record.

The number of debridement services required is variable and depends on numerous intrinsic and extrinsic factors. Debridement of the wound(s) when indicated must be performed discriminately and at appropriate intervals. ASH expects fewer than five debridement sessions involving removal of bone to be required for management of most wounds. Prolonged, repetitive debridement services require adequate documentation of complicating circumstances that reasonably necessitated additional services.

Local infiltration, metacarpal/digital block or topical anesthesia are included in the reimbursement for debridement services and are not separately payable. Anesthesia administered by or incident to the provider performing the debridement procedure is not separately payable.

Exclusion criteria: CPT® codes 11044 and 11047 are **NOT** appropriate for the following conditions:

- Skin breakdown under a dorsal corn is not considered an ulcer and generally does not require debridement. These lesions typically heal without significant surgical intervention beyond removal of the corn and shoe modification.
- Removing a collar of callus (hyperkeratotic tissue) around an ulcer is not debridement of skin or necrotic tissue.

Debridement for osteomyelitis is covered for chronic osteomyelitis and osteomyelitis associated with an open wound. It is expected that, with appropriate care, and no extenuating medical or surgical complications or setbacks, wound volume or surface dimension should decrease over time. It is also expected the wound care treatment plan is modified in the event that appropriate healing is not achieved. It is expected that the etiology of the wound has been determined and addressed as well as addressing patient compliance issues. This may include, for example, evaluation of pulses, ABI and/or possible consultation with a vascular surgeon.

ASH considers CPT® code 17250 (Chemical cauterization of granulation tissue (proud flesh, sinus, or fistula)) an integral service as part of a health care provider's medical or surgical care and not separately billable with surgical debridement CPT® codes listed in the table below.

CPT® Codes and Descriptions

CPT® Code	**CPT® Code** Description
11042	Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less

CPT® Code	**CPT® Code** Description
11043	Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); first 20 sq cm or less
11044	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less
11045	Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)
11046	Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)
11047	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)
17250	Chemical cauterization of granulation tissue (i.e. proud flesh)

Powered Negative Pressure Wound Therapy / Vacuum-Assisted Closure

ASH considers powered negative pressure wound therapy (NPWT)/vacuum-assisted closure (VAC) CPT® code 97605, 97606) (HCPCS code A6550, E2402) medically necessary upon meeting **ALL of** the criteria (1, 2, 3, and 4) below:

1. Individual is 12.0 years of age or older; and
2. A complete wound care program, which meets **ALL of** the requirements below, has been tried:
    - Documentation in the individual's medical record of evaluation, care, and wound measurements by a licensed medical professional; and
    - Application of dressings to maintain a moist environment; and
    - Debridement of necrotic tissue if present; and
    - Evaluation of and provision for adequate nutritional status; and
    - Underlying medical conditions (e.g., diabetes, venous insufficiency) are being appropriately managed; and

3. An eligible condition is documented (individual must meet **one or more** of the following):
    a. Stage III or IV pressure ulcers (see key terms below) at initiation of vacuum assisted wound therapy, in individuals who meet **ALL of** the following:
        i. The individual has been appropriately turned and positioned; and
        ii. The individual has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (no special support surface is required for ulcers not located on the trunk or pelvis); and
        iii. The individual's moisture and incontinence have been appropriately managed; or
    b. Neuropathic ulcers in individuals who meet **BOTH** of the following:
        i. The individual has been on a comprehensive diabetic management program; and
        ii. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; or
    c. Ulcers related to venous or arterial insufficiency, in individuals who meet **ALL of** the following:
        i. Compression bandages and/or garments have been consistently applied; and
        ii. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities; and
        iii. For initiation of therapy in the home setting, presence of the ulcer for at least 30 days; or
    d. Dehisced wounds or wound with exposed hardware or bone; or
    e. Post sternotomy wound infection or mediastinitis; or
    f. Complications of a surgically created wound where accelerated granulation therapy is necessary and cannot be achieved by other available topical wound treatment.
4. The wound to be treated is free from **ALL of** the following absolute contraindications to vacuum assisted wound therapy:
    a. Exposed anastomotic site; or
    b. Exposed nerves; or
    c. Exposed organs; or
    d. Exposed vasculature; or
    e. Malignancy in the wound; or
    f. Necrotic tissue with eschar present; or
    g. Non-enteric and unexplored fistulas; or
    h. Untreated osteomyelitis.

Continued use of electrically powered vacuum assisted wound therapy is considered medically necessary when:

- Weekly assessment of the wound's dimensions and characteristics by a licensed health care professional is documented; and
- Progressive wound healing is demonstrated.

Continued use of electrically powered vacuum assisted wound therapy is considered not medically necessary when the continuation of treatment criteria above have not been met.

NPWT is considered NOT medically necessary for one or more of the following situations:

- An appropriate health care provider is not supervising or performing weekly wound measurement and assessment functions and documentation, as well as the dressing changes required.
- Wound healing has occurred to the extent that NPWT is no longer needed.
- The depth of the wound is less than 1 mm, as wounds of this depth cannot accommodate the sponge.
- Uniform granulation tissue has been obtained.
- The individual cannot tolerate the use of NPWT.
- The wound is infected.
- There is no progression of healing of the wound on two successive dressing changes and/or up to 30 days.

Unproven and Not Medically Necessary:

- Electrically powered vacuum assisted wound therapy is considered unproven and not medically necessary for all other applications not meeting the medical necessity criteria above, including when any absolute contraindications to vacuum assisted wound therapy are present.
- Non-electrically powered vacuum assisted wound therapy (for example, the SNaP™ Wound Care Device) is considered investigational and not medically necessary for all conditions.
- Portable, battery powered, single use (disposable) vacuum assisted wound therapy devices (for example, the PICO™ Single Use Negative Pressure Wound Therapy System or the V.A.C. Via™ Negative Pressure Wound Therapy System) are considered investigational and not medically necessary for all conditions.

CPT®/HCPCS Codes and Descriptions

CPT®/HCPCS Code	CPT® Code Description
97605	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME) including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97606	Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing durable medical equipment (DME) including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories
E2402	Negative pressure wound therapy electrical pump, stationary or portable

Hyperbaric Oxygen (HBO)

ASH considers hyperbaric oxygen therapy medically necessary for the treatment of diabetic wounds of the lower extremities in patients who meet **ALL of** the following criteria:

1. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
2. Patient has a wound classified as Wagner grade III or higher; and
3. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 –days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes assessment of a patient's vascular status and correction of any vascular problems in the affected limb, if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Systemic Hyperbaric Oxygen Therapy (HBOT):	
CPT® codes covered if selection criteria are met:	
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session
HCPCS codes covered if selection criteria are met:	
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval
ICD-10 codes covered if selection criteria are met	
E08.51 - E08.59, E09.51 - E09.59	Diabetes mellitus due to underlying condition with peripheral circulatory disorders
E08.618 - E08.69, E09.618 - E09.69	Diabetes mellitus due to underlying conditions with other specified manifestations
E11.51 - E11.59, E13.51 - E13.59	Diabetes with peripheral circulatory disorders
E11.618 - E11.69, E13.618 - E13.69	Diabetes with other specified manifestations
I83.201 - I83.229	Varicose veins of lower extremities with ulcer and inflammation

Skin Substitutes and Soft Tissue Grafts

ASH considers Skin Substitutes and Soft Tissue Grafts for wound care medically necessary according to the criteria **indicated below**:

Application of a skin substitute graft/Cellular and Tissue-based Products (CTP) in the treatment of diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) is considered reasonable and necessary if the patient meets all criteria as outlined here:

1. The presence of a chronic, non-infected DFU having failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment* for a minimum of 4 weeks with documented compliance.
2. The presence of a chronic, non-infected VLU having failed to respond to documented SOC treatment* for a minimum of 4 weeks with documented compliance.
3. An implemented treatment plan to be continued throughout the course of treatment demonstrating all the following:
    - Debridement as appropriate to a clean granular base.
    - Documented evidence of offloading for DFUs.
    - Documented evidence of sustained compression dressings for VLUs.
    - Infection control with removal of foreign body or focus of infection.
    - Management of exudate with maintenance of a moist environment.

- Documentation of smoking history, and counselling on the effect of smoking on wound healing. Treatment for smoking cessation and outcome of counselling (if applicable).

4. The skin substitute graft/CTP is applied to an ulcer that has failed to heal or has stalled in response to documented SOC treatment*. Documentation of response to treatment requires measurements of the initial ulcer, pre-SOC ulcer measurements, weekly SOC ulcer measurements, post-completion SOC ulcer measurements following (at least) 4 weeks of SOC treatment, ulcer measurements at initial placement of the skin substitute graft/CTP, and before each subsequent placement of the skin substitute graft/CTP. Failure to heal or stalled response despite standard of care measures must have preceded the application for a minimum of 4 weeks and established SOC treatment must continue for the course of therapy. Continuous compression therapy for VLUs must be documented for the episode of care.
5. The medical record documentation must include the interventions having failed during prior ulcer evaluation and management. The record must include an updated medication history, review of pertinent medical problems diagnosed since the previous ulcer evaluation, and explanation of the planned skin replacement with choice of skin substitute graft/CTP. The procedure risks and complications must also be reviewed and documented.
6. The patient is under the care of a qualified provider for the treatment of the systemic disease process(es) etiologic for the condition (e.g., venous insufficiency, diabetes, neuropathy) and documented in the medical record.

*SOC treatment includes:

- Comprehensive patient assessment (e.g., history, exam, vascular assessment) and diagnostic tests as indicated as part of the implemented treatment plan.
- For patients with a DFU: assessment of type 1 or type 2 diabetes and management history with attention to certain co-morbidities (e.g., vascular disease, neuropathy, osteomyelitis), review of current blood glucose levels/hemoglobin A1c (HbA1c), diet and nutritional status, activity level, physical exam that includes assessment of skin, ulcer, and vascular perfusion, and assessment of off-loading devices or use of appropriate footwear.
- For patients with a VLU: assessment of clinical history (that includes prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies, and physical inactivity), physical exam (e.g., edema, skin changes and vascular competence), evaluation of venous reflux, perforator incompetence, and venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing is an essential component of SOC for venous stasis ulcers.

Coverage requirements for skin substitute grafts/CTPs

To qualify as a skin substitute graft/CTP the product **MUST** be:

1. A non-autologous human cellular or tissue product (e.g., dermal or epidermal, cellular and acellular, homograft or allograft), **OR** non-human cellular and tissue product (i.e., xenograft), **OR** biological product (synthetic or xenogeneic) applied as a sheet, allowing scaffold for skin growth, intended to remain on the recipient and grow in place or allow recipient's cells to grow into the implanted graft material **AND**
2. Supported by high-certainty evidence to demonstrate the product's safety, effectiveness, and positive clinical outcomes in the function as a graft for DFUs and/or VLUs. Substantial equivalence to predicate products does not allow sufficient evidence to support similar cleared products.

Note: Liquid or gel preparations are not considered grafts. Their fluidity does not allow graft placement and stabilization of the product on the wound.

<u>The following are considered reasonable and necessary (per episode of care):</u>

1. The maximum number of applications of a skin substitute graft/CTP within the episode of skin replacement therapy (defined as 12 to 16 weeks from the first application of a skin substitute graft/CTP) is 8 applications. The mean number of skin substitute graft/CTP applications associated with wound healing is 4; however, with documentation of progression of wound closure under the current treatment plan and medical necessity for additional applications, up to 8 applications may be allowed. Use of greater than 4 applications requires an attestation from the provider showing that requirements specified here have been met and the additional applications are medically necessary. In absence of this attestation, denial of the additional applications will occur.
2. The usual episode of care for skin substitute grafts/CTP is 12 weeks; however, some wounds may take longer to heal therefore 16 weeks is allotted with documentation that includes progression of wound closure under current treatment plan.
3. The skin substitute graft/CTP must be used in an efficient manner utilizing the most appropriate size product available at the time of treatment.
    - Excessive wastage (discarded amount) should be avoided by utilization of size appropriate packaging of the product consistent with the wound size. The graft must be applied in a single layer without overlay of product or adjacent skin in compliance with the correct label application techniques for the skin substitute graft/CTP.
4. Only skin substitute grafts/CTP with labeled indications for use over exposed muscle, tendon, or bone will be considered reasonable and necessary for those indications.

Limitations

The following are considered **NOT** reasonable and necessary:

1. Greater than 8 applications of a skin substitute graft/CTP within an episode of care (up to 16 weeks).
2. Repeat applications of skin substitute grafts/CTP when a previous application was unsuccessful. Unsuccessful treatment is defined as an increase in size or depth of an ulcer, no measurable change from baseline, and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closure).
3. Application of skin substitute grafts/CTP in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., active infection, progressive necrosis, active Charcot arthropathy of the ulcer extremity, active vasculitis, or ischemia).
4. Use of surgical preparation services (e.g., debridement), with routine, simple, or repeat skin replacement surgery with a skin substitute graft/CTP.
5. All liquid or gel skin substitute products/CTP for ulcer care.
6. Placement of skin substitute grafts/CTP on an infected, ischemic, or necrotic wound bed.

For more information on applicable codes for specific skin substitute products/CTP please refer to Local Coverage Determination (LCD): Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (L35041).

Surgical Preparation and Skin Replacement (CPT® codes 15002 – 15005)

1. Per the definitions and the guidelines in CPT® Code Book codes CPT® codes 15002/15005 are not appropriate codes to use when performing a non-surgical application of a skin substitute.
2. CPT® codes 15002/15005 are only appropriately used in place of service inpatient hospital, outpatient hospital or ambulatory surgical center with regional or general anesthesia to resurface an area damaged by burns, traumatic injury, or surgery. An operative report is required and must be available upon request.

CPT® codes 15002-15005 are to be used for the initial traumatic wound preparation (removal of appreciable nonviable tissue) and cleaning to provide a viable wound surface (primary intention healing) for placement of an autograft, flap, skin substitute graft or for negative pressure wound therapy. Primary intention presumes that the performance of the skin preparation and the application of the autograft, flap, skin substitute graft or for negative pressure wound therapy is to heal the wound.

CPT® codes 15002-15005 are NOT to be used for the removal of nonviable tissue/debris in chronic wounds left to heal by secondary intention. CPT® 11042-11047 and CPT® 97597-97598 are to be used for this.

CPT® codes 15002-15005 are selected based on the anatomic area and size of the prepared/debrided defect. For multiple wounds, the choice of code is based on the aggregate sum of the surface area of all similarly grouped wound types.

Codes 15002 - 15005 should NOT be reported for the removal of nonviable tissue/debris in a chronic wound (e.g., venous, or diabetic) when the wound is left to heal by secondary intention. Regarding CPT® codes 15002-15005:

- Use when preparing a proper wound surface for the placement of a graft, flap, skin replacement, skin substitute, or negative pressure therapy.
- Appreciable nonviable tissue is always removed.
- A clean wound bed may be created by incisional release of a scar contracture, resulting in a surface defect from separation of tissue.
- The purpose of these codes is to prepare the wound to heal by primary intention or negative pressure wound therapy.
- The patient's condition may require that final closure may be delayed.

Use CPT® codes 15271 - 15278 for the surgical preparation or creation of recipient site for the tissue skin graft. Regarding CPT® codes 15271-15278:

- Wound prep codes are separate from skin substitute graft application codes.
- The ankle is considered 'leg' in terms of skin substitute graft application.
- Wound areas that skin substitute grafts will be applied are measured AFTER prep/debridement.
- Bill either the 'small' leg/ankle skin substitute graft codes or the 'large' skin substitute graft codes (see description below).
- Bill either the 'small' foot/toe skin substitute graft codes or the 'large' skin substitute graft codes (see description below).
- It is acceptable to bill both the leg/ankle and the foot/toe skin substitute graft application codes if you are treating both the leg/ankle and the foot/toe.
- Do not discount an 'add-on code'; do not apply a '-51' modifier.

'Small Wounds' - for wounds known to have an aggregate wound size up to a maximum of 100 cm^2. The codes represent the first 25 cm^2 or 1% of body area in infants and children, and additional 25 cm^2 or 1% of body area in infants and children, up to that maximum 100 cm^2 wound area.

'Large Wounds' - for wounds known to have an aggregate wound size beginning at 100 cm^2 or greater. The 'small wound' codes would not be used in these cases; instead, surgeons would use the 'large wound' codes which begin with a wound area of 100 cm^2 or greater. "Large wound" codes refer to: 1) the initial 100 cm^2 or 1% of body area in infants and children, and 2) each additional 100 cm^2 or 1% of body area in infants and children.

CPT® Codes and Descriptions

CPT® Code	CPT® Code Description
15002	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; first 100 sq cm or 1% of body area of infants and children
15003	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, trunk, arms, legs; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15004	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; first 100 sq cm or 1% of body area of infants and children
15005	Surgical preparation or creation of recipient site by excision of open wounds, burn eschar, or scar (including subcutaneous tissues), or incisional release of scar contracture, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet and/or multiple digits; each additional 100 sq cm, or part thereof, or each additional 1% of body area of infants and children (List separately in addition to code for primary procedure)
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less of wound surface area

CPT® Code	CPT® Code Description
15272	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	Application of skin substitute graft to trunk, arms, legs, total wound surface greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

For preparation of wounds on the trunk, arms, and/or legs, report 15002 for the first 100 sq cm of site prep. For additional preparation (beyond 100 sq cm) in the same anatomic areas, report add-on 15003. Because 15003 is an add-on code, report it only in addition to 15002.

Likewise, for preparation of wounds of the face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, report 15004 for the first 100 sq cm of site prep. For additional preparation (beyond 100 sq cm) in the same anatomic areas, report add-on 15005—again, only in addition to 15004.

Surgical preparation may be reported only once per wound. If the wound is prepared, but not grafted (e.g., grafting won't occur until the next day), minimal preparation of the wound bed is included in the graft code, as is removing a previous graft.

Codes 15002-15005 apply specifically to describe the work of preparing a clean and viable wound surface for placement of an autograft, flap, skin substitute graft or for negative pressure wound therapy, according to CPT® guidelines. Surgical prep codes would not be reported for removal of nonviable tissue or debris in a chronic wound when it is left to heal by secondary intention. When a wound requires serial debridement, report active wound management (97597-97598) or debridement (11042-11047). If a wound requires negative pressure wound therapy, 15002-15005 are applicable in addition to 97605-97606.

DESCRIPTION/BACKGROUND

A wound by true definition is any disruption of the integrity of skin, mucous membrane, or organ tissue (Kujath & Michelsen, 2008). Wounds can be caused by mechanical, thermal, chemical, and radiogenic trauma. To be distinguished from these are those wounds that have their origin due to underlying pathologies, such as diabetes mellitus, chronic venous/arterial insufficiency, and immunological or dermatological diseases (Kujath & Michelsen, 2008). A wound may be classified in many ways; by its etiology, anatomical location, by whether it is acute or chronic, by method of closure, by its presenting symptoms or by the appearance of the predominant tissue types in the wound bed (Enoch et al., 2004). Some of the most common causes of chronic wounds are tissue loads over bony prominences and lower extremity wounds secondary to neuropathy and venous hypertension (Irion, 2010). Occasionally wounds are due to ischemia. It is critical that the clinician be able to perform a good differential diagnosis between the types of wounds (arterial, venous hypertension, neuropathic, and/or from lymphatic disease) because the management of each wound differs and may be contraindicated in the presence of ischemia.

Wound Types

The two major types of wounds are acute or chronic wounds. Acute wounds will heal in orderly and timely reparative processes that result in sustained restoration of anatomic and functional integrity, usually in 30 days or less (Lazarus et al., 1994). Chronic wounds, on the other hand, are wounds that fail to complete the reparative process of healing in the expected period, usually greater than 30 days, or proceeded through the healing phase without establishing the expected functional result due to an interruption in the biological or physiologic process of normal healing (ECRI, 2010). Chronic wounds generally do not achieve wound closure without some type of intervention. The common chronic cutaneous

wounds include venous stasis ulcers, arterial insufficiency ulcers, neuropathic ulcers, and pressure ulcers (Bello and Phillips, 2000).

Venous stasis ulcers occur when there is an improper functioning of the venous valves, usually in the lower extremities, causing a back flow and increased pressure in veins (Bello and Phillips, 2000; Palfreyman et al., 2007). The body needs the pressure gradient between arteries and veins in order for the heart to pump blood forward through the arteries and veins. When there is an interruption in this pressure gradient and the arteries have a significantly lower pressure than the veins, which is known as venous hypertension, the blood is not pumped as effectively and causes it to pool in the lower extremities (Brem et al., 2004; Stanley et al, 2005). The standard of care for venous stasis ulcers is compression therapy at 30 to 40 mm Hg (Bello and Phillips, 2000; Palfreyman et al., 2007). Treatment regimens focus on increasing venous return and decreasing edema (Burns et al., 2007; Palfreyman et al., 2007).

Arterial ulcers are caused by an insufficient arterial blood supply. Arterial ulcers occur because there is inadequate perfusion of skin and subcutaneous tissue, resulting in tissue ischemia and necrosis, usually due to a complete or partial blockage of the arteries (Bello and Phillips, 2000; Holloway, 1996). Arterial insufficiency occurs as a result of peripheral arterial disease (PAD) and causes decreased perfusion to the tissues distal to an arterial plaque formation. Reestablishment of an adequate vascular supply is a key factor to support proper healing. Comprehensive medical management would include wound care to the ulcer itself and management to include control of the common causes of arterial ulcers (diabetes mellitus, control of hypertension, smoking cessation, proper nutrition, and moderate exercise) (Bello and Phillips 2000; Guo and DiPietro, 2010).

Neuropathic ulcers form as a result of peripheral neuropathy, typically seen with diabetic patients but can be due to other metabolic disease process (renal failure), trauma, or surgery. Peripheral neuropathy affects the sensory nerves responsible for detecting sensations such as temperature or pain (American Diabetes Association (AMA), 1999). This loss of sensation causes local paresthesias, usually in the feet and/or lower extremities, which can lead to microtrauma, breakdown of the overlying tissues, and eventually ulceration, often seen over pressure points on the foot. Peripheral neuropathy can also damage motor nerves causing minor muscle wasting resulting in muscle imbalances that can cause foot deformities, which can lead to more prominent bony areas giving rise to additional pressure points prone to ulceration (AMA, 1999; Krestel Editors, 2010; Lazarus et al., 1994). In addition to basic wound care management, other medical management includes maintaining optimal blood sugar levels, pressure relief at the wound site, surgical debridement, control of infection, and arterial reconstruction.

A pressure ulcer is an injury to the skin and/or underlying tissue over a bony prominence that occurs as a result of pressure in conjunction with or without shear or friction. Pressure

ulcers can also result from poorly fitting casts or appliances. They can occur in soft tissue areas due to the pressure effects of a foreign object such as a medical device. Because muscle and subcutaneous tissue are more susceptible to pressure induced injury than dermis and epidermis, pressure ulcers are often worse than their initial presentation. Pressure ulcers are assessed and staged at the bedside as a clinical description of the depth of observable tissue destruction.

For the purpose of this clinical practice guideline, the staging of pressure ulcers can be classified according to the National Pressure Ulcer Advisory Panel as follows (Black et al., 2007):

Pressure Ulcer Stage	Description
(Suspected) Deep Tissue Injury	Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer, or cooler as compared to adjacent tissue.
Stage I	Intact skin with non-blanchable redness of a localized area usually over a bony prominence. Darkly pigmented skin may not have visible blanching; its color may differ from the surrounding area.
Stage II	Partial-thickness loss of dermis presenting as a shallow open ulcer with a red-pink wound bed, without slough. May also present as an intact or open/ruptured serum-filled blister.
Stage III	Full-thickness tissue loss. Subcutaneous fat may be visible, but bone, tendon, or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss. May include undermining and tunneling.
Stage IV	Full-thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. Often includes undermining and tunneling.
Unstageable	Full-thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green, or brown) and/or eschar (tan, brown, or black) in the wound bed.

The National Pressure Ulcer Advisory Panel (2009) recommends debridement of devitalized tissue within the wound bed or edge of pressure ulcers when appropriate to the individual's condition and consistent with the overall goals of care.

Osteomyelitis

Osteomyelitis is inflammation of the bone caused by an infecting organism. Although bone is normally resistant to bacterial colonization, events such as trauma, surgery, presence of foreign bodies, or prostheses may disrupt bony integrity and lead to the onset of bone infection. Osteomyelitis can also result from hematogenous spread after bacteremia. When prosthetic joints are associated with infection, microorganisms typically grow in biofilm, which protects bacteria from antimicrobial treatment and the host immune response.

Acute osteomyelitis presents with acute inflammatory cells, edema, vascular congestion, and small-vessel thrombosis. In early disease, infection extends into the surrounding soft tissue, which compromises the vascular supply to the bone, as well as host response, surgery, and/or antibiotic therapy. Chronic osteomyelitis presents with pathologic findings of necrotic bone, formation of new bone, and polymorphonuclear leukocyte exudation, which is joined by large numbers of lymphocytes, histiocytes, and occasional plasma cells.

Surgery is indicated to treat osteomyelitis when the patient has not responded to specific antimicrobial treatment, if there is evidence of a persistent soft tissue abscess or subperiosteal collection, or if concomitant joint infection is suspected. Debridement of necrotic tissues, removal of foreign materials, and sometimes skin closure of chronic unhealed wounds is necessary in some cases (Kishner et al., 2014). The Infectious Disease Society of America (IDSA) guideline for the treatment of diabetic foot infections (Lipsky et al., 2012) recommends surgical intervention ranging from minor (debridement) to major (resection, amputation) for diabetic foot infections such as osteomyelitis.

Wound Healing

Wound healing is traditionally divided into the following four phases: (1) exudative phase, (2) resorptive phase, (3) proliferative phase and (4) regenerative phase. Each of the traditional phases listed describe their biophysiological functions that occur during that phase that leads to the next phase (Kujath & Michelsen, 2008). In recent English language publications, wound healing is divided into the following four phases: hemostasis, inflammation, proliferation, and tissue remodeling or resolution (Guo and DiPietro, 2010; Kujath & Michelsen, 2008; Singer, 1999). There are many different medically accepted terms used for wound care that describe the phases of wound healing. For the purpose of this paper, wound healing will be referred to as a normal biological process in the human body that is achieved through four highly integrated and overlapping phases: hemostasis, inflammation, proliferation, and remodeling (Guo and DiPietro, 2010).

The primary goals of wound management are rapid wound closure and a functional, mechanically stable and aesthetically acceptable scar (Kujath and Michelsen, 2008). Wounds can heal either by primary intention or secondary intention depending upon whether the wound may be closed with sutures or left to repair on its own, whereby damaged tissue is restored by the formation of connective tissue and re-growth of

epithelium (Cooper, 2005). Cooper's definition of primary intention is when the edges of the wound are approximated, and the individual layers of tissue are joined together either by sutures, staples or tissue adhesives or a combination of all of these. Secondary intention is when the wound sustains a degree of tissue loss where it appears that the wound closure is impossible secondary to either the presence of infection and wound closure is undesirable or wound edges are so far apart (Cooper, 2005). Primary wound healing is the uncomplicated healing process that involves the non-infected, well-adapted wounds (Kujath & Michelsen, 2008). If the healing process is disturbed by local factors such as infections, dehiscence, inadequate blood perfusion or systemic factors such as immunocompromise, a situation of secondary wound healing develops (Cooper, 2005; Kujath & Michelsen, 2008; Guo and DiPietro, 2010).

For the normal healing process to occur, the four phases of healing and their biophysiological functions must occur in the proper sequence, at a specific time and continue for a specific duration at an optimal intensity (Mathieu et al., 2006). There are many factors that can affect wound healing which may interfere with one or more of the healing phases, thus causing improper or impaired tissue repair and delays in wound closure. Wounds that exhibit impaired healing, which can include delayed acute wounds and/or chronic wounds, have failed to progress through the normal stages of healing. Chronic wounds are examples of wounds that have a biological or physiological reason for not healing. It is the chronic wounds that frequently enter a state of pathological inflammation due to postponed, incomplete, or uncoordinated healing process (Guo and DiPietro, 2010).

Choice of Dressing

A wound will require different management and treatment at various stages of healing. No dressing is suitable for all wounds; therefore, frequent assessment of the wound is required. Considerations when choosing dressing products:

- Maintain a moist environment at the wound/dressing interface
- Be able to control (remove) excess exudates. A moist wound environment is good, a wet environment is not beneficial
- Not stick to the wound, shed fibers or cause trauma to the wound or surrounding tissue on removal
- Protect the wound from the outside environment - bacterial barrier
- Good adhesion to skin
- Sterile
- Aid debridement if there is necrotic or sloughy tissue in the wound (caution with ischemic lesions)
- Keep the wound close to normal body temperature
- Conformable to body parts and doesn't interfere with body function
- Be cost-effective

- Diabetes - choose dressings which allow frequent inspection
- Non-flammable and non-toxic

Dry wound	Minimal exudate	Moderate exudate	Heavy exudate
Non adherent island dressing	Hydrogel	Calcium alginate	Hydrofibre
Hydrocolloid	Hydrocolloid	Hydrofibre	Foam
Films semi permeable	Silicone absorbent	Foams	Absorbent dressing
		Negative Pressure	Negative pressure wound therapy
		Hydrocolloid: paste/powder	Ostomy

EVIDENCE REVIEW

While there are numerous treatments that have been proposed as interventions to treat chronic wounds, not all have been well-studied and there is not enough evidence to prove their safety and effectiveness. Some of the researched treatments that have some evidence (but may not be confirmatory) to support their safety and effectiveness include ultrasound, low level laser, electromagnetic (EM) therapy/diathermy, electrical stimulation (ES), hyperbaric oxygen, surgical debridement, surgical revascularization of the affected area, myocutaneous skin flaps or grafting, use of various dressings (e.g., wet to dry, multilayer compression bandages), negative pressure wound therapy (vacuum-assisted closure), and the use of certain bioengineered skin substitutes. This paper will focus on those interventions within the scope of practice of the wound care specialist.

Brolmann et al. (2012) completed a meta-analysis on the evidence for local and systemic wound care. Forty-four relevant reviews were included in this summary paper. Wounds included venous ulcers, acute wounds, pressure ulcers, diabetic ulcers, arterial ulcers, and miscellaneous chronic wounds. The authors summarized that strong evidence supports the effectiveness of therapeutic ultrasound, mattresses, cleansing methods, closure of surgical wounds, honey, antibiotic prophylaxis, compression, lidocaine-prilocaine cream, skin grafting, antiseptics, debridement, and hyperbaric oxygen therapy.

Electrical Stimulation (ES)

Electrical stimulation (ES) is one of several treatment modalities that have been studied for the use of healing chronic wounds. Several randomized controlled trials have evaluated ES with varying protocols using different currents and voltages for the healing of pressure ulcers, venous stasis ulcers, arterial insufficiency ulcers, surgical wounds, and diabetic wounds (Houghton, 2003; Feedar et al. 1991; Fernandez et al. 2004). It is known that living

tissues possess electrical potentials that may play a role in the healing process. In early studies by Wolcott et al. (1969), researchers showed that ischemic ulcers healed significantly faster with the use of electrical stimulation. Researchers have studied the use of ES with regards to the type of electrical current applied (low-intensity direct current, low-intensity pulsed current, or high-voltage pulsed current) and the placement of electrodes (in direct contact, close proximity, or to a skin wound), thereby creating an electrical current that passes through the wound (Houghton, 2003; Feedar, 1991; Fernandez, 2004; Ho, 2008; Recio et al., 2012).

Recio et al. (2012) studied the effectiveness of high-voltage electrical stimulation used to manage stage III and IV pressure ulcers among adults with spinal cord injury (SCI). Through retrospective studies the authors describe the care of adults with SCI with recalcitrant pressure ulcers below the level of injury. Electrical stimulation was applied directly into the wound bed: 60 minutes per session, 3-5 times per week; with an intensity of 100 milliamperes and frequency of 100 pulses per second. Polarity was negative, initially and was switched weekly. The amplitude and wave form were maintained throughout each treatment session. The results showed that the long-standing (11-14 months) pressure ulcers were completely healed after 7 to 22 weeks of treatment with high-voltage ES. The study concluded that ES is effective for enhanced healing of Stage III-IV ulcers otherwise unresponsive to standard wound care (Recio et al., 2012).

Houghton et al. (2003) studied the effect of high voltage pulsed current (HVPC) electrical stimulation on healing chronic leg ulcers. The authors studied twenty-seven people with a total of 42 chronic leg ulcers. The subjects were separated into subgroups according to primary wound type (venous stasis, arterial insufficiency, diabetes) and then randomly assigned to receive either HVPC (100 microseconds, 150V, 100Hz) or sham treatment for 45 minutes, 3 times weekly, for 4 weeks. Wound surface area and wound appearance were assessed during the initial evaluation, following 1- to 2- week period during which subjects received only conventional wound therapy, after 4 weeks of sham or HVPC treatments, and at 1 month post treatment. The results indicated that the use of HVPC to chronic leg ulcers reduced the wound surface area over the 4-week treatment period to approximately one half the initial wound sizes, which was over 2 times greater than that observed in wounds treated with the sham treatment. The authors concluded that HVPC administered 3 times a week is an effective treatment to accelerate wound closure of chronic lower extremity ulcers due to diabetes, or to arterial or venous insufficiency (Houghton et al., 2003).

Studies have not adequately evaluated the safety and effectiveness of unsupervised home use of the electrical stimulation devices by a patient. Evaluation of the wound is an integral part of wound management. It is recommended that when ES is used as an intervention to treat chronic wounds, treatment should be conducted under the direct supervision of a

medical professional with the expertise in wound evaluation and management (CMS, 2004, 2003).

Barnes et al. (2014) conducted a review and meta-analysis of RCTs on electric stimulation vs. standard care for chronic ulcer healing. This systematic review also aimed to investigate the effect of different types of electrical stimulation on ulcer size reduction. Twenty-one studies were eligible for inclusion in the meta-analysis. Authors concluded that electrical stimulation appears to increase the rate of ulcer healing and may be superior to standard care for ulcer treatment.

Lala et al. (2015) conducted a systematic review and meta-analysis on the effects of electrical stimulation therapy (EST) on healing pressure ulcers in individuals with spinal cord injury (SCI). A meta-analysis with five studies demonstrated that EST significantly decreased the ulcer size compared to standard wound care or sham EST. Another meta-analysis conducted with four studies showed that EST increased the risk of wound healing by 1·55 times compared with standard wound care or sham EST. Because of the wide array of outcome measures across studies, a single meta-analysis could not be conducted. However, EST appears to be an effective adjunctive therapy to accelerate and increase pressure ulcer closure in individuals with SCI.

Chen et al. (2020) evaluated the effectiveness of electric stimulation (ES) for diabetic foot ulcer (DFU) treatment. Of the 145 randomized clinical trials initially identified, 7 studies (with a total of 274 patients) met the inclusion criteria. The percentage decrease in ulcer area at 4 weeks was significantly greater in patients treated with ES and SWC than SWC alone. The ulcer healing rate at 12 weeks was also significantly faster in the ES group. Subgroup analysis showed comparable efficacies with different waveforms (monophasic vs biphasic). Authors concluded that electrical stimulation appears to be an effective adjunctive therapy for accelerating DFU healing.

Avendaño-Coy et al. (2021) examined the effectiveness and safety of electrical microcurrent therapy (EMT) for improving wound healing and pain in people with acute or chronic wounds. Eight RCTs were included in the qualitative summary and seven in the quantitative analysis (n = 337 participants). EMT plus standard wound care (SWC) produced a greater decrease in wound surface and healing time that SWC alone, showing moderate and low certainty in the evidence, respectively. However, no differences were observed in the number of healed wounds, with very low quality of evidence. EMT decreased perceived pain, but no differences in adverse effects were noted between groups. Authors concluded that EMT is an effective, safe treatment for improving wound area, healing time, and pain. Further clinical trials that include detailed intervention parameters and protocols should be designed to lower the risk of bias.

Electromagnetic Therapy (ET)/Diathermy

Aziz et al. (2013) completed a Cochrane review on electromagnetic therapy for treating venous leg ulcers to assess the effects of EMT on the healing of venous leg ulcers. Authors concluded that there was no high-quality evidence that electromagnetic therapy increases the rate of healing of venous leg ulcers, and further research is needed. Wang et al. (2024) evaluated the effects of electromagnetic therapy (EMT) on the treatment of venous leg ulcers (VLUs) by synthesizing and appraising available meta-analyses (MAs) and systematic reviews (SRs). The search yielded five eligible studies. The reviews collectively presented moderate methodological quality and a low risk of bias in several domains. Reporting quality was high, albeit with inconsistencies in fulfilling certain PRISMA checklist items. The evidence quality, primarily downgraded due to small sample sizes, was rated as moderate. While some studies suggest potential benefits of EMT in the treatment of VLUs, the overall evidence is inconclusive due to methodological limitations and limited sample sizes. This review underscores the need for future research with more rigorous methodologies and larger cohorts to provide clearer insights into the efficacy of EMT for VLUs.

Ultraviolet (UV) Light

Chen et al. (2014) sought to determine the effects of phototherapy on the healing of pressure ulcers. Seven RCTs involving 403 participants were selected. All the trials were at unclear risk of bias. Trials compared the use of phototherapy with standard care only (6 trials) or sham phototherapy (1 trial). Only one of the trials included a third arm in which another type of phototherapy was applied. Overall, there was insufficient evidence to determine the relative effects of phototherapy for healing pressure ulcers. Variations in studies did not allow for pooling of the studies to draw any conclusions as to whether phototherapy is effective or not. Authors conclude that uncertainty exists as to the effects of phototherapy in treating pressure ulcers. The quality of evidence is very low due to the unclear risk of bias and small number of trials available for analysis. The possibility of benefit or harm of this treatment cannot be ruled out. Further research is recommended.

Inkaran et al. (2021) examined the effect of UV light on wound healing and infection in patients with skin ulcers or surgical incisions. Outcomes of interest included healing time, wound size and appearance, bacterial burden, and infection. Comparative and noncomparative clinical studies were considered, including observational cohort, retrospective, and randomized controlled studies. They addressed the research question: "Does the use of UV light as an adjunct to conventional treatment help improve healing and reduce infection in wounds?" The search yielded 30,986 articles, and screening resulted in 11 studies that underwent final analysis. Of these (N = 27,833), seven (64%) demonstrated an improvement in healing outcomes with adjunctive UV therapy, and the results of four (36%) achieved statistical significance. Authors concluded there is limited research on the utility of adjunctive UV therapy to improve wound healing outcomes in humans. The majority of literature included in this review supported improved wound

healing outcomes with adjuvant UV therapy. Future well-designed randomized controlled trials will be essential in further determining the benefit and utility of UV therapy in wound healing.

Non-Contact Ultrasound

Olyaie et al. (2013) conducted a RCT to compare the effectiveness of standard treatment and standard treatment plus either high-frequency ultrasound (HFU) or noncontact low-frequency ultrasound (NCLFU) on wound outcomes. Outcomes of both methods of ultrasound therapy were better than standard care alone, and some differences between the two ultrasound therapy groups were observed, but they were not statistically significant. Beheshti et al. (2014) compared high-frequency and MIST ultrasound therapy for the healing of venous leg ulcers. All groups received standard wound care. In the ultrasound groups, HFU and MIST ultrasound therapy was administered to wounds 3 times per week until the wound healed. Time of complete wound healing was recorded. Wound size, pain, and edema were assessed at baseline and after 2 and 4 months. The authors stated that this study showed the significant effectiveness of ultrasound therapy in wound healing. Differences between the two ultrasound therapy groups were not statistically significant. White et al. (2015) compared non-contact low-frequency ultrasound therapy to the UK standard of care for venous leg ulcers. Both groups reported a reduction in pain score. The authors suggest that outcome measures favored the non-contact low frequency ultrasound therapy over standard of care, but the differences were not statistically significant. A larger sample size with longer follow up would be prudent to confirm results.

In a single-site, evaluator-blinded RCT, Gibbons et al. (2015) completed a prospective, randomized, controlled, multicenter trial comparing percent wound size reduction, proportions healed, pain, and quality-of-life (QOL) outcomes in patients randomized to standard care (SC) alone or SC and 40 kHz noncontact, low-frequency ultrasound (NLFU) treatments 3 times per week for 4 weeks. All participants received protocol-defined SC compression (30-40 mm Hg), dressings to promote a moist wound environment, and sharp debridement at the bedside for a minimum of 1 time per week. After 4 weeks of treatment, average wound size reduction was 61.6% ± 28.9 in the NLFU+SC compared to 45% ± 32.5 in the SC group (P = 0.02). Reductions in median (65.7% versus 44.4%, P = 0.02) and absolute wound area (9.0 cm2 versus 4.1 cm2, P = 0.003) as well as pain scores (from 3.0 to 0.6 versus 3.0 to 2.4, P = 0.01) were also significant. NLFU therapy with guideline-defined standard care should be considered for healing venous leg ulcers not responding to SC alone. Rastogi et al. (2019) compared the efficacy of noncontact, low-frequency airborne ultrasound (Glybetac) therapy with sham therapy added to standard treatment in patients with neuropathic, clinically infected, or noninfected diabetic foot ulcer (DFU) (wound size >2 cm2), Wagner grades 2 and 3. Patients received ultrasound or sham therapy for 28 days dosed daily for first 6 days followed by twice a week for next 3 weeks along with standard of care. The primary outcome was the percentage of patients with at least >50% decrease in wound area at 4 week of intervention. Fifty-eight patients

completed the study protocol. A >50% reduction in wound area was observed in 97.1% and 73.1% subjects in ultrasound and sham groups, respectively. Wound contraction was faster in the first 2 weeks with ultrasound therapy, 5.3 cm2, compared with 3.0 cm2 with sham treatment. Authors concluded that the airborne low-frequency ultrasound therapy improves and hastens the healing of chronic neuropathic DFU when combined with standard wound care.

Kotronis and Vas (2021) evaluated the current evidence behind the NCLFU. Several studies, especially those evaluating NCLFU technology, have demonstrated the potential of ultrasound debridement to effectively remove devitalized tissue, control bioburden, alleviate pain, and expedite healing. However, most of the studies are underpowered, involve heterogeneous ulcer types, and demonstrate significant methodological limitations making comparison between studies difficult. Future clinical trials on ultrasound debridement technology must address the design issues prevalent in current studies, and report on clinically relevant endpoints before adoption into best-practice algorithms can be recommended.

Ultrasound

A randomized controlled study of 305 subjects explored the efficacy of physical methods for healing venous leg ulcers, including high-voltage electrical stimulation, ultrasound, and low-level laser therapy, which was performed for 7 weeks (once a day, 6 days a week). Results indicated high-voltage stimulation and ultrasound therapy are useful methods in the conservative treatment of venous leg ulcers (Taradaj et al., 2012). Polak et al. (2014) evaluated the effectiveness of ultrasound in the treatment of Stage II and Stage III pressure ulcers in geriatric patients. Participants (age range of 71 to 95 years,) all with wounds that did not respond to previous treatment for at least 4 weeks, were randomly assigned to the treatment group or control group. All patients received standard wound care (SWC); with the treatment group also receiving ultrasound (1 MHz, 0.5 W/cm2, duty cycle of 20 %, 1 to 3 minutes/cm2; 1 session per day, 5 days a week). Patients were monitored for 6 weeks or until wounds closed. Percent change in wound surface area (WSA), the weekly rate of change in WSA, and the percentage of pressure ulcers that improved (i.e., decreased in size by at least 50 % or closed) were used to compare differences. After 6 weeks of treatment, the WSA of pressure ulcers decreased significantly in both groups with significantly greater improvement in the treatment group (an average of 68.80 % ± 37.23 % compared with 37.24 % ± 57.84 %; $p = 0.047$). The mean weekly change of WSA was greater in the treatment group as well, but only for Stage II pressure ulcers than in the control group. The authors concluded that the findings of this study showed US therapy can reduce the WSA of pressure ulcers regardless of their shape, but further research is needed to establish how ultrasound influences the healing of Stage III and Stage IV pressure ulcers. Tricco et al. (2015) identified effective interventions to treat complex wounds through an overview of systematic reviews. Overall, 99 systematic reviews were included; 54 were systematic reviews with a meta-analysis (including data on over 54,000 patients) and 45 were

systematic reviews without a meta-analysis. Overall, 4% of included reviews were rated as being of high quality (AMSTAR score greater than or equal to 8). Based on data from systematic reviews including a meta-analysis with an AMSTAR score greater than or equal to 8, promising interventions for complex wounds were identified. These included bandages or stockings (multi-layer, high compression) and wound cleansing for venous leg ulcers; 4-layer bandages for mixed arterial/venous leg ulcers; biologics, ultrasound, and hydrogel dressings for diabetic leg/foot ulcers; hydrocolloid dressings, electrotherapy, air-fluidized beds, and alternate foam mattresses for pressure ulcers; and silver dressings and ultrasound for unspecified mixed complex wounds.

Low-Level Laser Therapy (LLLT)

Many researchers have proposed that low-level laser therapy (LLLT) may be an effective treatment modality to promote wound healing and pain relief (Enwemeka, 2004; Hopkins, 2004; Posten, 2005). Samsun et al. (AHRQ, 2004) provided an overview of clinical and methodological issues relevant to evaluating the evidence on interventions for wound healing. The objective of this evidence report was to systematically review and synthesize the available evidence on the effectiveness of low-level laser treatment and vacuum-assisted closure for wound healing. Overall, the studies that met selection criteria for low-level laser were poor and do not permit definitive conclusions on whether low-light laser increases the rate of healing for chronic wounds. The available data suggest that the addition of laser therapy does not improve wound healing, as the vast majority of comparisons in these studies do not report any group differences in the relevant outcomes. With the majority of the studies, the low sample sizes and the lack of trends or patterns of outcomes could be the reason for no definitive conclusions. Low light laser therapy has potential to improve wound care, but there are limited reports of outcomes that have been demonstrated in well-controlled randomized trials (AHRQ, 2004). Additionally, laser parameters are not consistent from study to study and thus, results in difficulty in drawing conclusions.

Enwemeka et al. (2004) used statistical meta-analysis to determine the overall treatment effects of laser phototherapy (low-level laser) on tissue repair and pain relief. Thirty-four articles on tissue repair and nine articles on pain control met inclusion criteria. Meta-analysis revealed a positive effect of laser phototherapy on tissue repair and pain control. Further, analysis revealed the positive effects of various wavelengths of laser light on tissue repair, with 632.8 nm having the highest treatment effect and 780 nm the least. The overall treatment effect for pain control was positive as well. The authors concluded that laser phototherapy is a highly effective therapeutic modality for tissue repair and pain relief (Enwemeka et al., 2004). In another study by Enwemeka (2009), it was reported that inaccurate measurement and incorrect reporting dosages are major shortcomings of phototherapy research. Enwemeka reported that there are as many as 30% of published reports in the field lacking relevant information needed to determine a dosage or that

reported dosages that are not accurate. Further studies are needed to determine strategies to improve dosages in the use of low-level laser for tissue repair and pain relief.

Posten et al. (2005) studied the mechanism and efficacy of low-level laser therapy (LLLT) for wound healing. This group of researchers critically evaluated reported in vitro models and in vivo animal and human studies, to assess the qualitative and quantitative sufficiency for the efficacy of LLLT in promoting wound healing. After the authors examined the effects of LLLT on cell cultures in vitro, they concluded that some authors report an increase in cell proliferation and collagen production using specific and somewhat arbitrary laser settings with the helium neon (HeNe) and gallium arsenide (GaAs) lasers. Although increases in cell proliferation and collagen production using specific laser settings was reported, it could not be determined which properties (i.e., photothermal, photochemical, or photomechanical) of the LLLT produced the positive effect (Posten et al., 2005). Some studies using HeNe lasers reported improvements in surgical wound healing in a rodent model; however, the results have not been duplicated in animals such as pigs, which have skin that closely resembles that of humans. Studies that involved humans have beneficial effects on superficial wound healing found in small case series and have not been replicated in larger studies (Posten et al., 2005). Although applications of high-energy (10-100W) lasers are well established with significant supportive literature and widespread use, conflicting studies in the literature have limited LLLT use in the United States to investigational use only (Posten et al., 2005).

Another randomized, triple-blind, placebo-controlled design by Hopkins et al. (2004) assessed the putative effects of LLLT on healing using an experimental model. Subjects received LLLT from either a laser or a sham cluster head (8 J/cm2 for 2 minutes, 5 seconds) to one of two randomly chosen wounds. Data were analyzed for wound contraction (area), color changes (chromatic red), and luminance. The results for group by wound by time interaction showed at days 6, 8, and 10 follow-up testing revealed that the laser group had smaller wounds (decreased area measurements) than the sham group for both the treated and the untreated wounds. The authors concluded that LLLT resulted in the enhanced wound healing as measured by wound contraction. The untreated wounds in subjects treated with LLLT contracted more than the wounds in the sham group, thus LLLT may produce an indirect healing effect on surrounding tissues. Data indicates that LLLT is an effective modality to facilitate wound contraction of partial thickness wounds (Hopkins et al., 2004).

A double-blinded RCT of 23 patients with diabetic foot ulcers who were randomly assigned to LLLT or a sham control group. The treatment group received LLLT six times per week for a minimum of two consecutive weeks, then laser therapy every other day up to complete healing of the ulcer for a maximum of 20 weeks. After 4 weeks of treatment, the intervention group demonstrated significantly decreased ulcer size, but at 20 weeks, there was no statistically significant difference in ulcer healing time between the two groups.

The authors recommended completion of additional studies with larger samples and longer follow-up time (Kaviani et al., 2011). Another randomized controlled study of 34 patients with venous leg ulcers demonstrated no significant differences in reduction of ulcer size between the laser treatment and control groups following a 9-week intervention period (LeClere et al., 2010). A randomized controlled study of 305 subjects explored the efficacy of physical methods for healing venous leg ulcers, including high-voltage electrical stimulation, ultrasound, and low-level laser therapy, which was performed for 7 weeks (once a day, 6 days a week). Results indicated no significant effect or improvement in healing with the use of laser therapy for venous ulcers. (Taradaj et al., 2012). Beckmann et al. (2014) completed a systematic literature review of LLLT for wound healing of diabetic ulcers. They concluded that although the majority of clinical studies show a potential benefit of LLLT in wound healing of diabetic ulcers, there are several aspects in these studies limiting final evidence about the actual outcomes. In summary, all studies give enough evidence to continue research on laser therapy for diabetic ulcers, but clinical trials using human models do not provide sufficient evidence to establish the usefulness of LLLT as an effective tool in wound care regimes at present. Further well-designed research trials are required to determine the true value of LLLT in routine wound care.

Zhou et al. (2021) aimed to synthesize and systematically review the best evidence to assess the efficacy of low-level light therapy in improving healing of diabetic foot ulcers. Twelve randomized controlled trials were included. Meta-analysis revealed that 30.90% of the ulcer area was significantly reduced in the therapy group compared with the control group with a very large effect. A 4.2 cm2 reduction of the ulcer area was observed in the therapy group compared with the control group with a very large effect. In addition, diabetic foot ulcers in the therapy group were 4.65 times more likely to heal completely than those in the control group. Authors conclude that low-level light therapy accelerates wound healing and reduces the size of diabetic foot ulcers. However, the review does not allow any recommendation for the best treatment parameters required to achieve improved healing. Future trials need to include a good design and large sample size in defining the optimal treatment parameters for ulcers of different sizes.

Sutton et al. (2021) provided a comprehensive narrative review and critical appraisal of research investigating photobiomodulation (PBM), formerly known as low level laser therapy which includes lasers and light emitting diodes (LEDs), as a treatment to promote diabetic foot and lower leg ulcer (DFU) healing for humans. A total of 13 studies, with a total of 417 participants, were included in this review. The studies were critically appraised using the PEDro scale, which revealed weaknesses in study designs such as small sample sizes and problems with reproducibility with respect to the laser protocols. Characteristics of PBM that improved wound healing were wavelengths of 630 nm-660 nm and infrared wavelengths of 850 or 890 nm, and radiant exposure levels of 3 J/cm2-7 J/cm2. PBM was beneficial for superficial and deep DFUs. Controlled blood glucose levels and adherence to best practices (i.e., pressure off-loading, optimized wound dressing changes, appropriate

debridement) could have been a factor in the beneficial outcomes. Authors concluded that regardless of the laser characteristics chosen, in the majority of studies PBM as a treatment for DFUs improved healing rate when compared with standard wound care alone. However, weaknesses across the studies indicate that further research is required.

Zhang et al. (2024) evaluated the impact of red and infrared light on the healing of DFUs and provided evidence-based recommendations for future clinical adjunctive treatments of DFUs. A total of 28 studies, involving 1,471 patients, were included. The meta-analysis showed that groups treated with red and infrared light had a significantly higher ulcer healing rate, shorter ulcer healing time, increased peak blood flow velocity in the dorsalis pedis artery, and reduced wound pain score. Authors concluded that the use of red and infrared light as an adjunctive treatment for DFUs is more beneficial than conventional wound care. However, due to limitations in the quality and sample size of the included studies, further high-quality research is needed to validate these conclusions.

Negative Pressure Wound Therapy (NPWT)

Negative Pressure Wound Therapy (NPWT) is used to describe the treatment of a wound with topical negative pressure including atmospheric pressure therapy or dressing, vacuum sealing technique, foam suction dressing, vacuum compression, vacuum pack, sealed surface wound suction or sealing aspirative therapy (National Institute for Health and Clinical Excellence, 2005). The principles of the application of NPWT to a wound may aid in the healing process due to the following mechanisms: 1) wound contraction, 2) stimulation of granulation tissue formation, 3) continuous wound cleansing after adequate primary surgical debridement, 4) continuous removal of exudates, and 5) reduction of interstitial edema (AHQR, 2009; Willy et al., 2007). NPWT is primarily intended for chronic wounds that have not healed when treated with either standard care or other forms of wound care (ECRI, 2009). The development of negative pressure techniques for wound healing derives from two theories: removal of wound exudates while decreasing edema and concentrations of inhibitory factors and increasing blood flow; and negative pressure stretches and deforms the tissue and disturbs the extracellular matrix which induces biochemical responses that promote wound healing (ERCI, 2009).

The Centers of Medicare and Medicaid Services partnered with the Agency for Health Research and Quality (AHRQ) to commission a review of NPWT devices. AHRQ contracted with the Institute Evidence-based Practice Center to perform the review (AHRQ, 2009). The report specifically examined the use of NPWT for treatment of the following wound types: diabetic foot ulcers, pressure ulcers, vascular ulcers (both venous and arterial), burn wounds, surgical wounds (particularly infected sternal wounds) and trauma-induced wounds. This technology assessment report on NPWT found that the systematic reviews of NPWT reveal several important points about the use of NPWT modality. First, all the systematic reviews noted a lack of high-quality clinical evidence supporting the advantages of NPWT compared to the other wound treatments. The lack of

high-quality evidence resulted in many of the systematic reviewers relying on low-quality retrospective studies to judge the efficacy of NPWT technology. Secondly, the other systematic reviews found no studies published that directly compared the different types of NPWT devices or components. Direct comparison studies are needed to help determine the importance of the dressing approaches (foam or gauze) that may provide the best potential for wound healing. Thirdly, other systemic reviews concluded that NPWT must be evaluated according to wound type. Wound healing varies according to the type of wound being treated and NPWT benefits described for one type of wound cannot be transferred to other wound types (AHRQ, 2009). The overall assessment concluded that the available evidence cannot be used to determine a significant therapeutic distinction of a particular NPWT system (AHRQ, 2009). Due to lack of studies comparing one NPWT system to another NPWT system, the severity of adverse events for one NPWT compared to another could not be determined (AHRQ, 2009).

A multi-center randomized controlled study by Blume et al. (2008) evaluated the safety and clinical efficacy of NPWT compared with advanced moist wound therapy (AMWT) (predominately hydrogels and alginates) to treat foot ulcers in diabetic patients. Complete ulcer closure was defined as skin closure (100% reepithelization) without drainage or dressing requirements. Patients were randomly assigned to either NPWT or AMWT and received standard off-loading as needed. The trial evaluated treatment until day 112 or ulcer closure by any means. Patients whose wounds achieved ulcer closure were followed at 3 and 9 months. The authors showed a greater proportion of the foot ulcers achieved complete ulcer closure with NPWT than with AMWT within the 112-day active treatment phase. The patients that received the NPWT experienced significantly fewer secondary amputations. In assessing the overall safety, no significant difference between the groups was observed in treatment-related complications such as infection, cellulitis, and osteomyelitis at 6 months. The authors of this study concluded that NPWT appears to be as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers (Blume et al., 2008). In 2015, a Cochrane review was completed by Dumville et al. on NPWT for treating pressure ulcers in any care setting. Authors concluded that there is currently no high quality RCT available regarding the effects of NPWT compared to alternatives for the treatment of pressure ulcers. Also, they express that high uncertainty remains about the potential benefits or harms or both of treatment using NPWT. An update of the Cochrane review was completed in 2019. Despite the addition of 25 trials, results were consistent with the earlier review, with the evidence judged to be of low or very low certainty for all outcomes. Consequently, uncertainty remains about whether NPWT compared with a standard dressing reduces or increases the incidence of important outcomes such as mortality, dehiscence, seroma, or if it increases costs.

The US Food and Drug Administration (FDA) issued a Preliminary Public Health Notification: Serious Complications Associated with NPWT Systems. The FDA issued the alert to make individuals aware of deaths and serious complications, especially bleeding

and infection, associated with the use of NPWT systems, and to provide recommendations to reduce the risk (FDA, 2009; FDA, 2011). Although complications are rare, if NPWT is not used properly by trained medical personnel, complications can occur. The FDA recommends selecting patients for NPWT carefully, after reviewing the most recent device labeling and instructions, and that the patient is monitored frequently in an appropriate care setting by trained practitioner. The patient's condition, including the wound status, wound location, and co-morbidities must be considered and monitored prior and during NPWT treatment. The FDA recommends numerous patient risk factors/characteristics need to be considered before the use of NPWT. The FDA recommends that NPWT is contraindicated for these wound types/conditions:

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site
- Exposed organs, such as eyes

The FDA issued an updated report (February 2011) on the original Preliminary Public Health Notification: Serious Complications Associated with NPWT Systems, issued in 2009. The FDA received reports of an additional six deaths and 97 injuries, for a total of 12 deaths and 174 injury reports since 2007. The new recommendation was in regard to the safety and effectiveness of NPWT systems in newborns, infants and children; safety and effectiveness has not been established at this time and currently there are no NPWT systems cleared for use in these pediatric populations. The FDA will continue to monitor adverse events associated with NPWT systems and will make available any new information that might affect their use (FDA, 2009; FDA, 2011).

A systematic review of interventions to enhance healing of chronic ulcers of the foot in patients with diabetes concluded that overall, the heterogeneity and poor methodology made it difficult to draw conclusions (Game et al., 2012). Forty-three studies were selected for full review. They identified 10 categories: sharp debridement and wound bed preparation with larvae and hydrotherapy; wound bed preparation using antiseptics, applications and dressing products; resection of the chronic wound; hyperbaric oxygen therapy (HBOT); compression or negative pressure therapy; products designed to correct aspects of wound biochemistry and cell biology associated with impaired wound healing; application of cells, including platelets and stem cells; bioengineered skin and skin grafts; electrical, electromagnetic, lasers, shockwaves and ultrasound; other systemic therapies which did not fit in the above categories. Thus, for this specific condition and type of wound, conclusions as to the best evidence of treatment interventions are not possible due to lack of controlled studies and design issues (Game et al., 2012).

Seidel et al. (2020) evaluated effectiveness and safety of negative pressure wound therapy (NPWT) in patients with diabetic foot wounds in clinical practice. Three hundred sixty-eight patients were randomized, and 345 participants were included in the modified intention-to-treat (ITT) population. Adult patients suffering from a diabetic foot ulcer at least for 4 weeks and without contraindication for NPWT were allowed to be included. NPWT was compared with standard moist wound care (SMWC) according to local (Germany) standards and guidelines. Primary outcome was wound closure within 16 weeks. Secondary outcomes were wound-related and treatment-related adverse events (AEs), amputations, time until optimal wound bed preparation, wound size and wound tissue composition, pain, and quality of life (QoL) within 16 weeks, and recurrences and wound closure within 6 months.

Authors concluded that NPWT was not superior to SMWC in diabetic foot wounds in German clinical practice. Overall, wound closure rate was low. Documentation deficits and deviations from treatment guidelines negatively impacted the outcome wound closure. Norman et al. (2020) assessed the effects of NPWT for preventing surgical site infections (SSI) in wounds healing through primary closure, and to assess the cost-effectiveness of NPWT in wounds healing through primary closure. Trials were included if they allocated participants to treatment randomly and compared NPWT with any other type of wound dressing or compared one type of NPWT with another type of NPWT. In this third update, 15 new randomized controlled trials (RCTs) and three new economic studies were added, resulting in a total of 44 RCTs (7,447 included participants) and five economic studies. Studies evaluated NPWT in the context of a wide range of surgeries including orthopaedic, obstetric, vascular, and general procedures. All studies compared NPWT with standard dressings. Most studies had unclear or high risk of bias for at least one key domain. Authors concluded that people experiencing primary wound closure of their surgical wound and treated prophylactically with NPWT following surgery probably experience fewer SSI than people treated with standard dressings (moderate-certainty evidence). There is no clear difference in number of deaths or wound dehiscence between people treated with NPWT and standard dressings (low-certainty evidence). There are also no clear differences in secondary outcomes where all evidence was low or very low certainty. Most evidence on pain is very low-certainty, but there is probably no difference in pain between NPWT and standard dressings after surgery for lower limb fracture (moderate-certainty evidence).

Zens et al. (2020) performed a systematic review of randomized controlled trials (RCTs) comparing the patient-relevant benefits and harms of NPWT with standard wound therapy (SWT) in patients with wounds healing by secondary intention. Forty-eight eligible studies of generally low quality with evaluable data for 4,315 patients and 30 eligible studies with missing data for at least 1386 patients were identified. A meta-analysis of all wound healing data showed a significant effect in favor of NPWT. There was neither proof (nor indication nor hint) of greater benefit or harm of NPWT for other patient-relevant outcomes such as mortality and adverse events. Authors concluded that low-quality data indicate a greater

benefit of NPWT versus SWT for wound closure in patients with wounds healing by secondary intention. The length of hospital stay is also shortened. The data show no advantages or disadvantages of NPWT for other patient-relevant outcomes. Publication bias is an important problem in studies on NPWT, underlining that all clinical studies need to be fully reported.

Pedrazi et al. (2021) completed a systematic review, including a total of 466 patients, which shows that NPWT as the initial treatment for burned children and after skin grafting has been shown to produce promising results. In the majority of studies, skin graft take rate is close to 100%. This therapy is particularly beneficial in the pediatric population because of less frequent dressing changes and early mobilization. Authors note that NPWT is not in the subject of controlled clinical trials in pediatric; most publications are case reports or retrospective reviews. The sporadic complications include bleeding, local infections, and mechanical device issues. Prospective randomized studies are needed to provide validated rules. Putri et al. (2022) reviewed the risks and benefits of NPWT in surgical wounds with the underlying malignant disease compared with conventional wound care (CWC). The first outcome was wound complications, divided into surgical site infection (SSI), seroma, hematoma, and wound dehiscence. The secondary outcome was hospital readmission. Thirteen observational studies with 1,923 patients and seven RCTs with 1,091 patients were included. NPWT group showed significant decrease in the risk of SSI and seroma in observational studies with P value <0.05, as well as RCTs but were not significant. Wound dehiscence and hospital readmission showed lower risks in NPWT group but were not significant. Hematoma showed no significant difference. Authors concluded that NPWT is not contraindicated in cancer surgical wounds and can be considered a beneficial palliative treatment to promote wound healing. Gillespie et al. (2022) summarized the evidence on the effectiveness of negative pressure wound therapy (NPWT) for preventing SSI and other wound complications in obese women after CS. Ten RCTs with 5,583 patients were included; studies were published between 2012 and 2021. Nine RCTs with 5,529 patients were pooled for the outcome SSI. Meta-analysis results suggest a significant difference favoring the NPWT group, indicating an absolute risk reduction of 1.8% among those receiving NPWT compared with usual care. The risk of blistering in the NPWT group was significantly higher. All studies had high risk of bias relative to blinding of personnel/participants. Only 40% of studies reported blinding of outcome assessments and 50% had incomplete outcome data. Authors concluded that the decision to use NPWT should be considered both in terms of its potential benefits and its limitations.

Shi et al. (2023) evaluated the effectiveness of NPWT for treating adult with pressure ulcers in any care setting in a Cochrane Review. Authors included published and unpublished randomized controlled trials (RCTs) comparing the effects of NPWT with alternative treatments or different types of NPWT in the treatment of adults with pressure ulcers (stage II or above). This review included eight RCTs with a total of 327 randomized participants. Six of the eight included studies were deemed to be at a high risk of bias in one or more

risk of bias domains, and evidence for all outcomes of interest was deemed to be of very low certainty. Most studies had small sample sizes (range: 12 to 96, median: 37 participants). Five studies compared NPWT with dressings, but only one study reported usable primary outcome data (complete wound healing and adverse events). This study had only 12 participants and there were very few events; only one participant was healed in the study (risk ratio (RR) 3.00, very low-certainly evidence). There was no evidence of a difference in the number of participants with adverse events in the NPWT group and the dressing group, but the evidence for this outcome was also assessed as very low certainty. Changes in ulcer size, pressure ulcer severity, cost, and pressure ulcer scale for healing (PUSH) sores were also reported, but authors were unable to draw conclusions due to the low certainly of the evidence. One study compared NPWT with a series of gel treatments, but this study provided no usable data. Another study compared NPWT with 'moist wound healing', which did not report primary outcome data. Changes in ulcer size and cost were reported in this study, but evidence was assessed as being of very low certainty; One study compared NPWT combined with internet-plus home care with standard care, but no primary outcome data were reported. Changes in ulcer size, pain, and dressing change times were reported, but evidence was assessed as being of very low certainty. None of the included studies reported time to complete healing, health-related quality of life, wound infection, or wound recurrence. Authors concluded that the efficacy, safety, and acceptability of NPWT in treating pressure ulcers compared to usual care are uncertain due to the lack of key data on complete wound healing, adverse events, time to complete healing, and cost-effectiveness. Compared with usual care, using NPWT may speed up the reduction of pressure ulcer size and severity of pressure ulcer, reduce pain, and dressing change times. Still, trials were small, poorly described, had short follow-up times, and with a high risk of bias; any conclusions drawn from the current evidence should be interpreted with considerable caution. In the future, high-quality research with large sample sizes and low risk of bias is still needed to further verify the efficacy, safety, and cost-effectiveness of NPWT in the treatment of pressure ulcers. Future researchers need to recognize the importance of complete and accurate reporting of clinically important outcomes such as the complete healing rate, healing time, and adverse events.

Horn et al. (2023) examined the use of negative pressure wound therapy for the treatment of venous leg ulcers (VLU). Authors report that NPWT is underrecognized as a useful adjunct in the management of VLUs. The literature has shown NPWT to be beneficial by primarily reducing wound area while promoting granulation tissue formation; thus, this therapy is a valuable adjunct in preparing the wound for either a cellular and tissue-based therapy and, more notably, for Split-Thickness Skin Grafts (STSG). This is likely especially true for large VLUs. Although what is considered large may be somewhat arbitrary, it appears that the benefit of NPWT increases with wound size. Management of fluid and drainage appears to be a secondary reason to use NPWT. Most clinicians who treat VLUs with adjunctive NPWT use it in conjunction with multilayer compression. It is well recognized that increasing venous return with multilayer compression is mandatory

for good ulcer healing. Thus, in any setting other than the inpatient hospital setting, for most clinicians adjunctive NPWT is best used in addition to compressive dressing when treating VLUs.

Onderková et al. (2023) aimed to systematically review NPWT effectiveness, safety, and comparative efficacy for head and neck wound healing. Thirty-one studies from a systematic literature search were identified and analyzed for wound healing response, overall success rate, improvements compared to conventional wound care, and variation in pressure settings, treatment lengths, and dressing change frequency. NPWT showed enhanced outcomes across diverse head and neck wounds, particularly complex post-reconstructive wounds, and severe infections. Despite the predominantly case report/series evidence and lack of standardized NPWT protocols, its benefits over conventional care were clear. NPWT emerges as a promising approach for head and neck wound management, potentially improving patient outcomes and reducing complications. More randomized controlled trials are needed to solidify the evidence and standardize NPWT application protocols.

Chen et al. (2024) updated the 2019 IWGDF evidence-based guideline on wound healing interventions to promote healing of foot ulcers in persons with diabetes. Each recommendation is based on the evidence found in the systematic review and, using the GRADE summary of judgement items, including desirable and undesirable effects, certainty of evidence, patient values, resources required, cost effectiveness, equity, feasibility, and acceptability, recommendations were formulated that were agreed by the authors and reviewed by independent experts and stakeholders. Authors made a number of conditional supportive recommendations for the use of interventions to improve healing of foot ulcers in people with diabetes. These include the use of sucrose octasulfate dressings, the use of negative pressure wound therapies for post-operative wounds, the use of placental-derived products, the use of the autologous leucocyte/platelet/fibrin patch, the use of topical oxygen therapy, and the use of hyperbaric oxygen. Although in all cases it was stressed that these should be used where best standard of care was not able to heal the wound alone and where resources were available for the interventions.

Wu et al. (2024) investigated the efficacy and safety of extracorporeal shockwave therapy (ESWT) for DFUs. A total of 10 RCTs with moderate methodological quality were included for data analysis. The findings showed that ESWT was significantly associated with significantly complete healed ulcers and lower rate of unchanged ulcers compared to controls. Subgroup analysis further revealed that ESWT was better than both hyperbaric oxygen therapy (HOT) and the standard of care (SOC). Moreover, ESWT also significantly improved the average transcutaneous partial oxygen pressure. However, the rate of ≥ 50 % improved ulcers and treatment-emergent adverse events were not significantly different between the ESWT and controls. Authors concluded that ESWT has shown promising efficacy and a favorable safety profile in the treatment of DFUs.

Systemic Hyperbaric Oxygen Therapy (HBOT)

Systemic hyperbaric oxygen therapy (HBOT) involves the inhalation of pure oxygen gas while enclosed in a high-pressure chamber (defined as pressure greater than standard atmospheric pressure). The pressures used are usually between 1.4 to 3.0 atmospheres absolute (atm abs or ATA). The therapy works by supersaturating the blood tissues with oxygen via increased atmospheric pressure as well as increased oxygen concentrations. Studies have demonstrated that this therapy increases the available oxygen to the body by 10 to 20 times normal levels. Treatment may be carried out in either a mono-place chamber pressurized with pure oxygen or in a larger, multi-place chamber pressurized with compressed air, in which case the individual receives pure oxygen by mask, head tent, or endotracheal tube. The number and duration of treatment sessions and the atmospheric pressure during treatment varies depending on the specific condition being treated, the severity of the condition, and the procedures developed by individual hospitals and clinics. These individual procedures vary widely and have made the evaluation of the efficacy of hyperbaric oxygen therapy difficult. However, the medical specialty society which represents the physicians who specialize in this type of medical treatment, called the Undersea and Hyperbaric Medical Society (UHMS), created treatment recommendations for a wide variety of conditions for which HBOT has been proven to provide significant benefits.

The position regarding systemic hyperbaric oxygen is based on guidelines published by the Undersea and Hyperbaric Medical Society (2008). These guidelines provide recommendations for indications where hyperbaric oxygen therapy has been demonstrated to provide clinical benefits, and where there is adequate data to provide guidance regarding treatment duration, frequency, and depth of pressurization.

Lalieu et al. (2021) completed a retrospective, single-center cohort study between 2013 and 2019. All patients with a venous leg ulcer (VLU) from an outpatient clinic providing HBOT and wound care were included. The primary outcome measure was wound healing, determined at discharge from the center. Other outcome measures were improvement in patient related outcome measures (PROMs), as assessed by the EQ-5D-3L questionnaire and including quality of life (QoL) and pain score. Fifty patients were included, 53% female, with a mean age of 73.4 (±12.2). Most wounds (83%) had existed longer than 3 months before starting treatment. Patients received an average of 43 (±20) sessions of HBOT. After treatment, 37 patients (63%) achieved complete or near-complete wound healing. Wound size decreased from a median of 14 cm^2 to 0.5 cm^2, a median decrease of 7.5 cm^2 (94%). Patients mostly reported improvement for all health aspects on the questionnaire. Pain score decreased from 5.7 (±2.5) to 2.1 (±2.2) and health score increased from 57.2 (±15.6) to 69.9 (±18.9). Authors concluded that patients with non-healing VLUs may benefit from HBOT to achieve complete or substantial wound healing. They recommend a well-designed randomized clinical trial with several patients allowing

enough statistical power, and of a reasonable duration, to establish the potential of additional HBOT on hard-to-heal venous ulcers.

It is critical that interventions used to enhance the healing of chronic foot ulcers in diabetes are backed by high-quality evidence and cost-effectiveness. In previous years, the systematic review accompanying guidelines published by the International Working Group of the Diabetic Foot performed 4-yearly updates of previous searches, including trials of prospective, cross-sectional, and case-control design. Due to a need to re-evaluate older studies against newer standards of reporting and assessment of risk of bias, Chen et al. (2024) performed a whole new search from conception but limiting studies to randomized control trials only. The literature search identified 22,250 articles, of which 262 were selected for full text review across 10 categories of interventions. Overall, the certainty of evidence for a majority of wound healing interventions was low or very low, with moderate evidence existing for two interventions (sucrose-octasulfate and leucocyte, platelet and fibrin patch) and low-quality evidence for a further four (hyperbaric oxygen, topical oxygen, placental derived products and negative pressure wound therapy). The majority of interventions had insufficient evidence. Overall, the evidence to support any other intervention to enhance wound healing is lacking and further high-quality randomized control trials are encouraged.

Lalieu et al. (2023) analyzed wound healing results of hyperbaric oxygen therapy (HBOT) for a variety of different wound types. This retrospective cohort study included all patients treated with HBOT and wound care at a single hyperbaric center between January 2017 and December 2020. The primary outcome was wound healing. Secondary outcome measures were quality of life (QoL), number of sessions, adverse effects, and treatment cost. Investigators also examined possible influencing factors, including age, sex, type and duration of wound, socioeconomic status, smoking status, and presence of peripheral vascular disease. A total of 774 treatment series were recorded, with a median of 39 sessions per patient. In total, 472 wounds (61.0%) healed, 177 (22.9%) partially healed, 41 (5.3%) deteriorated, and 39 (5.0%) minor and 45 (5.8%) major amputations were performed. Following HBOT, median wound surface area decreased from 4.4 cm 2 to 0.2 cm 2, and patient QoL improved from 60 to 75 on a 100-point scale. Frequently recorded adverse effects were fatigue, hyperoxic myopia, and middle ear barotrauma. Attending fewer than 30 sessions and having severe arterial disease were both associated with a negative outcome. Authors concluded that adding HBOT to standard wound care increases wound healing and QoL in selected wounds. Patients with severe arterial disease should be screened for potential benefits. Most reported adverse effects are mild and transient.

Kwee et al. (2024) evaluated the effectiveness of hyperbaric oxygen therapy in the management of severe lower limb soft tissue injuries. In total 7 studies met the inclusion criteria, involving 229 patients. The studies included 2 randomized clinical trials, 1 retrospective cohort study, 3 case series and 1 case report. The randomized placebo-

controlled clinical trial showed a significant increase in wound healing and decrease in the need for additional surgical interventions in the patient group receiving hyperbaric oxygen therapy when compared to those undergoing sham therapy. The randomized non-placebo-controlled clinical trial revealed that early hyperbaric oxygen therapy reduces tissue necrosis and the likelihood of long-term complications. The retrospective cohort study indicated that hyperbaric oxygen therapy effectively reduces infection rates and the need for additional surgical interventions. The case series and case report presented beneficial results with regard to wound healing when hyperbaric oxygen therapy was added to the treatment regimen. Authors concluded that hyperbaric oxygen therapy is generally considered a safe therapeutic intervention and seems to have a beneficial effect on wound healing in severe lower limb soft tissue injuries when implemented as an addition to standard trauma care.

Ogbeide et al. (2024) summarized the current management principles and the development of new approaches to care in a narrative review. Authors noted that the management of DFUs has significantly advanced over time, with a clear trend toward a compact, patient-centered, multidisciplinary approach. Optimal glycemic control, infection control, pressure redistribution, re-vascularization, wound care, and debridement remain key to preventing and managing DFUs. Emerging trends like hyperbaric oxygen therapy, negative wound pressure therapy, skin substitutes, and growth factor therapy are promising, and there is a need for further randomized and observational studies.

Damineni et al. (2025) assessed the primary clinical evidence supporting hyperbaric oxygen therapy (HBOT) in the management of DFUs. Six studies with a total of 391 patients were included in the final analysis, after applying relevant inclusion and exclusion criteria. The majority of the studies indicated reduced major amputation rates, improved ulcer healing rates, and decreased ulcer size and depth with HBOT compared to standard care (SC). Most studies indicate that HBOT leads to lower rates of major amputations, better ulcer healing, and reduced ulcer dimensions than SC. However, one study found no significant differences in amputation rates or long-term wound healing between groups. While most studies showed a low risk of bias in certain areas, moderate-to-high bias in key aspects necessitated careful interpretation. Future high-quality RCTs with stringent blinding, standardized protocols, and defined patient selection criteria are crucial to confirm the effectiveness of HBOT, improve guidelines, and establish its long-term viability. Although this review suggests that HBOT may be valuable for DFUs, additional rigorous research is needed to reduce bias, enhance methodological consistency, and improve the reliability of the findings for clinical implementation.

Undersea and Hyperbaric Medical Society Guidelines

The Undersea and Hyperbaric Medical Society's (UHMS) 2008 Hyperbaric Oxygen Therapy Committee suggests utilization of systemic hyperbaric oxygen therapy pressurization or 'HBOT' guidelines as described below regarding wound care:

Arterial Insufficiencies – Treatment varies depending upon the severity of the condition and the type of chamber used. In large multi-place chambers, treatments delivered between 2.0 and 2.5 ATA of oxygen for 90-120 minutes once or twice daily is standard. In mono-place chambers, treatment at 2.0 ATA of oxygen for 90-120 minutes once or twice daily is standard. Once the patient is stabilized, once daily treatment is recommended. Details of specific conditions are below:

a. Diabetic lower extremity wounds
    - Patient with type 1 or type 2 diabetes with lower extremity wound due to diabetes; and
    - Wegner grade III or higher wound severity; and
    - Patient has failed an adequate course of standard wound therapy (defined as 30 days of standard treatment including assessment and correction of vascular abnormalities, optimization of nutritional status and glucose control, debridement, moist wound dressing, off-loading, and treatment of infection; and
    - Re-evaluations at 30 days must show continued progress.

b. Arterial insufficiency ulcers – May benefit patients who have persistent hypoxia despite attempts at increasing blood flow or when wound failure continues despite maximum revascularization.

c. Pressure ulcers – Not recommended for the routine treatment of decubitus ulcers. May be necessary for support of skin flaps and grafts showing evidence of ischemic failure, when the ulcer develops in the field of previous irradiated area for pelvic or perineal malignancies, or when progressive necrotizing soft tissue infection or refractory osteomyelitis is present.

d. Venous stasis ulcers – May be required to support skin grafting in patients with concomitant peripheral arterial occlusive disease and hypoxia not corrected by control of edema.

Stoekenbroek et al. (2014) completed a systematic review of randomized clinical trials (RCTs) to assess the additional value of hyperbaric oxygen therapy (HBOT) in promoting the healing of diabetic foot ulcers and preventing amputations was performed. Eligible studies reported the effectiveness of adjunctive HBOT with regard to wound healing, amputations, and additional interventions. Seven of the 669 identified articles met the inclusion criteria, comprising 376 patients. Authors concluded that current evidence shows some evidence of the effectiveness of HBOT in improving the healing of diabetic leg ulcers in patients with concomitant ischemia. Larger trials of higher quality are needed before implementation of HBOT in routine clinical practice in patients with diabetic foot ulcers can be justified. A Cochrane Review (2015) by Kranke et al. assessed the benefits and harms of adjunctive HBOT for treating chronic ulcers of the lower limb. Randomized controlled trials (RCTs) comparing the effect on chronic wound healing of therapeutic regimens which include HBOT with those that exclude HBOT (with or without sham therapy). Twelve trials (577 participants) were included. In people with foot ulcers due to

diabetes, HBOT significantly improved the ulcers healed in the short term but not the long term and the trials had various flaws in design and/or reporting that means we are not confident in the results. More trials are needed to properly evaluate HBOT in people with chronic wounds; these trials must be adequately powered and designed to minimize bias. Kumar et al. (2020) evaluated the efficacy of hyperbaric oxygen therapy (HBOT) as an adjuvant to standard therapy for treatment of diabetic foot ulcers. A total of 54 patients with diabetic foot ulcer of Wagner grade II-IV were recruited in this prospective, randomized, double blind study. Patients were randomized to receive HBOT along with standard therapy (group H; $n = 28$) or standard therapy alone (group S; $n = 26$). Patients were given 6 sessions per week for 6 weeks and followed up for 1 year. Outcomes were measured in terms of healing, and need for amputation, grafting or debridement. The diabetic ulcers in 78% patients in Group H completely healed without any surgical intervention while no patient in group S healed without surgical intervention. 2 patients in group H required distal amputation while in Group S, three patients underwent proximal amputation. Authors concluded that hyperbaric oxygen therapy is a useful adjuvant to standard therapy and is a better treatment modality if combined with standard treatment rather than standard treatment alone for management of diabetic foot ulcers.

Dauwe et al. (2014) completed a systematic review on whether hyperbaric oxygen therapy works in facilitating acute wound healing given that the majority of the literature supports its use for chronic wounds. A total of eight studies were found to meet criteria for evaluation of adjunctive hyperbaric oxygen therapy in the treatment of complicated acute wounds, flaps, and grafts. Authors concluded that when combined with standard wound management principles, hyperbaric oxygen therapy can augment healing in complicated acute wounds. However, it is not indicated in normal wound management. Further investigation is required before it can be recommended as a mainstay in adjuvant wound therapy.

Wound Dressings

Application of wound dressing continues to be the standard of care for wound treatment; however, the literature is inconclusive as it relates to standardized topical preparations and types of dressings. Palfreyman et al. (2007) completed a Cochrane review and meta-analysis on dressings for venous leg ulcers. Dressing wounds is standard care. However, there are different types of dressings that may improve healing. The authors reviewed all randomized controlled trials (RCTs) that evaluated dressings applied to venous leg ulcers. Two hundred and fifty-four studies were discovered but only 42 of these fulfilled inclusion criteria. Findings suggest that hydrocolloids were no more effective than simple low adherent dressings used beneath compression. No other comparisons could be stated due to insufficient evidence. Overall, no particular class or type of dressing appeared to be better from a healing perspective than any other. According to the authors, determining which dressing to apply should be based on local costs and preference of patient and practitioner.

Roehrs et al. (2023) evaluated the effects of hyaluronic acid (and its derivatives) on the healing of chronic wounds. Authors included randomized controlled trials that compared the effects of hyaluronic acid (as a dressing or topical agent) with other dressings on the healing of pressure, venous, arterial, or mixed-etiology ulcers and foot ulcers in people with diabetes. Twelve trials (13 articles) were included in a qualitative synthesis, and four trials in a quantitative analysis were combined. Overall, the included trials involved 1108 participants (mean age 69.60 years) presenting 178 pressure ulcers, 54 diabetic foot ulcers, and 896 leg ulcers. Sex was reported for 1022 participants (57.24% female). Pressure ulcers: It is uncertain whether there is a difference in complete healing; change in ulcer size; or adverse events (none reported) between platelet-rich growth factor (PRGF) + hyaluronic acid and PRGF because the certainty of evidence is very low (1 trial, 65 participants). It is also uncertain whether there is a difference in complete healing between lysine hyaluronate and sodium hyaluronate because the certainty of evidence is very low. Foot ulcers in people with diabetes It is uncertain whether there is a difference in time to complete healing between hyaluronic acid and lyophilized collagen because the certainty of evidence is very low. It is uncertain whether there is a difference in complete ulcer healing or change in ulcer size between hyaluronic acid and conventional dressings because the certainty of evidence is very low. Leg ulcers: Authors are uncertain whether there is a difference in complete wound healing, percentage of adverse events, pain, or change in ulcer size between hyaluronic acid + hydrocolloid and hydrocolloid because the certainty of evidence is very low (1 study, 125 participants). It is uncertain whether there is a difference in change in ulcer size between hyaluronic acid and hydrocolloid because the certainty of evidence is very low. Authors are uncertain whether there is a difference in complete wound healing between hyaluronic acid and paraffin gauze because the certainty of evidence is very low. When compared with neutral vehicle, hyaluronic acid probably improves complete ulcer healing (4 studies, 526 participants; moderate-certainty evidence); may slightly increase the reduction in pain from baseline (3 studies, 337 participants); and may slightly increase change in ulcer size, measured as mean reduction from baseline to 45 days (2 studies, 190 participants). It is uncertain if hyaluronic acid alters incidence of infection when compared with neutral vehicle (3 studies, 425 participants). Authors are uncertain whether there is a difference in change in ulcer size (cm2) between hyaluronic acid and dextranomer because the certainty of evidence is very low 1 study, 50 participants). The authors downgraded the certainty of evidence due to risk of bias or imprecision, or both, for all of the above comparisons. No trial reported health-related quality of life or wound recurrence. Measurement of change in ulcer size was not homogeneous among studies, and missing data precluded further analysis for some comparisons. Authors concluded that there is currently insufficient evidence to determine the effectiveness of hyaluronic acid dressings in the healing of pressure ulcers or foot ulcers in people with diabetes. Authors found evidence that hyaluronic acid probably improves complete ulcer healing and may slightly decrease pain and increase change in ulcer size when compared with neutral vehicle. Future research into the effects of hyaluronic acid in

the healing of chronic wounds should consider higher sample size and blinding to minimize bias and improve the quality of evidence.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* policy for information.

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