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Clinical Guideline

Oscar Clinical Guideline: Negative Pressure Wound Therapy and Negative Pressure Infusion/Instillation Therapy for the Treatment of Complicated Wounds for Outpatient and Home Care Settings (CG068, Ver. 4)

Negative Pressure Wound Therapy and Negative Pressure Infusion/Instillation Therapy for the Treatment of Complicated Wounds for Outpatient and Home Care Settings

Summary

Negative Pressure Wound Therapy (NPWT) of complex wounds can speed time to heal, speed the deposition of granulation tissue, increase wound contraction, keep a moist environment to allow cell migration and tissue deposition, and be used to prevent infection. It is also termed Vacuum-Assisted Wound Closure (VAWC). It can serve to both drain fluid away from an area while keeping a wound sealed and moist. The wounds can be pathologic (i.e., due to a disease such as diabetes or venous insufficiency), idiopathic (no definitive cause identified), ischemic (due to a poor blood supply), created surgically, or created due to a trauma. Multiple companies have entered the market to provide this technology as it has been shown to be effective for multiple types of wound care. A new form of this technology called an Instillation or Negative Pressure Wound Therapy Infusion (NPWTi) treatment can also instill agents that either assist in wound healing or the prevention or treatment of infection. NPWTi has been shown to decrease the number of operative debridements in chronic wounds. It is used to decrease the bioburden (i.e., bacteria that are non-pathogenic, but prevent healing). NPWTi has been shown to increase the depth of granulation tissue. The duration of therapy is based on repeated re-evaluation of the size and depth of wounds, or based on scientific studies on the optimal time to be used for both the treatment and prevention of disease. This guideline will discuss the various uses of this

technology and the clinical criteria for implementation, continuation, and termination of treatment. NPWT or NPWTi is indicated for use in the inpatient setting (both acute care, long term, and subacute facilities) as well as in the outpatient and home care settings. This clinical guideline will focus on outpatient and home care NPWT and NPWTi requests for initial and subsequent requests (regardless of location of initial application of wound therapy).

Definitions

"Dermal Substitute" refers to covering a wound with a biological mesh that functions the same as a skin graft. This can be bioengineered to be either skin or soft tissue in nature. The substitute can be cellular or acellular (e.g. hyaluronic acid). The substitute may be from another species (porcine, bovine) or may be completely artificial.

"Eschar" refers to a thickened rind of scar tissue overlying the wound. It is typically blackened or yellowed, firm, and may have a foul odor associated with it.

"Exposed'' means visible to the naked eye. This can be bone, muscle, tendons, blood vessels, or organs.

"Granulation tissue" refers to pink or red tissue that has grown over an exposed area. It is made up of microscopic blood vessels and is a sign of healing.

"Instillation" and "Infusion" are referred to as NPWTi. These are specialized systems that add medical treatments into the wound, while still creating a negative pressure to aid in healing, a moist environment, and decrease bioburden and infection. Solutions approved for use are:

- Hypochlorite/hypochlorous acid
- Acetic acid
- Sulfur Solutions (e.g. Mafenide Acetate), and
- Biguanides (Polyhexanide)
- Saline
- Antibiotics

"Leak" refers to the inability to maintain a seal due to moisture or location (such as the pre-sacral area). A leak is often audible, and fluid will often run out from under the occlusive dressing.

"Necrosis" refers to dead tissue in the wound.

"Osteomyelitis" refers to an infection within the bone itself. The infection destroys the bone and can be seen on x-rays and pathologic exams. Once treated by some combination of surgery and/or antibiotics, the bone is no longer infected although the damage to the bone may still be present, palpable, or visible. The inclusion and exclusion criteria for osteomyelitis are listed below under Condition-Specific Criteria or Not Medically Necessary criteria.

"Seal" refers to the ability to achieve and maintain the suction and negative pressure on the sponge and wound.

"Silver Sponge'' and "Silver Foam" refer to a sponge or foam that is impregnated with silver to act as an antimicrobial surface that will be in contact with the tissues.

"Skin Graft" refers to skin that is moved from one area to another to allow healing. They can be "Full thickness (FTSG)" meaning all layers of skin, or "split thickness (STSG)" where only the top layer or partial layer of skin is transferred. Partial thickness skin grafts are typically meshed meaning intentional defects were created to allow moisture out and and allow skin cells to migrate to more efficiently grow and heal an covered wound.

"Sponge" or "Foam" refers to the substance placed in or on an area that will be suctioned to create the negative pressure to remove liquid and create the environment needed to accelerate healing. This foam can be a variety of colors that represent its purpose (i.e., white foam is less likely to stick to tissue) or its manufacturer (one company may use black foam, another blue, or green).

"Slough" refers to a membrane of tissue, typically made from white cells and fibroblasts, which overlies healthy tissue and prevents healing. It is a rind of dead or infected tissue in the base or on the walls of the wound.

"Tendon" and "Ligament" refer to a fibrous attachment between bone and muscle, bone and bone, or muscle to muscle.

"Tunneling" refers to pathways under skin, soft tissue, or muscle. Some pathways travel deep into the surrounding tissues as well.

"Undermining" refers to areas in a wound that represent absent tissue bridged by skin, soft tissues, or muscle. This leaves a defect below the superficial tissues.

"Ulcer" refers to a skin defect caused by a non-traumatic condition (diabetes, venous stasis, arterial insufficiency). An ulcer can be acute (less than 30 days old) or chronic (more than 30 days old).

"Wound" refers to an area that is not intact and can be created either spontaneously, traumatically, or surgically. A wound can be open (tissue exposed) or closed (skin is together but can leak fluid or allow infection to enter below the skin).

Clinical Indications

General Criteria

NPWT is considered medically necessary for outpatient and home care services when the General Criteria are met in addition to one of the Condition-Specific Indications below. (For NPWTi please see criteria below on page 7). NPWT is considered medically necessary when ALL of the following are met for initial requests or subsequent requests:

1. The therapy was initiated or ordered by ONE of the below:
    a. In an inpatient hospital setting; *or*
    b. An acute or subacute rehabilitation facility; *or*
    c. A skilled nursing facility; *or*
    d. An outpatient office or wound care facility; *and*
2. NPWT is able to be implemented and managed in the outpatient setting (e.g., wound care center, provider office) or the home setting through a licensed agency approved to manage and service the device; *and*

3. The NPWT has documented ALL of the following:
    a. A signed order by a licensed provider (MD, DO, PA, NP) for NWPT is present; *and*
    b. Wound Measurements including length, width, and depth, are documented by a licensed professional; *and*
    c. A description of the wound is present including color, odor, drainage, purulence, necrosis, and the presence of eschar; *and*
    d. Undermining is documented if present; *and*
    e. There is less than 20% slough in the wound base or sides; *and*
    f. No eschar is present; *and*
    g. For wounds NOT created by trauma, or for wounds treated with infusion therapy (NPWTi):
        i. NPWT cannot be used on any exposed or visible tendon that is not fully covered by granulation tissue; *and*
        ii. NPWT cannot be used over exposed blood vessels; *and*
        iii. NPWT cannot be used over exposed nerves; *and*
    h. A seal can be maintained over the area; *and*
    i. The NPWT dressings and sponge are changed no more than three times a week by a licensed professional, unless one or more of the following is present:
        i. Documentation of loss of seal or suction; *or*
        ii. Documentation of equipment failure leading to a loss of seal or suction; *and*
    j. NPWT is utilized as part of a comprehensive wound care program; *and*
4. For initial requests, NPWT may be considered medically necessary up to 1 month:
    a. For subsequent requests, new clinicals must be provided to show medical necessity for the number of additional days requested:
        i. Documentation of assessment by an appropriate medical professional on a weekly basis; and
        ii. The documentation must show that the new measurements of the wound are smaller in at least 2 out of 3 dimensions (e.g., length, width or depth) since the previous month; and
        iii. Each subsequent request is no more than 1 month at a time.

Condition-Specific Indications

The Plan considers NPWT medically necessary for outpatient or home health care when the General Criteria are met AND one of the following condition-specific criteria are met.

Diabetes

The Plan considers NPWT for diabetic wounds medically necessary when the General Criteria are met AND any ONE of the following are met:

1. Leg elevation and compression are part of a comprehensive treatment program; *or*
2. The lesion is superficial (ulcer or wound) and chronic; *or*
3. The ulcer is complex in nature, meeting one of the following:
    a. Wagner Grade 2 or higher; *or*
    b. University of Texas grade 1 A-D, or Grade 2; *or*
    c. SINBAD 0 or 1; *or*
    d. DUSS 0 or 1; *or*
4. The wound is post-amputation; *or*

5. That the wound was due to a repaired open fracture; *or*
6. Any post surgical sternal wound (open wound or closed wound if NPWT was placed in the operating room, and requires placing a new one once discharged to home); *or*
7. Any diabetic wound that has failed conservative treatment for at least 2 weeks and glycemic control has been optimized.

Open Fractures
The Plan considers NPWT for any open fracture medically necessary when the General Criteria are met AND any one of the following are met:

1. The fracture has been reduced or repaired; *or*
2. The wound cannot be closed primarily; *or*
3. NPWT is being used as a bridge to primary closure; *or*
4. If osteomyelitis is present, it must be actively treated, as documented by ALL of the following:
    a. Debridement has been performed if indicated; *and*
    b. Is actively being treated with antibiotics, or has completed a full course of antibiotics; *and*
    c. Granulation tissue or muscle/soft tissue covers the bone.

Pressure Ulcers
The Plan considers NPWT for Stage 3 and Stage 4 pressure ulcers medically necessary when the General Criteria are met AND when ALL of the following are met:

1. Conservative measures have been tried and failed, or considered and ruled out as an effective option; *and*
2. All eschar and necrosis has been debrided; *and*
3. Optimal nutritional status can be maintained; *and*
4. A good seal can be maintained (keep a negative pressure); *and*
5. Moisture is controlled.

Mixed Ulcers (more than one etiology, e.g., diabetic, neuropathic, venous insufficiency, arterial insufficiency)
The Plan considers NPWT for mixed ulcers medically necessary when the General Criteria are met AND when ALL of the following are met:

1. The ulcer has been present for at least 3 months (Note: This can pre-date the request and does not have to be contiguous with a hospital admission); *and*
2. Ulcers must be chronic (more than 30 days old); *and*
3. Conventional wound care has been utilized for more than 30 days; *and*
4. Documentation of prior care is present, and ALL of the following:
    a. All necrotic tissue has been debrided; *and*
    b. Nutritional status has been evaluated, and provisions made to improve nutrition if deficient; *and*
    c. Glycemic control has been optimized if diabetic, and a comprehensive diabetic treatment plan is being followed.

Arterial Insufficiency Ulcers
The Plan considers NPWT for arterial insufficiency ulcers medically necessary when the General Criteria are met AND when ALL of the following are met:

1. The criteria for Mixed Ulcers have been met; *and*

2. If rest pain is present, dangling of the legs improves pain; *and*
3. Medications that improve vascular flow (e.g., Cilostazol, Pentoxyfyliine, anticoagulants, aspirin, etc.) are being administered, or have been tried and failed, or are documented to be contraindicated; *and*
4. Revascularization has been attempted and documented to improve arterial flow into the affected area (e.g., bypass, endarterectomy, atherectomy, balloon dilatation, stents, etc.) or there is documentation submitted that shows that arterial revascularization has failed or is contraindicated.

Venous Insufficiency Ulcers

The Plan considers NPWT for venous insufficiency ulcers medically necessary when the General Criteria are met AND when ALL of the following are met:

1. The criteria for Mixed Ulcers have been met; *and*
2. Acute DVT is absent in the affected segment; *and*
3. Medical therapy has been maximized including elevation, compression, Unna boots; *and*
4. Medications that improve vascular flow (e.g., Cilostazol, Pentoxyfyliine, anticoagulants, aspirin, etc.) are being administered, have been tried and failed, or are documented to be contraindicated.

Complications of Surgically Created Wounds and Traumatic Wounds

The Plan considers NPWT for complications of surgically planned or created wounds, and traumatic wounds medically necessary when the General Criteria are met AND when ONE of the following are met:

1. There is documentation submitted to show that accelerated granulation tissue is required for healing:
    a. Accelerated granulation tissue cannot be met by other treatments; *or*
    b. Shortened healing times are not achievable with topical therapies; *or*
2. There is dehiscence of a surgically created wound (abdominal, sternal, orthopedic, soft tissue); *or*
3. The individual has comorbidities that preclude wound healing in a normal time and achievable by other topical therapies (i.e diabetes, steroid dependence, immunocompromised, or other maladies deemed medically necessary); *or*
4. Traumatically created wounds that require accelerated granulation tissue not achievable by other treatments including one or more of the following:
    a. Exposed bone; *or*
    b. Exposed tendons; *or*
    c. Pre-operative for a flap or graft.

Prevention of Wound Infections

NPWT can be utilized prophylactically to prevent wound infections in closed surgically created wounds if initially placed in the operating room, or after an inpatient dressing change. These devices (e.g., Prevena) are typically a single unit that is fully disposable. The use of NPWT to prevent wound infections can be extended beyond inpatient settings if ALL of the following are met:

1. The member is to be discharged with the NPWT device and sponge in place and intact for use in the home with home health care (e.g., Prevena™); or the sponge has been temporarily removed to be replaced in the outpatient setting; *and*
2. The NPWT is a single use device; *and*

3. A signed order by a provider is present that a new single use device is needed in the home; *and*
4. Instructions are provided for the replacement of the single use device in the home care setting; *and*
5. The request is for any of the following conditions:
    a. Prevention of Sternal wound infections; *or*
    b. Prevention of Orthopedic wound infections; *or*
    c. Prevention of Neurosurgical wound infections; *or*
    d. Prevention of Traumatic wound infections if one of the following is met:
        i. To cover a defect in preparation of another surgery; *or*
        ii. To maintain a sterile environment, when a single use NPWT device is placed immediately at the time of surgery in a sterile operating field; *or*
    e. For specific requests of prophylactic single use NPWT dressings on abdominal wounds that are placed in the operating room, but may extend into the home care setting to prevent seromas and wound infections for any of the following:
        i. Open incisional Hernia Repairs including exposed mesh; *or*
        ii. Open reoperative exploration of the abdomen; *or*
        iii. Following secondary wound closure of large open abdominal incisions; *or*
        iv. Prevention of wound dehiscence.

Silver Impregnated Foams and Sponges

The Plan considers the use of antimicrobial silver impregnated sponges with negative pressure wound therapy medically necessary when the following are met:

1. The request is part of a complex planned wound reconstruction when ALL of the following are met:
    a. Complete medical records are submitted with a detailed explanation of why this type of sponge is needed; *and*
    b. The culture results of the wound documented bacterial colonization of named organisms (i.e. cannot be "polymicrobial"); *and*
    c. At least 2 cultures documenting colonization that has either remained stable or has had an increase in the number of colony forming units of the identified organism(s); *and*
2. The member meets General Criteria and one Condition-Specific Criteria.

For requests for bioengineered tissue substitutes, please see Oscar Clinical Guideline: (CG030) Bioengineered Skin and Soft Tissue Substitutes.

NPWT with Infusion Therapy (NPWTi) for Home Use

The Plan considers NPWT with infusion Therapy (NPWTi) for home use medically necessary when General Criteria are met AND when ALL of the following criteria are met:

1. NPWTi may be used as an adjunct therapy in any ONE of the following acute, chronic, or infected Condition-Specific wound types:
    a. traumatic wounds; *or*
    b. surgical wounds, including dehisced wounds; *or*
    c. diabetic wounds; *or*
    d. venous leg ulcers; *or*
    e. pressure injuries/ulcers; *or*
    f. wounds with exposed intact bone; *or*
    g. wounds with treated, underlying osteomyelitis; *or*

h. infected or contaminated wounds in the presence of orthopedic fixation hardware; *or*
i. full thickness burns after excision; *or*
j. wounds resulting from evacuation of a haematoma and when haemostasis is achieved; *or*
k. wounds that are a bridge between staged/delayed amputation;*or*

2. NPWTi can be utilized in ventral hernia with wound dehiscence that has exposed mesh to prevent wound infections when ALL of the following are met:
    a. Traditional topical therapies have been tried and have documentation of failure, unless ONE or more of the following is met:
        i. The treatment was initiated in the inpatient setting; *or*
        ii. This was determined to be the best treatment as determined and documented by a medical provider; *and*
    b. Standard NPWT has failed to provide adequate healing as indicated by:
        i. Less than a 20% reduction in length, width, or depth over at least 30 days; *and*
    c. At least 2 sequential cultures show that the bioburden has remained stable or increased with standard NPWT sponges or other non-instillation therapy; *and*
    d. The utilization follows the FDA approved placement times and solution running times; *and*
3. The request is for wounds with ONE of the following:
    a. Appropriately protected organs (i.e no exposed liver); *or*
    b. No exposed blood vessels; *or*
    c. Protected intact bone (i.e. no fracture or exposed hardware); *and*
4. NPWTi can be utilized when ALL of the following are met:
    a. If the initiation of treatment starts in the home care setting or is a continuation of already established therapy at an inpatient facility or outpatient setting (e.g., wound care center, provider office); *and*
    b. NPWTi is for a wound that is chronic (more than 30 days old); *and*
        i. The instillation solution is one of the following:
            1. Sodium Hypochlorite (Dakin's) solution; *or*
            2. Normal saline; *or*
            3. Acetic Acid solution (0.25% up to 1.0%); *or*
            4. Biguanides (Polyhexadine); *or*
            5. Silver Nitrate Solution; *or*
            6. Antibiotics based on documented organisms and sensitivities; *or*
            7. Sulfur based solutions (e.g. Mafenide Acetate); *and*
5. NPWTi should not be requested for any of the following conditions:
        i. Skin Grafts or flaps; *or*
        ii. Cellular, acellular, or bioengineered tissues; *or*
        iii. Wounds where hemostasis is poor.

Experimental or Investigational / Not Medically Necessary

The Plan considers the following conditions as not medically necessary:

- For wounds that are non-traumatic, and not being actively treated with infusion therapy (NPWTi), or otherwise specified in the above criteria (i.e. open fracture), NPWT cannot be utilized for visible tendons, organs, nerves, or blood vessels.
- NPWT is contraindicated if used directly on exposed bone, with or without osteomyelitis.

- NPWT cannot be used on necrotic wounds that have one or more of the following:
    - An eschar, OR
    - More than 20% slough, OR
    - Have not not been or will not be debrided.
- If osteomyelitis is in the vicinity of the wound AND there is no intent to pursue cure.
- If an amputation is planned or scheduled to be performed as a definitive treatment.
- If cancer is present in the wound.
- If an open fistula to an organ or body cavity is within the vicinity of the wound.
- If an enterotomy is draining in the vicinity of a wound.
- If no measurable healing has occurred for the prior 30 days, NPWT should be discontinued.
- The NPWT should be discontinued after a maximum of four months time (including being placed at an inpatient or other acute or subacute facility) regardless of how well treated the wound appears.
- NPWT should be discontinued if the treating provider has determined that it is no longer needed.
- PICO Single Use Negative Pressure Wound Therapy System (Smith & Nephew) for Cesarean Birth Wound Care

Applicable Billing Codes

CPT/ HCPCS Codes considered medically necessary if clinical criteria are met:	
97602	Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (eg, wet-to-moist dressings, enzymatic, abrasion, larval therapy), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session
97605	Negative pressure wound therapy (eg, 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 (eg, 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
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment,

	and instructions 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
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each
E2402	Negative pressure wound therapy electrical pump, stationary or portable

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