NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Prescribing Larvae, Unlicensed Medicine Protocol

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Approval Group:	Non Medicines Utilisation Subcommittee of ADTC

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Contents

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Introduction

Larval Therapy

Larval Therapy is a natural form of wound debridement using living Larvae of the green bottle fly species Lucillia Sericata. Larval therapy is indicated for the debridement of necrotic, sloughy wounds including pressure ulcers, diabetic foot ulcers, surgical and traumatic wounds such as haematomas.

The larvae produce enzymes which contain a variety of proteolytic enzymes which break down the devitalised tissue and bacteria into a liquid form which they then remove and digest reducing the bioburden within the wound. They are highly precise in removing devitalised tissue as well as micro massage the wound and stimulate healing. They need to be able to penetrate their 'mandibles' to achieve mechanical debridement, the physical action assists in liquidisation of the devitalised tissue and physical removal of the slough.

Prescription for larvae

All patients with a wound requiring debridement must have holistic assessment, diagnosis and treatment plan initiated to optimise positive patient outcomes.
Larvae are classified as an Unlicensed Medicinal Product. For this reason, clinical staff should be aware of and follow the advice in the Unlicensed Medicines Protocol and Medicines and Healthcare products Regulatory Agency (MHRA) guidance. At present, the following healthcare professionals can prescribe an unlicensed medicine or medicinal product: doctors, independent prescribers and supplementary prescribers (on completion of a Clinical Management Plan). This protocol is to support the appropriate use of larvae across NHS GGC healthcare services.

The larvae must be signed for on receipt by a health care professional. If delivered to a pharmacy or health centre, details of patients address should be included on the script. (Appendix 4) It is considered best practice to ensure that the receiving health centre or pharmacy, is aware that live larvae will be delivered, to prevent risk of inadequate storage temperatures, which may affect viability of larvae, if there are delays in uplifting them for use. Larvae should be uplifted and used on day of delivery.

"All healthcare professionals who can prescribe are subject to: their individual clinical competence; the professional codes and ethics of their statutory bodies; and the prescribing policies of their employers." (MHRA, 2009)

Prior to initiating the prescription of larvae, the clinician prescribing the therapy should be satisfied that an alternative, licensed product would not provide a similar clinical outcome. See Appendix 1 and NHS GGC Wound Formulary . The clinician will take responsibility for prescribing larvae and provision of a plan of care. If other clinicians are involved in the patient care this should be communicated by the prescribing clinician prior to administration to those involved.

If at any time in the process one of the multi-disciplinary team decide that the larvae prescription should not be processed, in favour of a licensed product, it is considered best practice to discuss the rationale for this, with the patient and the originating prescribing clinician or multidisciplinary team.

Patient consent

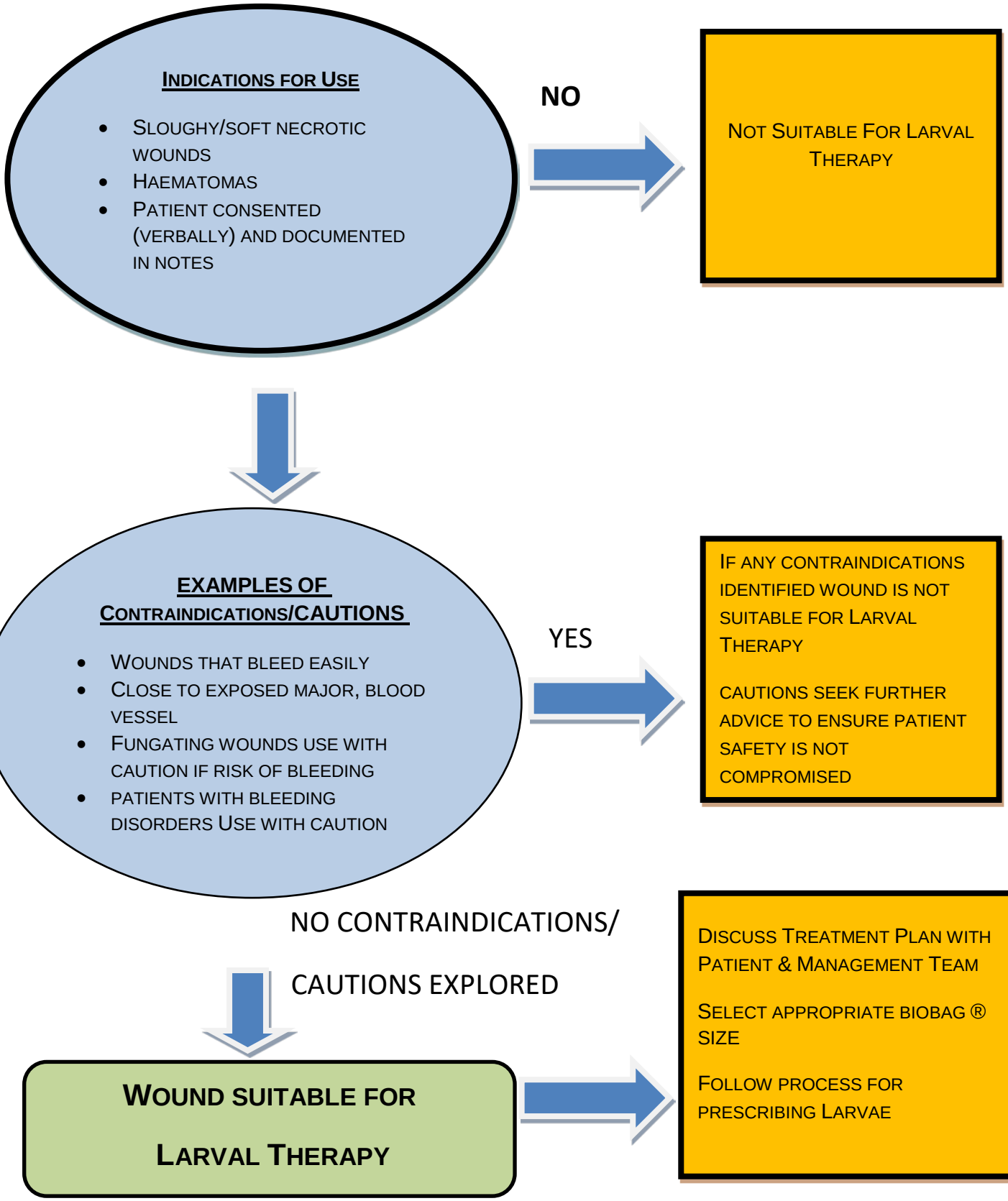
"It is good practice to give as much information as patients or carers require or may see as relevant. (MHRA, 2009). There are no known serious adverse effects in the use of larvae; however, patients must be aware of any common adverse reactions, which may relate to their condition or wound type, to enable them to make an informed decision"

Application of Sterile Larvae

Healthcare professionals are accountable for their practice and when they consider larvae therapy to be optimum clinically effective choice must be competent in the application and ongoing management.

Clinicians, who are involved in the clinical management team and require further support, should contact the relevant service involved e.g. Vascular Liaison Nurse, Podiatrist or Tissue Viability Nurse. Information on correct clinical management can also be accessed on www.biomonde.com.

Larval Therapy Flowchart



Presentation of Larvae

Larvae are available in a heat-sealed mesh pouch (BioBag®). The BioBag® is a sealed mesh bag containing the larvae; it provides ease of application and allows examination of the wound. It is placed directly onto the wound and can be used on almost all wound types.

Products are delivered in a polystyrene temperature-controlled box and should be stored at room temperature until use. Delivery is available Monday to Saturday and can be delivered to Acute Care, Pharmacy and Care Homes.

1. BioBags® are enclosed in a sealed container.
2. Sudocrem® is supplied to protect the peri-wound margins from enzymes produced by the Larvae. Wound should be cleaned with water/saline and Sudocrem applied to wound margins.
3. If patient is allergic to Sudocrem, strips of hydrocolloid can be used to frame the peri-wound margins to protect skin
4. The BioBag® is placed directly onto the wound (see below for details on retention).

Application and daily care guides are supplied with each delivery. A moist gauze swab should be placed over the BioBag® and held in place with a simple secondary non-occlusive dressing applied on top. Refer to NHS GGC Wound Formulary for further information on product choices.

NEVER apply foams, dressings with gelling agents or coated dressings on BioBag®. These will suffocate the Larvae.

Nb superabsorbent dressings contain polymers which gel – use simplest dressing possible, such as gauze swabs to retain BioBag® and ensure any tape to retain dressing does not cause occlusion.

Dosage and duration of treatment:

For guidance on volume or larvae required refer to BioBag® (Appendix 2)

- One or more BioBags® can be applied to cover the entire area of devitalised tissue, taking care not to overlap them.
- BioBags® can be left in place for a maximum of four days, depending on the wound environment and the progress of the treatment.
- The wound should be reviewed on day three as the larvae will have achieved 90% of their potential by that stage; consider prescribing another supply of larvae to reapply on day four to prevent break in treatment.
- Treatment should be discontinued once the wound is suitably debrided, or if minimal or no progress can be observed after two applications.
- If slough on wound continues to reappear between wound management interventions, patient may have inadequate perfusion to wound bed. Consider if vascular intervention is required.

Additional information on application:

Clinical management and patient information leaflets can be obtained from Larval Therapy Specialists Clinicians are advised to access this site prior to use of larvae and seek additional support if required, to ensure that they are working to their level of competency.

To support Continuous Professional Development and evidence for Revalidation/ePortfolio on accredited on line learning for larval debridement therapy access. Biomonde Academy

Acute Care Process for prescribing Larvae via Pharmacy Distribution Centre

Do not prescribe/order larvae direct from BioMonde.

This will be processed by your Pharmacy Distribution Centre

Process steps: Ward or clinical department

1. Larvae must be prescribed on patient prescription chart (Kardex or HEPMA) as with any medication.
2. Complete Larvae Proforma to be delivered to local pharmacy for Pharmacy Distribution Centre (PDC) (Appendix 3)

In order to ensure timely delivery and accurate order ensure all details are complete prior to sending Proforma.

Information required by BioMonde:

Delivery date, place of delivery including full address and postcode, Ward/Clinic Ascribe Code, Patient Initials and what is needed (i.e. presentation BioBag® with size required). (Appendix 2)

The remaining information on form is necessary for GGC internal use.

3. Deliver Proforma and a copy of the prescription form to your LOCAL Hospital Pharmacy Department (local numbers provided on following page)

Process steps: once Proforma sent to Pharmacy Distribution Centre (PDC)

4. Ensure contact telephone number for your area is included in case you need to be contacted to prevent any unnecessary delays.
5. Once this is complete your pharmacy department will email the Proforma to the Pharmacy Distribution Centre (PDC) during working hours, 9am – 5pm, Monday to Friday

Note: it is imperative that orders for larvae are placed with your LOCAL Pharmacy Department no later than 9.30am to ensure delivery the next day

Action required on receipt of larvae:

1. Receiving areas must confirm receipt of larvae by emailing a copy of the delivery note (which will accompany the larvae) to PDC Customer Service Department at the following e-mail address: support@ggcpdc.zendesk.com
2. Queries should be directed to PDC Customer Services at 0141 347 8974.

Contact Numbers for LOCAL Pharmacy Departments (Acute Care)

Delivery of Larvae Order Proforma delivery and contact number for Local Pharmacy Departments.

Hospital Site	Larvae Order Proforma Delivery	Telephone Number
Beatson Gartnavel General	• Internal Mail • Hand Deliver	0141 211 (5) 3315
Inverclyde	• Fax 01475 504930 • Internal Mail • Hand Deliver	01475 504620
Stobhill Hospital Glasgow Royal Infirmary	• Internal Mail • Hand Deliver	Stobhill (satellite) 0141 211 (1) 1653 Royal 0141 (2) 211 5004
Royal Alexandra Hospital	• Pod System • Internal Mail • Hand Deliver	0141 314 (0) 7070
Queen Elizabeth University Hospital	• Pod System • Internal Mail • Hand Deliver	0141 452 (8) 2957
Vale of Leven	• Internal Mail • Hand Deliver	01389 817540 87540

Do not prescribe larvae direct from BioMonde®

1. Medical or independent prescriber may prescribe with completion of prescription form as per procedure for prescribing medication, with prescription submitted to community pharmacist. (Appendix 4)

2. Supplementary prescribers must have a completed Clinical Management Plan (CMP) and follow above steps. The CMP is retained in the patient's notes.

3. In order to ensure timely delivery and accurate order BioMonde must have information on the required delivery date, place of delivery, and what is needed (i.e. presentation BioBag® with code and size required).(Appendix 2)

4. Community pharmacist will order the product from BioMonde and submit the prescription and invoice for payment in the usual way.

5. Delivery of larvae to be arranged between the Community Pharmacist and the Prescriber detailing name and address with postcode of the health centre and named nurse delivery to the relevant health centre.

It is essential that completed prescription details the delivery address as the Health Centre/Clinic/Care Home with post code and NOT patient home to ensure documentation is received and completed by health care professional.

Further information:

1. All Wales Tissue Viability Nurse Forum (2013) All Wales Guidance for the use of larval debridement accessed 13.5.2022

2. Wounds UK (2013): Effective debridement in changing NHS: a UK consensus: https://lohmann-rauscher.co.uk/downloads/clinical-evidence/Effective_debridemen.pdf

3. JWC Wound Care International Consensus Document- Defying hard-to-heal wounds with an early antibio intervention strategy: wound hygiene

4. BioMonde® Applying BioBag (application) accessed 13.5.2022

5. BioMonde Patient Information Guide accessed 13.5.2022

6. Gov.Uk Report a problem with a medicine or medical device (Yellow card) accessed 13.5.2022

7. NHS GGC Acute Unlicensed Medicines Policy (ULM Policy) section 5.7 accessed 13.5.22

8. General Pharmaceutical Council (GPhC): Standards accessed 13.5.2022

9. Health & Care Professions Council (HCPC) Standards of conduct, performance and ethics accessed 13.5.2022

10. Nursing & Midwifery Council: Standards accessed 13.5.2022

11. Royal Pharmaceutical Society (RPS): A Competency Framework for all Prescribers accessed 13.5.2022

Appendix 1: Debridement selection Tool – two pages

This tool can aid you in your choice of appropriate debridement method, reducing risk to the patient, ensuring a positive patient experience, promoting continuity of care, and reducing variations in practice - thereby delivering cost effectiveness. The method of debridement chosen must deliver a patient centred approach taking into account patient issues such as pain, comorbidity and lifestyle choices.

More than one method of debridement may be required for a wound dependent on a number of wound bed factors, including perfusion; to wound bed; presence or absence of infection; stage of hydration and viscosity of slough or necrotic tissue.

Removing barriers to healing through debridement will reveal underlying wound bed, reduce bacterial burden, and promote healthy growth of granulating tissue and wound contraction and support ongoing management plan.

Choice of debridement method does *not* therefore follow a hierarchy from gel to surgical debridement.

For information on NHS GGC wound formulary products noted below refer to https://ggcmedicines.org.uk/other-formularies/non-medicines-formularies/ and this document

Key and definitions

L: Larval Therapy	Larvae debrides and reduces bacterial burden over a period of 3 – 5 days, revealing underlying wound bed. There is no need for additional dressing changes or products.
A: Autolytic: e.g. hydrogel, hydrocolloid and hydrofibre dressings*	The destruction of non-viable tissue by hydration/donation action. Products vary in duration taken to hydrate slough and sequester into dressing. Dressing changes will be dependent on method chosen and level/viscosity of exudate
M: Mechanical Debridement- Debrisoft® monofilament pad (Acute and Primary care) and UCS cloth™ (Acute).	Enables debridement and cleansing of wounds by removing moist slough. Efficacy of debridement is apparent at time of use. Requires wound dressings between changes e.g. hydrofibre dressings to facilitate further debridement and manage exudate.
↑ **GENERALIST USE**	↓ **SPECIALIST USE**
H: Hydrosurgical: Versajet™	Excises and evacuates necrotic tissue, bacteria and contaminants from wounds, using a razor-thin saline jet that spares viable tissue. Procedure can remove all slough/necrosis at one intervention and can be carried out in outpatient department or theatre. Specialist use only.
S: Sharp/surgical:	Use of scalpel to remove slough/necrosis and infected tissue. Specialist use only. May not always achieve full debridement at one intervention. Risk of disrupting viable tissue. Surgery may be required with general anaesthetic to carry out extensive debridement, due to proximity to vital organs/blood supply, pain.
Nb if wound slough continues to reappear between wound management interventions, the patient may require vascular referral to assess perfusion and possible vascular intervention/review care plan.	

2. Assessment of the Wound – selected debridement therapy guidance

L = Larvae **A**= Autolytic **M** = Mechanical

H = Hydrosurgery **S** = Sharp **SU** = Surgical

Suitability of selected treatment choices:

Sloughy wound bed

Thin, watery, white mobile slough			M		S	SU
Stringy, yellow, patchy slough	L	A	M	H	S	SU
Yellow, thick tenacious slough	L	A		H	S	SU
Thick tenacious gum-like slough	L	A		H	S	SU

Necrotic wound bed

Soft islands of necrosis	L	A	M		S	
Soft soggy necrosis	L	A	M			
Black/brown eschar with loose edges	L	A		H	S	
Hard, brown/black eschar firmly fixed		A		H		SU
Haematoma	L	A	M			

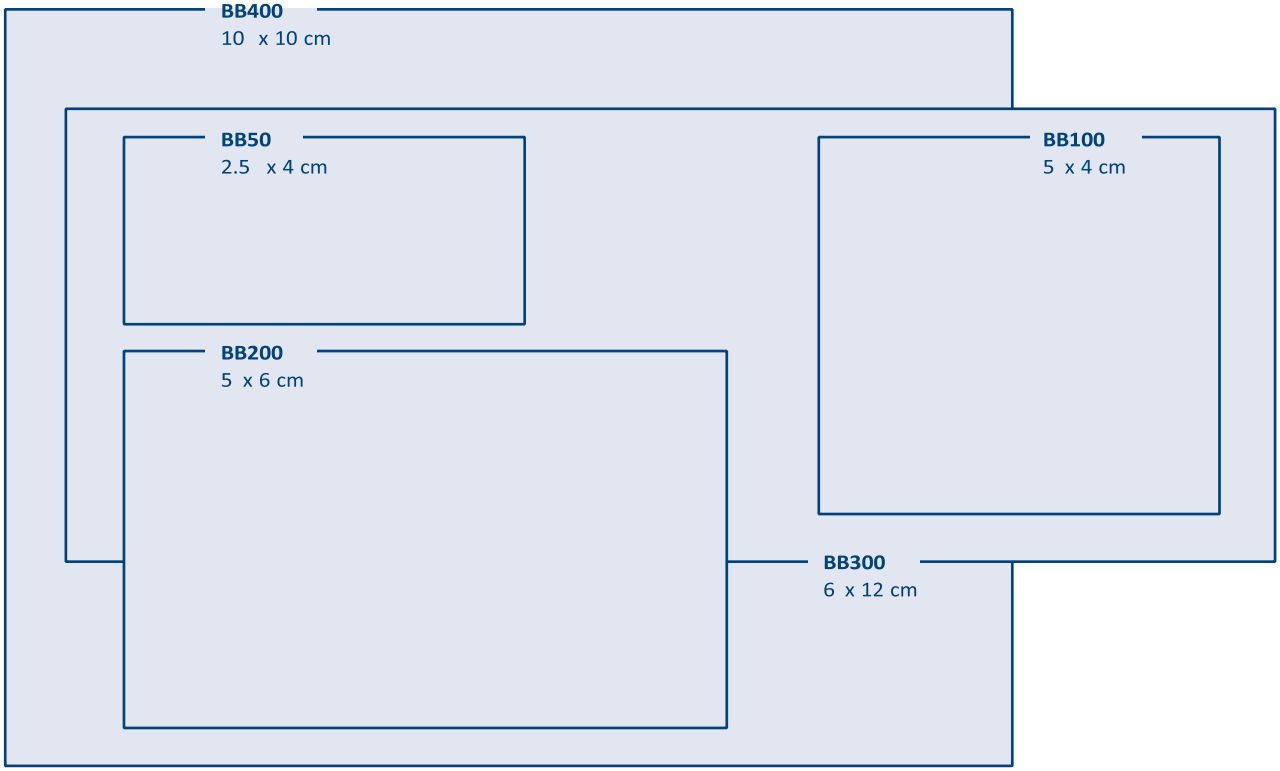
Key Points

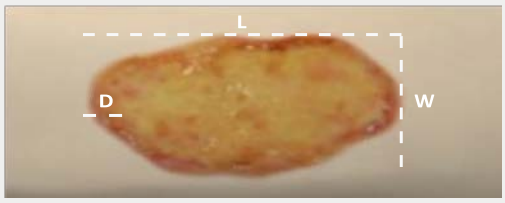
- Remember debridement may remove surface contaminants as well as barriers to healing such as bacteria and dressing residue to reveal wound bed
- Choose appropriate debridement method from above, based on your clinical Judgement
- If wound continues to produce slough or is resulting in unwanted side effects e.g. peri-wound maceration, odour, review if method of debridement is appropriate or consider further referral for investigation of perfusion or underlying cause
- Apply **SIMPLE** acronym to double check correct treatment choice. This should include consideration to cost of debridement choice, number of expected interventions and clinician time.

SIMPLE: Safe, Indicated, Measurable, Patient advantage, Longevity, End point

Appendix 2 Guide to sizes of Biobag

BioBag ® Size Guide





Choosing the right size

- Measure the length, width and depth of the wound
- Cover the wound bed and overlap onto the wound margins
- BioBag ® must have direct physical contact with the area to be treated

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www.biomonde.com

Appendix three: Sample prescription

FORM GP10N

NATIONAL HEALTH SERVICE

Name: Anonymous Patient

Address: 111 Main Street, Anytown

Age if under 12yrs

Postcode

No. of Days Treatment` 4

CHI 0105662145

No. 1111111111

Dispensing

Endorsements

Pack size

Numbers only

Biomonde larvae BioBag x 1

Size 5x6cm

Zoobiotic product code : BB200Ascribe NVS code: **PDC795O**

Delivery address: Possilgreen Health Centre;

62 High Street, Glasgow G21 8YZ

Pack size

Numbers only

Pack size

Numbers only

xxxxxx Extended Formulary Prescriber

A. Smith NMC 99X9999X

Contact number Tel: 9999 999 9999

Please read notes overleaf and complete relevant parts BEFORE going to a pharmacy.

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Appendix 4: order form (acute care)

NHS Greater Glasgow and Clyde

LARVAE ORDER PROFORMA: FORWARD TO LOCAL PHARMACY DEPARTMENT FOR AUTHORISATION

Purchase Order Number .....

To: CUSTOMER SERVICE PHARMACY DISTRIBUTION CENTRE Tel: 0141 347 8974

WARD/CLINIC ASCRIBE CODE:

PATIENT INITIALS:

DELIVERY DATE REQUIRED:

AUTHORISATION SIGNATURE:

REGISTRATION NUMBER:
(GMC/NMC/HCPC/GPhC)

YOUR NAME **YOUR SIGNATURE** **TEL NO:**

ZOOBIOTIC PRODUCT CODE	ASCRIBE NSV CODE	QTY	DESCRIPTION
BB50	PDC793M		Larvae BioBag 2.5cm x 4cm
BB100	PDC794N		Larvae Biobag 5cm x 4cm
BB200	PDC795O		Larvae Biobag 5cm x 6cm
BB300	PDC796P		Larvae Biobag 12cm x 6cm
BB400	PDC797Q		Larvae Biobag 10cm x 10cm

*** Receiving area must confirm receipt by scanning a copy of the company delivery note to support@ggcpdc.zendesk.com ***

Version 1 – 27.03.20