SCHEDULE 2 PART A
SERVICE SPECIFICATION

Service Specification No.	**03/CVDS/0026**
Service	**Leg Ulcer Service Pan Dorset, including Levels 2a, 2b and 3 (Ambulatory Patients)**
Commissioner Lead	**Clinical Commissioning Programme For Cardio-Vascular Disease And Stroke**
Provider Lead	
Period	**2014 – 2015**
Date of Review	

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 life. 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 the purpose of this specification a leg ulcer is defined as 'Tissue breakdown on the leg or foot due to any cause' (Callum N 1994).There is evidence of wide variations in the assessment and management of leg ulcers including assessment skills (RCN)

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)

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

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:

- Reduces admissions into secondary care for leg ulcer associated problems, through effective leg ulcer management
- 98% of patients to be contacted within 3 working days and offered an appointment within 10 working days of the referral being received.
- 98% concordance with the care plan at 4 weeks
- A satisfactory patient reported outcome to be reported (TBA)
- Healing times meeting best practice:
    - To heal 70% of venous leg-ulcers care Level 2 within a 12 week period (18 weeks from the start of wound management)
    - To heal 70% of venous leg- ulcers care Level 3 within an18 week period (24 weeks from the start of wound management)

Appropriate referral to consultant led services when required

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 that are registered with a Bournemouth, Poole and Dorset GP.

Leg Ulcer services for housebound patients are delivered through the community services.

- 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
- Those with profound or severe learning difficulties

The commissioned model will provide leg ulcer care that adheres to current best practice

recommendations and will be able to reflect changing health technologies. It will provide a consistently high level of service delivery to prevent people from getting leg ulcers to minimise the length of time people have leg ulcers and reduce the likelihood of recurrence.

3.2 Service description/ care pathway

This section sets each of the 5 levels of the leg ulcer pathway. This commissioning specification is for

- ambulatory patient requiring a service for levels 2a and 2b where Dorset Healthcare is the agreed provider for a general practice registered population
- Level 3, where Dorset Healthcare is the pan-Dorset provider

Levels 1, 4 and 5 are commissioned through existing health services, such as General Practice, community health services, nursing homes, and hospital outpatient and inpatient services.

The care pathway is described as comprising of five levels. However, it is recognised that not all patients will be easily categorised and that there will need to be flexibility between the levels of care. There will be fast tracking of patients into other levels of the service as needed to ensure best, safe practice at all times, and meeting quality standards. The flow diagram describing the pathway is appended at the end of this document

Level 1: Basic wound management (not within this specification)

This level of care is commissioned from both General Practitioners and delivered by practice nurses and the Community Health Services and delivered by Locality Community Care teams, through existing contractual arrangements, e.g. GMS contract, and the community contract. This level of assessment and care is also provided by nurses in nursing homes.

Level 1 will consist of basic wound assessment, treatment and patient education for all patients with an injury to the lower leg. Predominantly practice nurses will manage ambulant patients and Locality Community Care teams will manage the non-ambulatory patients. 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 $10cm^2$
- Not present for more than 1 year on presentation
- Reduced in size by 20-40% at four weeks
- Healed within 6-8 weeks

As part of this assessment, if clinically indicated, Doppler assessment and compression therapy will be applied.

At initiation of 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

If, at 6 weeks, the wound has not healed or progressed, the patient will be referred into level 2a service, The leg ulcer service.

Indications for Fast Tracking:

A patient who has had a recurrence of a complex leg ulcer can be fast tracked into either level 2a or

3. A patient who has evidence of **arterial disease within the six weeks should be 'fast tracked' into level 3** of the leg ulcer service.

Suspected arterial leg ulcer signs and symptoms may present with:

- Ischaemic 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 ischaemia **Refer to level 5**
- ABPI <0.8 and >1.3
- Unable to occlude blood vessel in affected leg due to arteriosclerosis

A patient with a medical history of peripheral vascular disease (i.e. previous arterial leg ulcer, angiogram, angioplasty, Bypass graft), potential malignant disease or a medical history of Diabetes or a smoking history can be **Fast Tracked to level 2a or 3**

Maintenance clinics (part of Level 1)
These should be provided for all patients with leg ulcers that have healed. The review will include, assessment, education and the provision of new hosiery (as clinically indicated) at least every 6 months.* The model of service delivery for the maintenance clinics will be informed by best practice evidence including the evidence related to social/non medical approaches.

* Note: This service provision would cater for maintenance post healing. 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. Callum (1995) estimates that 21% of patients can have 6 recurrent episodes of leg ulcers without maintenance within an effective leg ulcer service.

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Level 2 – (This specification)

Assessment, management and education of patients' who have a wound to the lower leg that has not progressed and or healed in the 6 weeks following injury, or have been fast tracked from level 1 service due to leg ulcer recurrence or signs of venous or arterial disease.

This level has two components:

2a) Full assessment and care planning

This group of patients will be assessed by a registered nurse with post registration competencies in leg ulcer management, who have 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

At initiation of 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

➢ **Full reassessment**
Every 6 months

➢ **Appropriate time allocation**
It is envisaged that a full initial assessment will take up to approximately 1 hour and ongoing leg ulcer care will take up to approximately 30 minutes per limb. This will vary according to the patients' individual needs.

➢ **Quality Assurance and training of level 1 and 2b practitioners**
Contribute, with level 3 providers, to the quality assurance and training programme of level 1 and 2b practitioners.

If a patient does not heal or progress within 18 or 24 weeks of initial onset of the wound the patient will be referred to the level 3 service.

Note: If leg ulcer is not easily diagnosed, to be referred to level 3.

The level 2a service provider, in discussion with the patient, will make an onward referral to the level 2b provider, and with the patients consent share the care plan and determine and notify the level 2b provider whether the patient will enter into either the standard leg ulcer pathway/package – 18 weeks (from the initial onset of the wound) or the complex leg ulcer pathway – 24 weeks (from the initial onset of the wound) as defined below:

Criteria for inclusion in the Complex Care Pathway (24 weeks) –

 Wound has been present for more than 1 year on first presentation to the service

 Patient has Lymphovenous disease (in some circumstances this comorbidity will not necessarily result in a classification of complex and will be agreed with providers/local health economy)

 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 on the Level 1 pathway

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.

The referrer (level 2a service provider) will be informed that the patient has been accepted by the provider of the Level 2b service, given information about the agreed care plan and expected care pathway.

The service provider for level 2a) and 2b) services may or may not be the same.

2b) ongoing wound management

The ongoing wound assessment, dressings and bandaging of patients with leg ulcers, once a full leg ulcer assessment, diagnosis and plan of care have been undertaken by the level 2a or level 3 service.

The level 2a service provider, in discussion with the patient, will make an onward referral to the level 2b provider, and with the patients consent share the care plan and determine and notify the level 2b provider whether the patient will enter into either the standard leg ulcer pathway/package – 18 weeks (from the initial onset of the wound) or the complex leg ulcer pathway – 24 weeks (from the initial onset of the wound) as defined above in level 2a.

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.

This level of the service will provide the following:

- **ongoing care to patients who have been assessed and prescribed care from level 2a, including:**

    - Full wound assessment
    - Planning of appropriate care to include:
        - Review of the wound at least every 6 weeks
        - Delivery and completion of care planning and documentation
        - Application of appropriate evidence based dressings and bandaging
    - Liaison with level 2a service for patients needing shared care
    - Patient education
    - Referral to GP as clinically indicated

At initiation of 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

- **Quality Assurance and training of level 1 practitioners**
  Contribute, with level's 2a and 3 providers, to the quality assurance and training programme of level 1 practitioners.

The patient will be reviewed every 6 months (or as determined by the individual care plans) by the level 2a service.

If a patient does not heal or progress within 18 weeks of initial onset of the wound the patient will be referred to the level 3 service.

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Level 3; Management of complex leg ulcers

Management of patients with complex or problematic leg ulcers, which are either not progressing, eg; not healed within 18 weeks of presentation of wound, or not easy to diagnose.

This level of service will be commissioned from advanced specialist practitioners (Leg Ulcer Nurse Specialists) with additional theoretical knowledge and experience. They will have enhanced skills in assessing and managing patients with leg ulcers.

The service at this level could be delivered in any appropriate care setting.

Patients referred into level 3 will have complex leg ulcer care needs:

- Failing to progress with standardised leg ulcer care (level 1 or 2), for 18 weeks
- Deteriorating without obvious clinical indications
- Practitioners in level 1 or 2 concerned about diagnosis, presentation or symptoms.
- Recurrence of leg ulcer

This level of service will provide the following:

- Specialist nurse patient assessment & review
- Reviewing and prescribing of care at an advanced level
- At initiation of 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

- Patient education
- Referral to GP or into secondary care as appropriate
- Leading the provision of a quality assurance and education programme for all appropriate practitioners in levels 1, 2a, 2b and 4.
- Relevant prevention programmes
- Annual audit of the clinical and cost effectiveness of the service, including service levels 2a and 2b.
- Relevant research pertaining to leg ulceration.
- Practitioners who carry out projection planning of future strategic service developments, to

include development of specific skills i.e. portable Duplex, Biopsy, photoplethysmography.

- Professional leadership of leg ulcer services.
- Effective 'virtual' team working with level 5 providers.

Note: shared care will occur between service providers at levels 1, 2 & 3

Level 4 - (not within this specification)

Management of patients with leg ulcers who have been assessed by the advanced specialist practitioner in tissue viability as requiring bed rest management through an admission to an inpatient service. This level of service is for patients with highly complex care needs requiring complex medications and/or bed rest, which requires an admission to a hospital bed**.** Access to this level of service will be via level 3, in consultation with the patients GP, and the receiving inpatient provider, whether this is community or secondary care hospitals.

This level of service will provide the following:

The level 4 care providers deliver care as set out in level 1 &2b, in addition the service will access appropriate medications and medical input as necessary. Multi-disciplinary involvement will include assessment and care planning. The Multi disciplinary team may include Diabetic podiatrists, Dermatology specialist, Dietetics, Radiologists etc.

Level 5; (not within this specification)

Management of patients with leg ulcers requiring secondary care consultant led management either in an acute in-patient setting or in an outpatient setting.

This level of service is commissioned for patients with highly complex or specialist care needs that require secondary care consultant led management e.g. Vascular surgeon, Dermatologist, Plastic surgeon. Access to this level will be via level 3, in consultation with the patients GP.. This will be a highly complex, acute episode requiring a short term medical, surgical or dermatological intervention i.e. Angioplasty. Angiogram. Surgical debridement. Skin grafting. Amputation. IV's related to Bacteraemia / Septicaemia (if not appropriately delivered in community setting)

NB. Patients with leg ulcers may be admitted into secondary care for reasons other than leg ulcer management for reasons identified as above. E.g. acute admissions for Myocardial infarction, Cerebral Vascular Accident etc. In this instance secondary care will meet all care needs of the patient whilst they are an in-patient.

This service is commissioned through contracts with acute/secondary care providers.

3.3 Acceptance and exclusion criteria and thresholds

The delivery of this service will ensure an equitable service operates to all those registered with a Dorset CCG GP and that individuals are not disadvantaged because of their geographical location or because they are hard to reach.

Acceptance Criteria;

- These are described in 3.2 above

Exclusion criteria

- People under the age of 18 years
- Patients fitting into level one, four and five of the leg ulcer care pathway
- People who have dermatological condition including suspected melanoma should be

referred to the dermatology services in line with the dermatology pathway.

2.4 Interdependencies with other services

- Primary care providers
- Tissue Viability Service
- Secondary care – dermatology, vascular medicine and plastic surgery
- Community pharmacy and Medicines Management
- Any planned sub-contracting arrangements should be discussed and agreed with the commissioners.

2.5 Days/Hours of operation

The provider must ensure a comprehensive availability of the service to meet the individual clinical needs.

2.6 Response time and prioritisation

Patient to be contacted within 3 working days and offered an appointment within 10 working days of the referral being received.

2.7 Discharge criteria

The provider will ensure that as an individual is accepted they will be provided with an estimated date of discharge. Patients will be discharged from care at the appropriate point on the care pathway.

4. Applicable Service Standards

3.1 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.

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The Provider must be registered with and meet approved quality services in line with The Care Quality Commissions regulations and standards (2009)

The provider will be expected to comply with the clinical governance framework for Dorset CCG and to function under agreed operational and clinical policies.

Clinical Obligations:

- If Statutory/Professional Registration is required it must be maintained at all times.
- The providers must ensure that each clinician takes responsibility for maintaining continuous professional development in order to meet requirements of professional registration
- All Clinicians must work within the boundaries of professional registration and relevant professional Code of Conduct.
- 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 in accordance with the service specification.

- All staff will ensure compliance to statutory and legal frameworks implementing service developments in a timely manner as new directives are published

3.2 Applicable local standards

Core requirements for service providers of all levels in the pathway;

Any and all treatments undertaken by the providers as part of the service must be robust, evidence based; clinically effective treatments and the provider must be qualified and registered to provide these treatments with the appropriate regulatory or professional body.

The provider is required to meet, as a minimum, requirements set out in the NHS Contract and the Care Quality Commission 15.

The provider must ensure systems and processes are in place to ensure continuity of care based on clinician, information and treatment.

The service must have a clinical risk management system in place

The provider must ensure that a senior lead clinician with a managerial responsibility takes the lead for the day to day running of the service.

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 must be responsive to people with learning disabilities, mental health problems and those from ethnic minority groups. The provider must ensure all staff undertakes mental capacity training equality and diversity training and conflict resolution training.

The provider must ensure that the best interests of people are maintained through constant evaluation with a system for continuous improvement.

The provider must raise awareness of the service amongst other health care professionals to minimise referral delays.

The provider must fulfil patient and public expectations of:

- Empathetic and compassionate care provision
- Staff who have specialist skills and knowledge with experience and undergo regular training
- Holistic approach, understanding and supporting the impacts of the condition on the users quality of life
- Encouraging self-care and empowering service users to be proactive and involved in the management of their condition
- An Annual patient satisfaction questionnaire to be completed

The Provider must also ensure that the following levels of supervision are provided to the clinical staff team:

- Management supervision
- Clinical supervision
- Safeguarding Supervision

Workforce

The service must:

- Provide fully skilled and trained, appropriately qualified and experienced personnel and provide a competency based training package and regular update training to ensure staff have the required

knowledge and skills to deliver safe and effective practice.

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

The professional head of the leg ulcer service providing level 3 service and providing professional quality assurance to providers of levels 2a and 2b, must hold professional registration with a minimum of 5 years experience and appropriate specialist training in both theoretical and practical concepts and evidence

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.

Identify a governance lead, with responsibility for National Patient Safety Agency (NPSA) alerts. Risk management must include the reporting of all clinical incidents to the NPSA anonymously and have a broadcasting system to all health professionals within the service regarding NPSA, MDA and medication alerts. The provider must demonstrate the evidence on how this mechanism functions. A governance framework should stipulate the operational management, resources and identify staff numbers, title and WTE. Information governance toolkit must demonstrate level 2 and above.

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.

The provider must ensure the safe delivery of clinical services providing a leadership structure and governance that is fit for purpose. The provider will be expected to promote a culture of learning within its organisation ensuring the following are provided:

- Clinical leadership;
- Integrated governance;
- Clinical safety and medical emergencies;
- Incident reporting

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

This is intended as a non-exhaustive list. Clause [16] takes precedence

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.

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6. Individual Service User Placement

[Insert details including price where appropriate of Individual Service User Placement]

Draft Leg Ulcer Pathway Diagram V 5