

SCHEDULE 2 PART A SERVICE SPECIFICATION

Service Specification No.	03/CVDS/0013 v3
Service	Ambulatory Leg Ulcer Service
Commissioner Lead	Clinical Commissioning Programme for LTC
Provider Lead	
Period	1 April 2016 to 31 March 2017
Date of Review	January 2018

1. Population Needs

1.1 National/ local context and evidence base

In the United Kingdom it is estimated that 1% of the population will suffer from leg ulceration during their lifetime. Approximately 60% - 80% of leg ulcers will have a venous component and the remaining will have arterial or mixed arterial and venous disease as well as prevalence increasing with age (SIGN). Chronic venous leg ulceration has an estimated prevalence of between 0.1% and 0.3% in the United Kingdom. The ageing population means that demand for leg ulcer assessment, treatment and management is set to rise substantially.

Chronic venous leg ulcer is defined as an open lesion between the knee and the ankle joint that remains unhealed for at least four weeks and occurs in the presence of venous disease. Venous ulcers arise from venous valve incompetence and calf muscle pump insufficiency, which leads to venous stasis and hypertension. This results in microcirculatory changes and localised tissue ischemia (SIGN 2010).

Leg Ulcer is not a clinical condition by itself. There is always an underlying problem that causes the skin to break down and healing may be delayed by contributing factors.

For clarity diabetic foot/stump ulcers are not considered to be defined as a leg ulcer and should be managed in conjunction with the specialist diabetic foot services, in line with NICE guidance.

A study involving specialist trained nurses following an evidence based protocol found no significant difference in outcomes for patients based on the setting in which they received their care and concluded that the organisation of care and not the setting where the care is delivered, is the factor which most influences healing rates (SIGN section 6)

2. Outcomes

NHS Outcomes Framework Domains and Indicators

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	√
Domain 3	Helping people to recover from episodes of ill-health or following injury	√
Domain 4	Ensuring people have a positive experience of care	√
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	√

Local Defined outcomes:

- 98% of patients to be contacted within 3 working days and offered an appointment within 10 working days of the referral being received i.e. 2 weeks.
- 100% of patients transferred from primary care services into the enhanced service within 15 working days of referral i.e. 3 weeks.
- 70% of patients will be placed on the Standard pathway of care
- Healing rates will meet best practice:
 - 60% of leg-ulcers in the Standard pathway of care.
 - 45% of leg- ulcers in the Complex pathway of care.
- All people with a healed leg-ulcer will be seen for full reassessments 6 monthly and re-ulceration rates within a year will meet best practice -25%.
- People with non-healing ulcers will be managed on an ongoing basis.

3 Scope

3.1 Aims and Objectives of Service

This document sets out the service specification for Leg Ulcer services for ambulatory patients with leg ulceration.

Leg Ulcer services for housebound patients are delivered through the community services. Integrated nursing teams may manage people in different ways and not differentiate between ambulatory and non-ambulatory care. The following groups of patients are more likely to be treated at home and are not included in this service specification. Housebound patient criteria:

- Those who are so elderly and frail or infirm that it prevents them leaving the house;
- Those with severe physical disability that it prevents them leaving the house;
- Those with certain mental health problems which make it difficult to leave the home;
- Those with sensory disabilities especially severe visual impairment; and/or
- Those with profound or severe learning difficulties.

3.2 Service Description/ Care Pathway

This commissioning specification is for

- **ambulatory patients requiring a service for assessment and treatment of a leg ulcer.**

Inter-dependencies with the core GMS service and more specialist services are summarised for information only.

Some patients will be required to be fast tracked into the leg-ulcer pathway and to other more specialist services.

The provider will seek to ensure best, safe practice at all times, and meet quality standards. The provider will take account of the Dorset Carers Strategy to ensure that all carers are fully informed, involved and valued, and that they receive the right support, at the right time in the right place.

3.2.1 Core GMS Services: Basic wound management – THIS IS FOR INFORMATION ONLY AND IS NOT PART OF THIS SERVICE SPECIFICATION

The primary care team provide to both ambulatory and non-ambulatory patients:

- Basic wound assessment; Doppler assessment may be required to inform compression therapy,
- Treatment including compression therapy for approximately 6 weeks, and
- Patient education for all patients with an injury to the lower leg.

Predominantly practice nurses will manage ambulant patients and locality integrated nursing teams will manage the non-ambulatory patients. This level of assessment and care may also be provided by nurses in nursing homes.

An appropriate plan of care will be implemented and the patient will be reviewed on a regular basis, during the 6 weeks post injury period.

Basic wound management consists of assessment treatment and management of patients with:

- No previous leg ulcer
- Wound less than 10cm²
- Wound not present for more than 1 year on presentation
- Reduced in size by 20-40% at four weeks
- Healed within 6-8 weeks

For patients who do not meet the above criteria they will require fast tracking to the leg ulcer service (see 3.2.2)

At initiation of compression, the patient should be assessed for skin complications within 24-48 hours. When considering the type of compression to use, the provider will take into account:

- Patient preference, lifestyle and likely concordance
- Required frequency of application
- Size and shape of leg
- The CCG formulary

If, at 6 weeks, the wound has not healed the patient will be referred into the leg-ulcer services covered by this specification (3.2.3 below). For continuity of care practices will continue to provide basic wound care until the leg ulcer service takes over ongoing care.

Following healing of a leg-ulcer people will be supported within primary and community nursing services. This will include on-going assessment, education and provision of hosiery as clinically indicated. The model of service delivery for these maintenance attendances/clinics will be informed by best practice evidence including the evidence related to social/non-medical approaches.

Maintenance clinics are an essential part of a leg ulcer service as Moffatt and Dorman (1995) suggest that 69% of leg ulcer recur within one year but this can be reduced to 25% with effective prevention strategies. These strategies include review of lower legs, Doppler assessment and prescription of hosiery every 6 months.

Every 6 months people will be formally reviewed within the service covered by this service specification (3.2.3 below). These formal 6 monthly re-assessments are not considered part of the core practice service.

3.2.2 Indications for Fast Tracking to the service covered by this service specification:

A patient who is being fast-tracked to the leg-ulcer service should receive basic wound care as detailed above, within the practice until transfer of care to the leg ulcer service.

A patient can be fast tracked when they:

- do not meet the criteria for basic wound management detailed in section 3.2.1
- have had a recurrence of a leg ulcer
- have evidence of arterial disease
- have a medical history of peripheral vascular disease (i.e. angiogram, angioplasty, Bypass graft)
- have potential malignant disease
- have a medical history of smoking

Suspected arterial leg ulcer signs and symptoms may present with:

- Ischemic pain; patient complains of pain at night, on elevation or cramp on walking i.e. intermittent claudication
- Limb mottled, pale and white
- Limb cold to touch
- Limb pale on elevation, dusky pink on dependency
- 'Punched out' ulcer, cliff shaped edges
- Deep ulcer i.e. tendon visible

On Doppler assessment;

- Monophasic sounds
- ABPI <0.5 – critical ischemia - **referral to more specialist services should be discussed with the Community specialist leg ulcer service.**
- ABPI <0.8 and >1.3
- Unable to occlude blood vessel in affected leg due to arteriosclerosis

The **Community Specialist Leg-Ulcer Service** (referred to as **Level 3** services) should be involved in the treatment planning for all patients with arterial leg ulcers.

3.2.3 Assessment and Treatment of Ambulatory Leg-Ulcers (THIS SPECIFICATION)

This service provides the assessment, management and education to patients' who have:

- a wound to the lower leg that has not healed in the 6 weeks following injury, or
- been fast tracked from primary care services.

This service has two stages;

- Assessment including care planning; and
- Wound management.

Assessment and Care Planning

This group of patients will be assessed by a registered nurse with post registration competencies in leg ulcer management, who has up-to-date knowledge and skills to ensure effective, safe treatment for patients attending the service. This level of the service will provide the following:

Full holistic leg ulcer assessment - which includes:

- ABPI and interpretation (likely diagnosis)
- Blood screening

- Weight, blood pressure, BMI
- Nutritional assessment
- Standardised leg ulcer documentation
- Medical History

Planning of appropriate care to include:

- Skin care
- Review of the wound
- Measurement / photography of the wound
- Full care planning and documentation
- Measurement of ankle and calf circumference
- Application of appropriate dressing and bandage system
- Referral to GP as clinically indicated

Appropriate time allocation

It is envisaged that a full initial assessment will take up to approximately 1 hour. This will vary according to the patients' individual needs.

Recording

The clinical assessment will use an up to date wound assessment tool which will enable audit of outcomes and sharing of information with more specialist services if an onward referral is required.

The Service will ensure:

- 98% of patients are contacted within 3 working days of referral and offered an appointment within 10 working days of the referral being received i.e. 2 weeks.
- 100% of patients will be transferred from primary care services into the enhanced service within 15 working days of referral i.e. 3 weeks.

This means primary care will continue treatment beyond 6 weeks until transfer of care. Sometimes, the leg ulcer may heal within this additional time period and the patient will not need to convert into ongoing wound management. They will however require re-assessments at 6 monthly intervals within this service.

Note: If leg ulcer is not easily diagnosed, patients should be referred **Community Specialist leg-ulcer service** (referred to as **Level 3** services) who will help inform the care plan.

Assessment Outcome

Following assessment the patient will be assigned to either the Standard or Complex pathway of care. Records will be accessible and be able to evidence the rationale for assignment to the Complex Pathway of Care in line with the criteria below. The nature of the likely treatment and care package will be explained to the patient and their informed consent will be obtained. Information will also be given to the patient on good self-care so as to promote healing.

It is expected that 70% of people will be assigned to the Standard pathway of care.

- A Standard Pathway of Care will average a 12 week treatment timescale (excludes basic wound management time in primary care)
- A Complex Pathway of Care will average a 18 week treatment timescale (excludes basic wound management time in primary care)

Criteria for inclusion in the Complex Pathway of Care –

- ☐ Wound has been present for more than 1 year on first presentation to the service
- ☐ Patient has Lymphovenous disease
- ☐ Patient has current infection and/or has history of recurrent infections
- ☐ Patient has elevated protease activity (measured with a recognised diagnostic tool)
- ☐ Wound area is greater than 10 cm²
- ☐ Patient has history of non-concordance
- ☐ Wound has failed to reduce in size by 20 - 40% despite best practice at 4 weeks whilst in the primary care core services

Wound Management

This is the ongoing wound treatment, dressings and bandaging of patients with leg ulcers, following a full leg ulcer assessment, diagnosis and development of a plan of care. Ongoing leg ulcer care will take up to approximately 30 minutes per limb. This will vary according to the patients' individual needs. This group of patients will be treated by a registered nurse with post registration competencies in leg ulcer management, who has up-to-date knowledge and skills to ensure effective, safe treatment for patients attending the service.

This service will provide the following:

Ongoing care to patients who have been assessed and prescribed care including:

- Care delivered in line with the care plan
- Review of the wound at least every 6 weeks
- Completion of care planning documentation
- Application of appropriate evidence based dressings and bandaging in line with the CCG formulary (including 4 layer/multilayer, K2 and short stretch)
- Patient education
- Referral to GP as clinically indicated

At initiation or changes to compression, the patient will be assessed for skin complications within 24-48 hours. When considering the type of compression to use, the provider will take into account:

- Patient preference, lifestyle and likely concordance
- Required frequency of application
- Size and shape of leg
- The CCG formulary

If a patient does not heal or progress within the expected treatment timescales the patient should be referred to the **Level 3** service. If the patient has not healed at the end of the planned Standard or Complex pathway they should be placed on a second pathway which must be considered as a Complex pathway of care. **Level 3** services will provide assessment and treatment guidance during the second treatment pathway, including dressings and bandaging. The practice will retain responsibility for treatment and dressings/bandaging although some treatment may be joint.

Patients who complete 2 continuous pathways of care, the second being a Complex pathway with a maximum treatment of 18 weeks, will be classified as non-healing requiring ongoing care.

The Service will aim to achieve healing rates of:

- 60% for leg-ulcers within the Standard pathway of care
- 45% for leg- ulcers within the Complex pathway of care

Many people will heal within the average Standard (12 weeks) or Complex (18 weeks) pathway.

People can be in a Standard or Complex pathway and be having treatment on 2 or more ulcers on 2 different limbs at the same time and this will still constitute one pathway of care.

Re-Ulceration

Re-ulceration within the average pathway length will not mean people commence a new treatment pathway. For example:

- If a patient is on a Standard pathway and healing occurs at 6 weeks and re-ulceration occurs within the following 6 weeks then they should re-commence treatment within a Standard pathway without triggering a new referral, assessment. OR
- If a patient is on a Complex pathway and healing occurs at 8 weeks and re-ulceration occurs within the following 10 weeks then they should re-commence treatment.

People may re-ulcerate outside of the average pathway length and this will trigger a fast track referral new assessment and Complex pathway of care of care. For example:

- If a person on a Standard pathway heals at 11 weeks and then 6 weeks later re-ulcerates.
- If a person on a Complex pathway heals at 14 weeks and then re-ulcerates 8 weeks later.

It is therefore possible that the same person is treated twice within a quarter. Re-ulceration may be in the same or a different place.

Re-assessment for People with Healed Ulcers

The service will undertake a re-assessment at 6 months and one year after healing to identify patients most likely to re-ulcer and seek to maximise patient compliance with preventative treatment plans. This assessment can be part of the patient maintenance regime and will take account of patient choice.

The assessment may be undertaken face to face or by phone depending on the patients' individual needs.

The service should seek to meet best practice with re-ulceration rates within a year of 25%.

Patients that have developed new ulcers in the preceding 6 months will be within a treatment pathway and will not require an additional six month re-assessment.

Ongoing Care Pathway for Non-Healing Patients

There will be a group of patients that require on-going treatment in services. These will have been:

- Assessed by services;
- Completed a Standard or Complex pathway and not healed;
- Continued in treatment whilst referring to the **Level 3** service for assessment and treatment guidance;

- The second completed treatment pathway will be classified as a Complex pathway and will have not healed at 18 weeks;

It is at this point that people will become classified as Non-Healing.

- The **Level 3** service will notify the commissioner of numbers of people in each provider. They will contribute to/participate in one re-assessment per year with the provider covered by this service specification.

Some patients will heal with longer treatment timescales and concordance and may not require on-going treatment for ever.

Acceptance and Exclusion Criteria

Acceptance criteria are described above.

Exclusion criteria

- People under the age of 18 years.
- People who have dermatological condition including suspected melanoma should be referred to the dermatology services in line with the dermatology pathway.
- People who have diabetes and a foot ulcer should be referred to the diabetes foot clinic services in secondary care in line with the NICE pathway.
- People treated outside the practice by the community nursing team (even when prescribing responsibility sits with the practice)

Days/Hours of Operation

The provider must ensure a comprehensive availability of the service 52 weeks per year, to meet the individual clinical needs.

Level 3; Community Specialist Leg-Ulcer Service (NOT WITHIN THIS SPECIFICATION)

The level 3 service will provide rapid access to advice and guidance on treatment plans for non-healing and arterial leg ulcers. This may involve transfer of photographs to help advise on treatment plans. Relatively few people will be seen in a separate venue by this service unless a specific need is identified.

The service will also provide:

- annual visits to every practice to jointly assess non-healing patients with leg ulcers and provide advice and guidance on treatment plans for other patients requested by the practice;
- an education programme for practice and community nurses delivered across the County at regular intervals throughout the year;
- support the development of leg ulcer clubs across groups of GP practices, non-ambulatory patients and the interface with secondary care.

3.4 Specialist Services (NOT WITHIN THIS SPECIFICATION)

Some patients will require treatment in a specialist outpatient or inpatient setting. Referrals to specialist services for care requiring complex medications and/or bed rest will be made in consultation with the patients GP and involve the community specialist leg-ulcer service **Level 3** service. Community or secondary care hospitals will be considered for delivery of recommended treatment plans.

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3.5 Interdependencies of All services provided to People with Leg Ulcers

- Primary care providers
- Tissue Viability Service
- Secondary care – dermatology, diabetology, vascular medicine and plastic surgery and interventional radiologists
- Community pharmacy and Medicines Management

Any planned sub-contracting arrangements should be discussed and agreed with the commissioners.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE, Royal College

The service model will comply with best practice and it is the responsibility of the provider to ensure implementation of any best practice evidence based guidance. Services will be assessed against National Clinical Strategies, National Institute for Health & Clinical Excellence (NICE) Guidance, and agreed best practice.

Supporting information/References:

1. BMJ - http://clinicalevidence.bmj.com/ceweb/conditions/wnd/1902/1902_background.jsp
2. Leg Club - www.legclub.org
3. Leg Ulcer Forum - www.legulcerforum.org
4. RCN Guidelines - <http://www.rcn.org.uk/development/practice/clinicalguidelines>
5. Tissue Viability Society - <http://www.tvs.org.uk/>
6. NHS Choices - <http://www.nhs.uk/conditions/leg-ulcer-venous/Pages/Introduction.aspx>
7. Map of Medicine - http://eng.mapofmedicine.com/evidence/map/venous_leg_ulcers1.html
8. SIGN - <http://www.sign.ac.uk/guidelines/fulltext/120/contents.html>
9. European Wound Management Association - www.ewma.org
10. Callum N (1994) The Nursing management of leg ulcers in the community: a critical review of research. Liverpool: The University of Liverpool Department of Nursing

4.2 Applicable local standards

Clinical Obligations:

- The professional head of the leg ulcer service must hold professional registration and appropriate specialist training in both theoretical and practical concepts and evidence
- The provider must demonstrate that systems are in place to ensure that competencies are maintained and skills are up to date.
- The provider must ensure that sufficient numbers and grades of staff are employed in order to provide an appropriate skill mix and to ensure the service can be consistently delivered 52 weeks per year in accordance with the service specification.

The provider must supply information in a variety of ways to patients for example, advice leaflets, DVD, visual tools, and a website for patients. Other formats, such as Braille, large print, audio cassette or CD, must be made available if the need has been identified. Facilitate a group approach and expert patient involvement where appropriate and support carers as required. Information should be age and language appropriate.

The provider is required to take account of the Pan Dorset Carers Strategy 2016-2020, which aims to work ensure that all carers are fully informed, involved, and valued, and that they receive the right support, at the right time in the right place.

The provider must encourage self-care and empowering service users to be proactive and involved in the management of their condition

Workforce

In order to work unsupervised, staff must be able to demonstrate that they are knowledgeable and competent in key areas / skills indicated below:

- Fully understand the implications/impact of leg ulcers on patients' health and wellbeing. Patient history taking and clinical assessment
- Assessment of arterial supply by which ever method is used in local practice e.g. Doppler
- Wound assessment
- Appropriate dressing selection and application to achieve wound healing
- Measurement of limbs
- Application of compression system(s) as used locally
- Documentation and effective communication
- Prescribing where required

Non-medical prescribers working within the service must meet Post Registration Education and Practice (PREP) standard from the National Medical Council (NMC) and adhere to the standard operating procedures for prescribing dressings and wound care products.

Support continuing professional development for all staff with clinical leadership and supervision and all clinicians where appropriate to attend regular meetings including MDT for peer support. Clinicians must be encouraged to engage with relevant networks for the management of leg ulcers across the health economy and should be multi professional.

Facilities and Equipment

The Providers facilities / premises must comply with the relevant requirements as set out by the Care Quality Commission and as set out in the Contract for NHS Services

All equipment where appropriate should be regularly maintained to relevant national or international requirements and undergo regular checks (Stage A, Stage B or Stage C checks) in accordance with national recommendations

Equipment and electrical connections should meet the NHS requirements of safety of equipment used with patients and comply with the relevant NHSE recommendations.

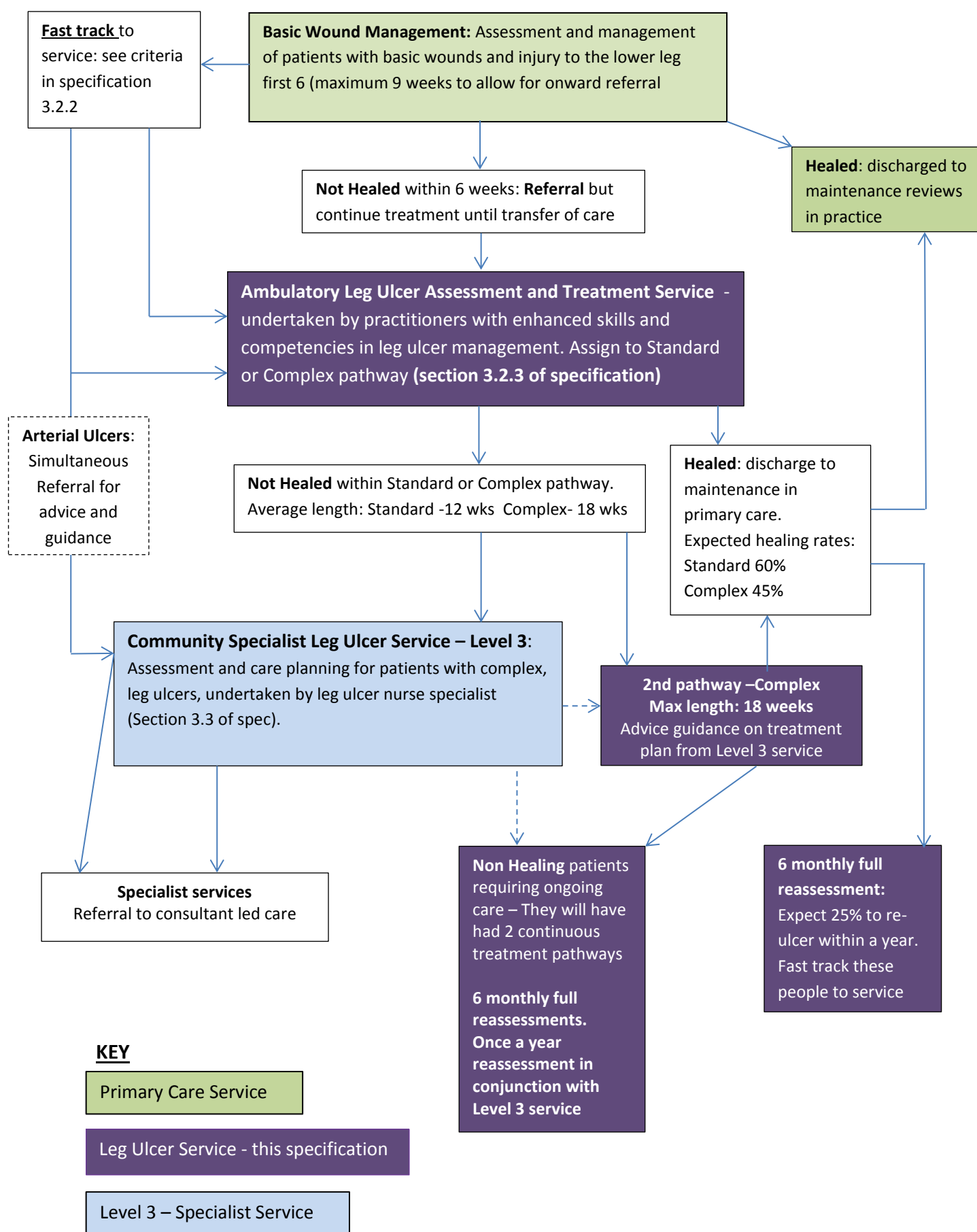
The provider will ensure access to the following more specialist equipment; Doppler and camera.

5. Location of Provider Premises

Location(s) of service delivery

Services will be delivered in a variety of settings identified as being most appropriate to meet the individuals' need, while ensuring compliance with best practice care pathways.

LEG ULCER PATHWAY



GUIDE TO PRIMARY CARE LEG ULCER SERVICE PAYMENT STRUCTURE
(To be viewed in conjunction with the Clinical Pathway)

