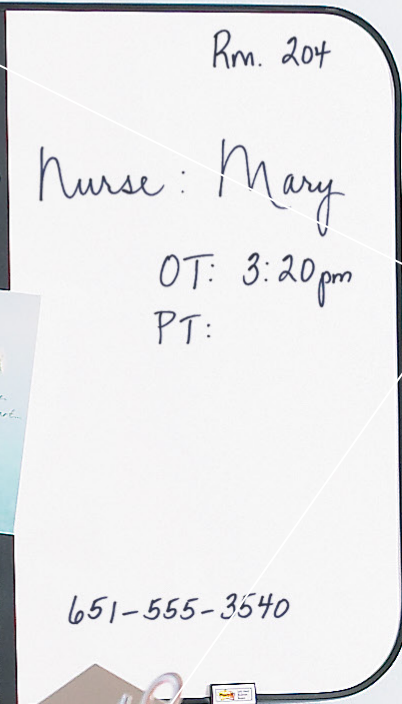


Recommendations for use of Negative Pressure Wound Therapy Systems

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From 3M™ V.A.C.® Veraflo™ Therapy to 3M™ Snap™ Therapy System: Recommendations for use of Negative Pressure Wound Therapy Systems throughout the care continuum in the United Kingdom

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Introduction

3M's family of negative pressure wound therapy (NPWT) systems (3M™ Veraflo™ Therapy, 3M™ V.A.C.® Therapy or 3M™ Snap™ Therapy System) can be used for a wide range of chronic wound aetiologies and patient characteristics. Ideally, selection of the NPWT device and dressing for the chronic wound being treated is based on patient and wound characteristics derived from careful initial assessment. The patient and wound then progress on a pathway toward healing through different care settings, transitioning to the most suitable NPWT system based on ongoing observations of patient condition and wound characteristics.

However, chronic wound healing is an extremely complex process, and these complexities combined with hospital and healthcare system-related factors, such as reimbursement status, can cause deviations from the optimal clinical pathway. Variable patient, wound, and system-related factors all influence NPWT product selection and transition throughout the continuum of care. In addition, options for chronic wound management are ever expanding and varied, which can create confusion about product selection for providers, particularly with respect to transitioning between wound care therapies and care settings.

Methods

An advisory panel meeting was held on 3–4 June 2019 in Gothenburg, Sweden, to identify clinical and reimbursement step-down pathways from Veraflo Therapy to Snap Therapy System for chronic wound management throughout the continuum of care in the United Kingdom. Pressure ulcers, venous leg ulcers, diabetic foot ulcers and post-surgical wounds were chosen as a focus for discussion and development of algorithms, since they are the most commonly seen wounds in wound care practice.¹

This white paper summarises recommendations from the advisory panel members to help guide 'step-down' use of 3M's spectrum of NPWT technologies in managing chronic wounds throughout all care settings, based on wound, patient and hospital/healthcare system factors that influence choice and optimum care in the UK.



Results

Burden of chronic wounds in the UK

Chronic wounds impact the quality of life of affected patients and their families, impose an increased burden on their daily lives and represent significant costs to the National Health Service (NHS). Due to multiple factors including rises in the ageing population, obesity and incidence of diabetes, the frequency of chronic wounds is predicted to increase annually.² Despite progress since 2012 in the management of pressure ulcers, they remain a sizeable healthcare problem, with over 1,300 new ulcers reported each month³ with up to 200,000 people developing a new pressure ulcer in 2017/18.⁴ A study of 2012–2013 NHS data determined there were approximately 730,000 leg ulcers (venous, arterial, mixed, and unspecified), equating to 1.5% of the adult population, and an estimated 169,000 diabetic foot ulcers, equating to 5% of adult diabetic patients.⁵ Annual costs attributable to wound management and associated comorbidities were approximately £5.3 billion, equating to 4% of total 2013 public health expenditures in the UK.⁵

A follow-up study of the same data showed estimated average per patient NHS annual expenditures of £2,638–£4,447 per diabetic foot ulcer, £788–£4,472 per venous leg ulcer, £2,343–£4,186 per pressure ulcer and £3,122–£5,833 per surgical wound after adjusting for comorbidities.⁴ Approximately 78% of costs for chronic wounds were incurred in the community, with the remainder incurred in secondary care (hospitals and specialists).⁴

Factors that influence choice of NPWT system

With the range of available NPWT systems (Veraflo Therapy, V.A.C. Therapy or Snap Therapy System), patients may be transitioned from one system to another as treatment progresses and therapeutic goals change. For example as wound size and/or exudate level decreases, the patient is discharged from hospital to home, and the patient becomes increasingly mobile and/or returns to day-to-day activities. Numerous factors influence how and when a patient transitions through the care continuum with a NPWT system.

Patient condition, wound characteristics, as well as the UK healthcare system and its payment/decision-making policies^{6–8} all influence selection of the NPWT system and the process of transitioning to different products and care settings (Figure 1).



**A study of 2012–2013
NHS data determined
there were approximately**

**730,000
leg ulcers**

Equating to 1.5% of the adult population.⁵



**Estimated average cost
per patient**

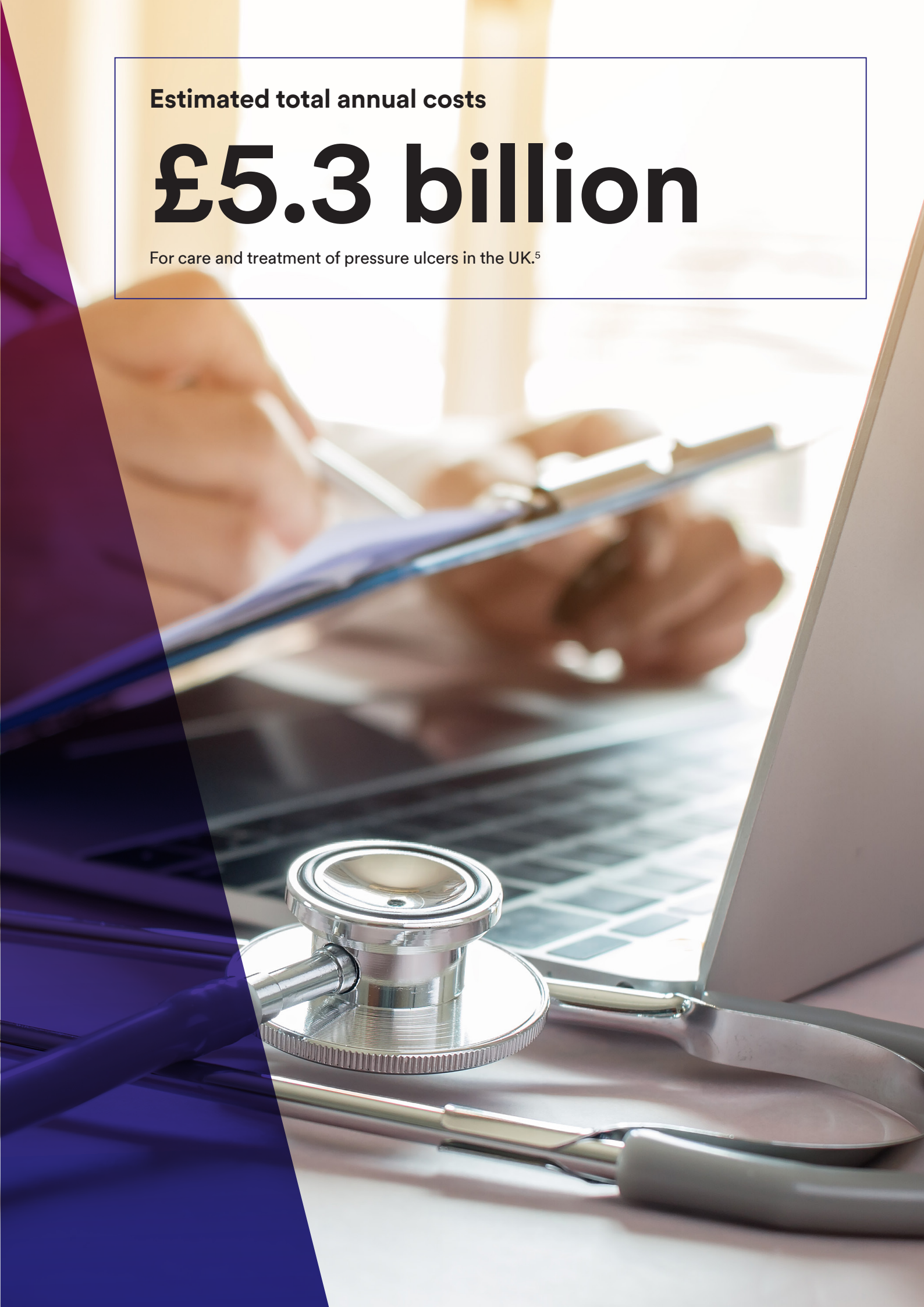
**£2,638 –
£4,447**

Per DFU in UK.⁴

Estimated total annual costs

£5.3 billion

For care and treatment of pressure ulcers in the UK.⁵



Holistic approach for treating all wounds

Panel members stressed the importance of a systematic, patient-centric, multidisciplinary team approach in evaluating each patient at every wound assessment, in order to treat patients and wounds in the most cost-effective, efficient manner. This supports the World Health Organisation's position that interprofessional collaboration in education and practice is key to providing the best patient care, enhancing clinical and health-related outcomes and strengthening the healthcare system.⁹

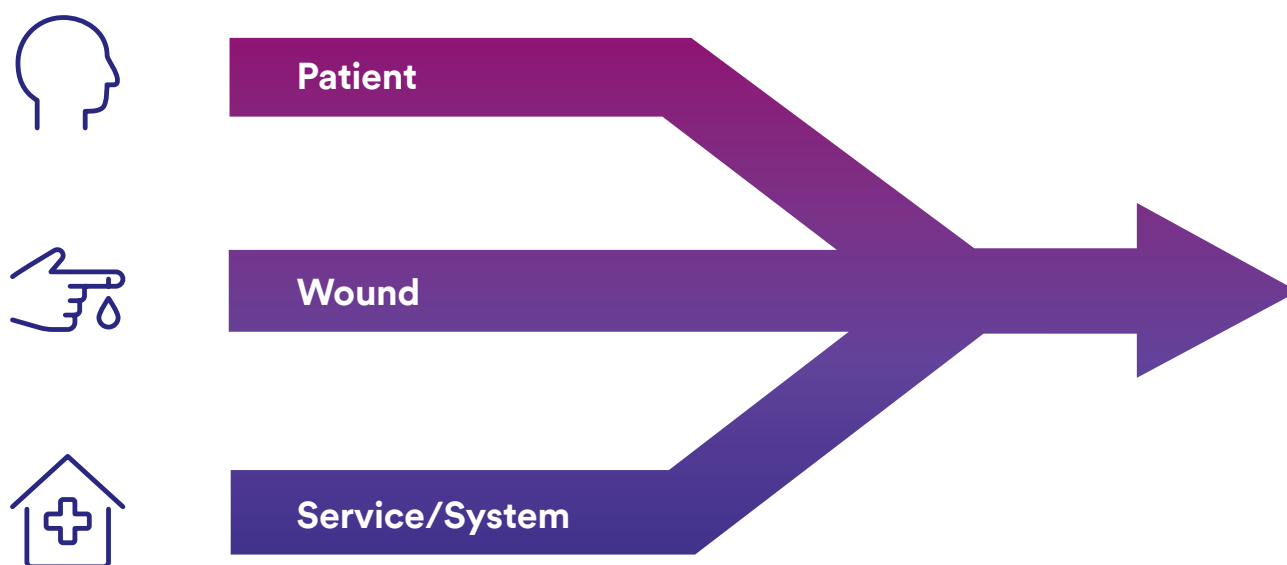


Figure 1. Patient, wound, and service/system are primary influencing factors in wound care decision-making.

Patient and wound

Before treatment, all aspects of the patient and wound should be assessed and the wound-related diagnosis, patient-centred concerns, and risk factors for delayed healing or recurrence should be documented in order to guide the management plan.^{10,11}

- ▶ Medical history should be assessed, including age, nutrition, medications, wound duration, and comorbidities, e.g., diabetes mellitus, obesity, chronic kidney disease, and immunosuppression
- ▶ Quantity and type of exudate should be recorded
- ▶ Peri-wound skin should be assessed for infection, erythema, inflammation and edema, and should be proactively managed
- ▶ The wound bed should be adequately prepared, including debridement of devitalised tissue, cleansing and irrigation as needed if possible
- ▶ Presence of infection should be identified and treated as appropriate
- ▶ Pain should be assessed and managed

Patient- and wound-related considerations per wound type are outlined in **Table 1**.^{14–18}



Pressure ulcer



Diabetic foot ulcer



Venous leg ulcer



Surgical wound

Table 1. Clinical considerations for assessing and optimizing patient and wound condition for healing.^{12–16}

Clinical consideration	Pressure ulcer	Diabetic foot ulcer	Venous leg ulcer	Surgical wound
Patient				
Impaired sensation/neuropathy	X	X		
Urinary and fecal incontinence	X			
Repositioning and mobilisation	X		X	
Full vascular assessment: refer for appropriate vascular diagnostics and revascularisation if needed		X	X	
Critical ischemia		X	X	
Arterial disease		X	X	X
Lower limb edema			X	X
Systemic inflammation	X	X	X	X
Document post thrombotic syndrome or venous insufficiency			X	
Leg elevation as appropriate			X	
Presence of stasis dermatitis				
Wound				
Exposed bone: treat osteomyelitis if present	X	X		X
Exposed tendon		X	X	
Reduction of shear forces	X			
Offloading/pressure relief	X	X		
Exudate management	X	X	X	X
Perfusion and oxygenation	X	X		X
Ongoing use of compression as appropriate			X	
Extension to or exposure of organs/implant	X			X
Presence of undermining or tunneling	X	X		X
Hematoma, seroma or abscess below surface of the incision				X

Wound size and complexity

Generally, patients and wounds with greater complexity are more appropriate for Veraflo Therapy, and smaller, less complex wounds are better suited for Snap Therapy System.

Patient cognitive and physical abilities

The patient's cognitive and physical abilities can influence compliance with any NPWT system. In choosing the optimal NPWT system, it is important to determine the patient's abilities in terms of mobility, occupation, level of compliance, and capability of routinely monitoring the therapy system to be used. Probing the home environment and/or psychological/social issues that would prevent use of the Snap Therapy System is critical for success. Patients with cognitive abilities can be taught to keep the NPWT device on and alert caregivers of leaks. Despite the relative simplicity of Snap Therapy System, this and other therapy units used in the home setting requires patients follow certain steps to ensure proper use of the product, including changing the canister and regular inspection of the unit. Patients who are mobile, active, or who work outside the home, may be well-suited for Snap Therapy System, but patients with dementia or elderly patients with little or no caregiver support may not be good candidates for the therapy.¹⁷

Wound

Establish treatment goals

After a thorough patient and wound assessment and proper diagnosis, treatment goals can be established with the patient. When determining an appropriate NPWT system, treatment goals should be a major focus and can include any of the following:

- ▶ Wound cleansing for bioburden reduction.
- ▶ Wound bed optimisation.
- ▶ Reduction in wound size.
- ▶ Removal of exudate and infectious material.
- ▶ Preparation for definitive reconstruction, e.g., flap or graft.

Determine wound characteristics that help guide optimal NPWT system selection.

General wound characteristics and care setting status that influence transition throughout NPWT product continuum are shown in **Figure 2**.



Transition between different NPWT systems for pressure ulcers

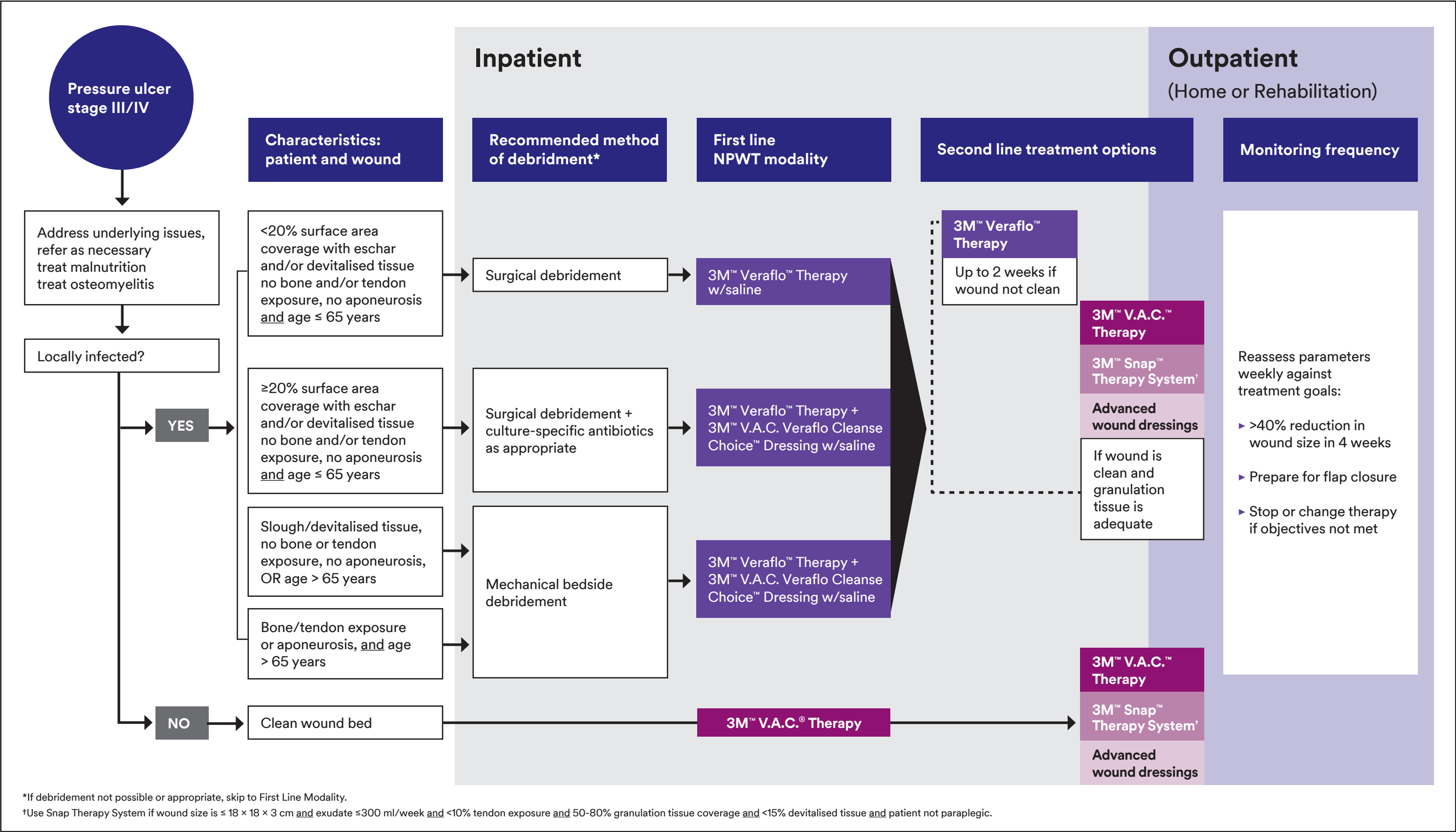


Figure 2. Algorithm to guide transition between different NPWT systems based on clinical and healthcare system considerations for pressure ulcers.

Transition between different NPWT systems for diabetic foot ulcers

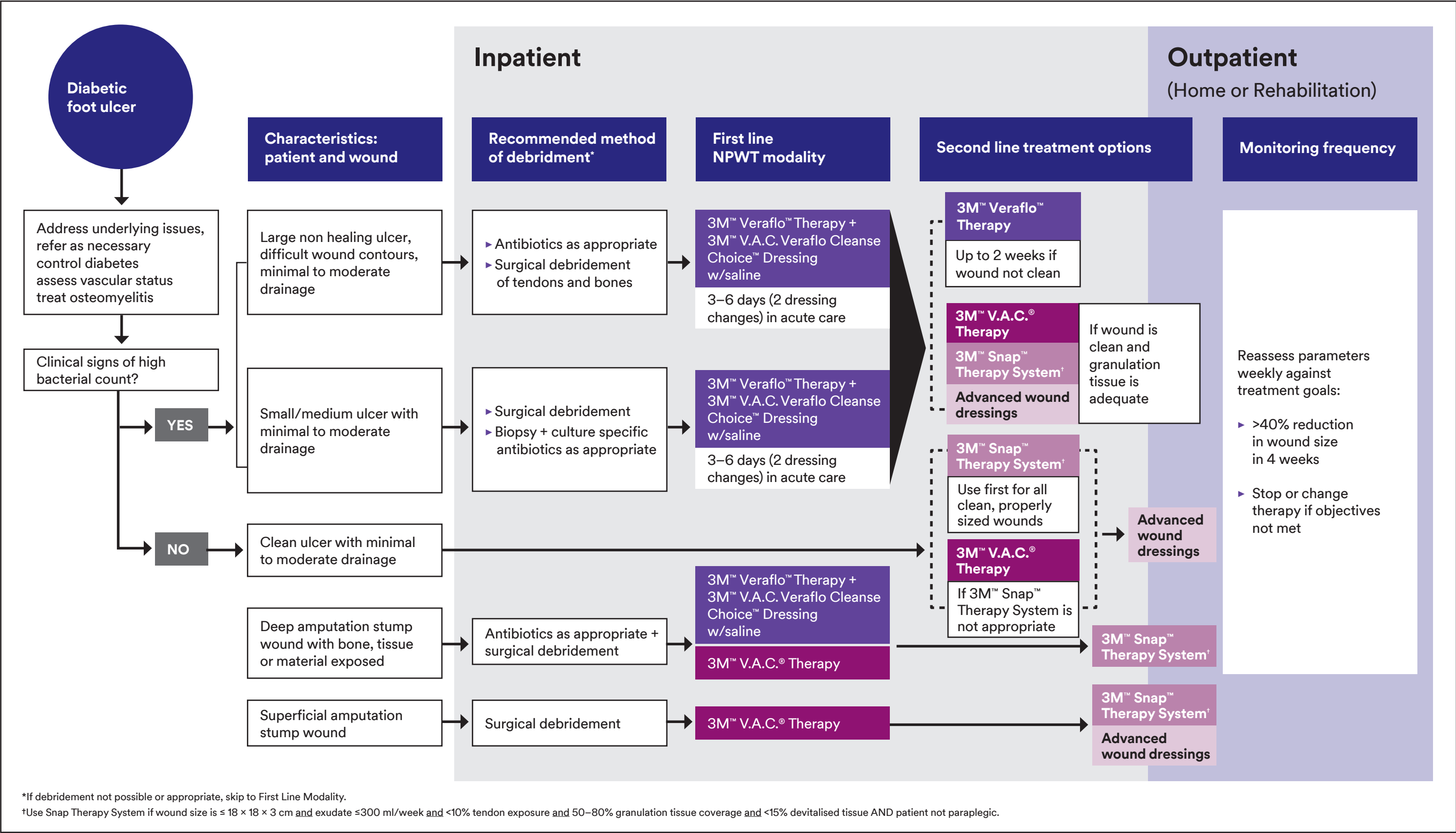


Figure 3. Algorithm to guide transition between different NPWT systems based on clinical and healthcare system considerations for diabetic foot ulcers.

Transition between different NPWT systems for venous leg ulcers

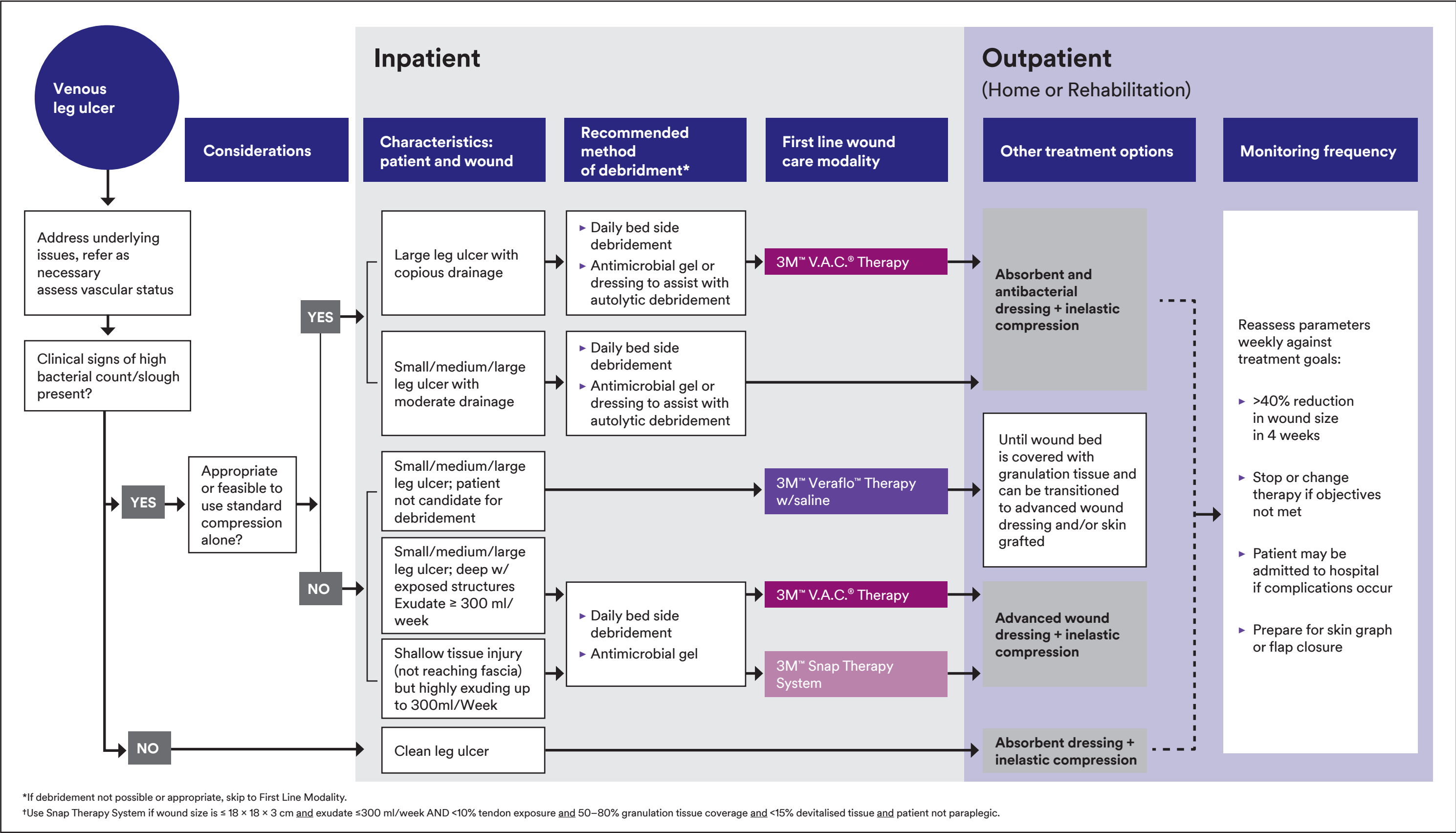


Figure 4. Algorithm to guide transition between different NPWT systems based on clinical and healthcare system considerations for venous leg ulcers.

Transition between different NPWT systems for surgical wounds

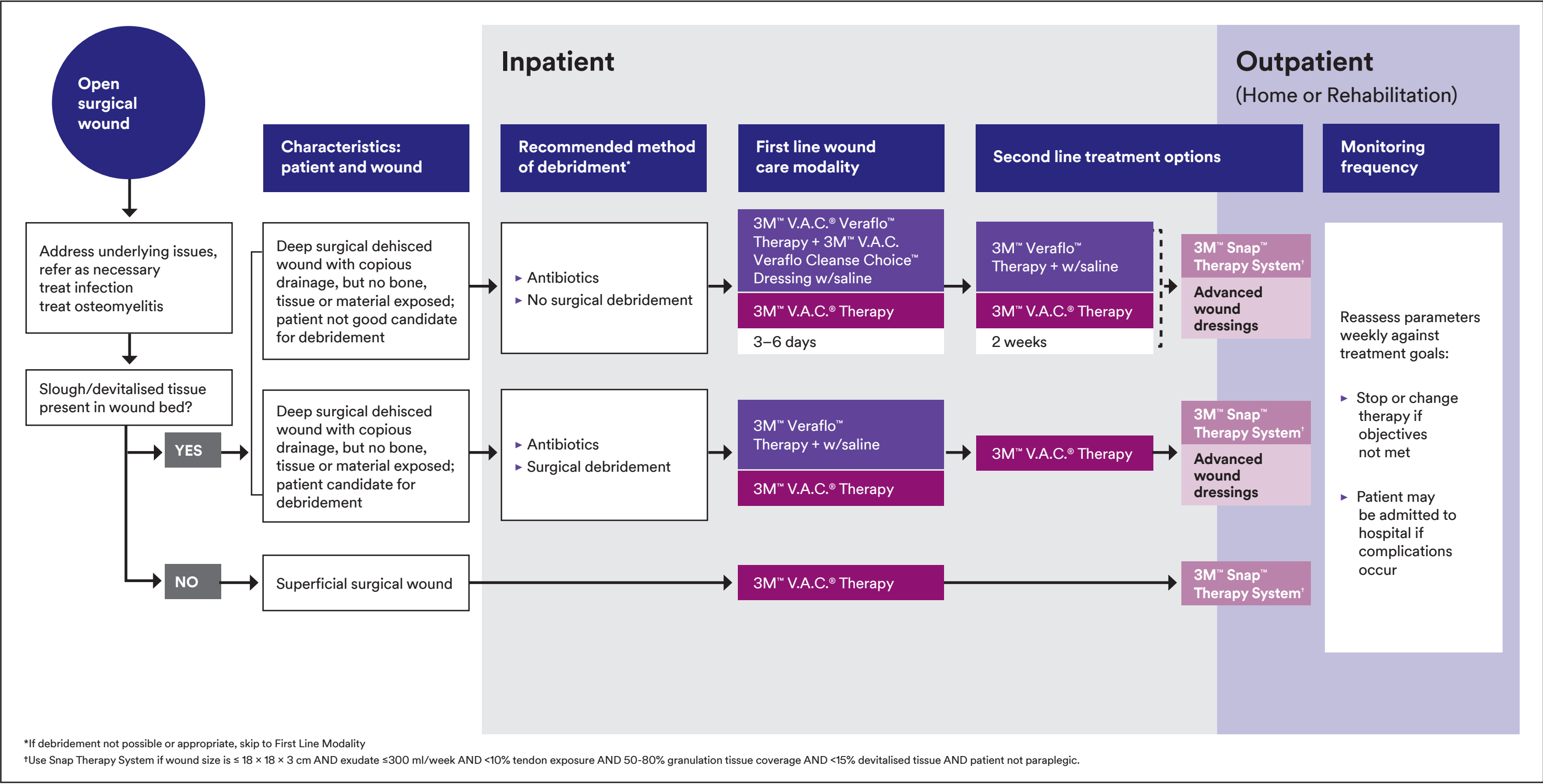


Figure 5. Algorithm to guide transition between different NPWT systems based on clinical and healthcare system considerations for surgical wounds.



Healthcare/Institution system

Healthcare system considerations that may influence use of NPWT systems include national healthcare trends and government payment policies, administrative cost containment, and variable skill sets of healthcare providers.

UK healthcare trends

Although the NHS is often touted as a good example of how universal health care can succeed, the system faces many challenges in supporting good wound care practices. The NHS has been facing severe financial pressures for years, with trusts across the country spending more than they're bringing in.¹⁸ In fact, the UK government does spend a lower proportion on health care versus other EU countries. The result is fewer beds, doctors and nurses per patient in the UK. Ongoing funding problems have led to chronic nursing staff shortages, minimal investment in NHS staff training, rationed access to some treatments, and diluted quality of care in some services. In July 2018, a five-year funding deal was approved for the NHS that will see some health care spending rise by 3.4 per cent on average from 2019/20 to 2023/24, however it doesn't include money for capital investment or training.

The COVID-19 pandemic of 2020 has stretched already thin resources even thinner. While the NHS had been radically mobilised to respond to the acute needs of people infected with the virus, non-COVID-19 health care had been scaled back. Postponement of elective surgeries has created the prospect of a huge backlog in the future.¹⁸ 'Payment by results' has been suspended and replaced with emergency block contracts, as well as a mechanism to ensure hospitals are reimbursed if they overspend.¹⁸ During these unprecedented circumstances, it is impossible to predict a total financial picture for 2020–2021, but the effects may be felt across the entire 10-year lifetime of the NHS Long Term Plan.¹⁹

With a trend toward decreased length of hospital inpatient stays, and with the increased availability of portable NPWT devices, clinicians working in the community are increasingly likely to be involved in the care of patients with wounds being managed with NPWT.²⁰ While there is growing consensus that wound care should be viewed as a specialised segment of healthcare that requires clinicians with specialist training to diagnose and manage wounds appropriately,^{21,22} evidence suggests most wounds in the UK are managed by practice nurses,^{23–25} who lack formal training in wound care. A data analysis of UK wound care patients that showed approximately 30% of wounds lacked a differential diagnosis⁵ is indicative of practical difficulties experienced by non-specialist clinicians.

Members of an NPWT advisory board that recently convened in London agreed that in many clinical settings, NPWT is generally underused in practice in the UK.²⁶ There are a variety of reasons for this, according to advisory panel members, including National Institute for Health and Care Excellence (NICE) guidelines that discourage routine use of NPWT in some wound types,²⁷ a tendency toward treating wounds 'passively', cost and resource/time constraints in the NHS, and a fear among nurses of advanced adjunctive treatments. To increase use of NPWT systems in the UK, the expert group²⁸ stressed the importance of the following:

- ▶ Product/wound care training of nurses and ongoing communication with nurses
- ▶ Encouragement of nurses to take ownership of healing (not just managing) wounds
- ▶ Regular discussions of total wound care costs including benefits gained from progressing a wound to healing in a timely manner
- ▶ Support of a patient-centric multidisciplinary team approach that focuses on addressing treatment goals and achieving healing

NHS payment for acute care and post-acute care

	Acute care payment	Home care payment
3M™ Veraflo™ Therapy	NHSSC Acute Contract/ Provider-absorbed costs	Not indicated for use in the community
3M™ V.A.C.® Therapy	NHSSC Acute Contract/ Provider-absorbed costs	All dressings associated with V.A.C. Therapy are available via drug tariff. The device itself is normally lent from the hospital and therefore, covered from hospital budget. A very small number of units are funded in the community via the CCG, but this is not normal practice.
3M™ Snap™ Therapy System	None	If available on the community formulary, will be prescribed by the district nurses and paid for by payer via Drug Tariff prescriptions from CCGs payer budget. Two Snap Therapy dressings/canisters may be provided at discharge from acute to community setting.



Acute care reimbursement for NPWT

Negative pressure wound therapy is used variably across the NHS and many trusts have purchased or hired negative pressure wound therapy devices. As of 2019, NICE has estimated that 3M™ Veraflo™ technology is being used in 85 NHS trusts across the UK.²⁹ NICE published a Medtech innovation briefing (MIB) in 2019 regarding recommendations and evidence that promote Veraflo Therapy use in chronic and acutely infected wounds.³⁰ According to NICE, costs for the technology may be offset with potential savings related to decreases in dressing changes and nursing time, number of sharp debridements and shorter hospital stays.³⁰



Outpatient reimbursement for NPWT

The acute care trust plays a major role in deciding on the treatment protocols for patients, however it is the clinical commissioning groups (CCGs) that pay for hospital procedures and any continuing care in the community. NPWT use in the community is considered appropriate when the wound has not progressed for 6 weeks or longer, when the wound is being re-dressed three or more times per week, and when the patient has been receiving NPWT in acute care and has been discharged to the community.³¹

CCGs each have their own constitution and governing bodies, and they are accountable to NHS England. There are approximately 211 CCGs throughout England, with different organisational structures in place across Scotland, Wales, and Northern Ireland.³²



Pressure from facility administrators to contain cost

Pressure by the NHS to contain cost can result in denial of use of NPWT for clinically indicated patients based on the cost of the therapy alone. Or for wounds that are particularly well-suited for Veraflo Therapy, such as infected wounds with areas of devitalised tissue, hospital administrators may allow use of V.A.C. Therapy only, since daily materials costs are less expensive. Economic discussions regarding the value of Veraflo Therapy should focus on estimated overall cost of care savings of improving clinical outcomes (reduction in hospital length of stay, faster time to closure, reduced number of dressing changes) versus the daily material cost of the therapy. Overall cost effectiveness with use of Veraflo Therapy has been shown in terms of reduced debridements^{33–37} and length of time to surgical closure^{33–35} compared to NPWT alone or advanced wound dressings. The value of Snap Therapy System is the relatively quick application time,³⁸ reduced dressing changes (twice per week), and support of patient quality of life due to silent operation and small size that allows mobility in order to return to activities of daily living.³⁸



Skill set of health care provider

Successful use of any NPWT System requires training and an environment in which leadership promotes accountability of all clinicians in supporting use of the therapy. In general, of all NPWT systems, use of Veraflo Therapy may require a higher level of clinician skill due to the introduction of solutions and the advanced complexity of the patient and wound. Clinical guidelines have been released to help improve ease of use of Veraflo Therapy;³⁹ also software upgrades have been implemented to make the therapy easier to use. Success with Snap Therapy System depends on the training of both the provider and the patient.¹⁷ Transferring NPWT patients into clinical care environments in which there is high turnover, low accountability, and no NPWT product champion among providers can lead to failure with the therapy.³⁹ Before placement of any NPWT System in any setting, it is important to ensure that the provider(s) have adequate training and capacity to manage it.

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