

## FINAL Key Questions and Background

### Negative Pressure Wound Therapy (Home Use)

#### Background

Chronic wounds include venous ulcers, diabetic foot ulcers, and pressure sores, with causes that are related to venous insufficiency, pressure, diabetes, vascular disease, and immobilization. Although the causes for chronic wounds vary, in all cases, at least one of the phases of wound healing is compromised. Surgical wounds include clean, closed incisions expected to heal by primary intention as well as wounds that are left open to heal by secondary intention. Negative pressure wound therapy (NPWT), also referred to as subatmospheric pressure wound therapy or vacuum-assisted wound therapy, involves the application of subatmospheric pressure to an open wound with the goal of creating a controlled, closed wound amenable to surgical closure, grafting, or healing by secondary intention. NPWT has also been applied to closed surgical wounds that continue to drain after closure. NPWT is thought to promote wound healing by providing a warm, moist wound bed while removing wound fluid. This removes molecular factors that inhibit cell growth, improves blood flow to the wound, enhances wound oxygenation, and also improves the flow of nutrients to the wound. NPWT may also create mechanical forces that influence the wound macroscopically, by drawing the wound edges together, and microscopically, by exerting mechanical forces on tissue that induce cell proliferation, cell migration to the wound, and angiogenesis.

#### Policy Context

NPWT is used in the treatment of slow or non-healing wounds. Home use of NPWT includes use of a portable device in the home and/or outpatient setting. Concerns are considered medium for safety, medium/high for efficacy, and medium for cost-effectiveness.

#### Scope

**Population:** Patients diagnosed with chronic wounds (e.g., venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers, and mixed etiology chronic wounds) or non-healing surgical wounds

**Interventions:** Negative pressure wound therapy (NPWT)

**Comparators:** Other wound care methods; placebo; comparison of NPWT devices

**Outcomes:** Clinical outcomes (complete wound healing; time to complete wound healing; time to surgical readiness of the wound bed or time to wound closure; proportion of wounds closed; seroma/hematoma; re-operation; mortality; wound healing rate for healed wounds); patient-centered outcomes (return to prior level of functional activity; pain; health-related quality of life); safety (infection rates; extremity amputation; emergency room visits related to the NPWT or treated wound; unplanned hospitalizations or surgeries related to the NPWT or treated wound; blood transfusions/bleeding).

**Settings:** Home or outpatient setting.

**Key Questions**

- 1a. What is the clinical effectiveness of NPWT in the home or outpatient settings for treatment of chronic wounds (i.e., venous leg ulcers, arterial leg ulcers, diabetic foot ulcers, pressure ulcers, and mixed etiology chronic wounds)?
- 1b. What is the clinical effectiveness of NPWT in the home or outpatient settings for treatment of non-healing closed or open surgical wounds (i.e. incisions expected to heal by primary intention or incisions expected to heal by secondary intention)?
2. What are the harms associated with NPWT?
3. Does the effectiveness of NPWT or incidence of adverse events vary by clinical history (e.g., diabetes), wound characteristics (e.g., size, chronicity), duration of treatment, types of device, or patient characteristics (e.g., age, sex, prior treatments, smoking, or other medications)?
4. What are the cost implications and cost-effectiveness of NPWT?

**Public Comment and Response**

See Draft Key Questions: Comment and Response document published separately.