



CLINICAL GUIDELINE

UNLICENSED MEDICINE PROTOCOL: PRESCRIBING LARVAE

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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Prescription for Larvae

Larvae are classified as an Unlicensed Medicine (ULM). For this reason clinical staff should be aware of and follow the advice in the ULM policy and Medicines and Healthcare products Regulatory Agency (MHRA) guidance. At present, the following healthcare professionals can prescribe an unlicensed medicine: doctors, independent prescribers and, supplementary prescribers (on completion of a Clinical Management Plan). This protocol is to support the appropriate use of larvae across GGC healthcare services.

“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 medicine would not meet the patient's needs. (Appendix 1). 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 anytime in the process one of the team decide that the larvae prescription should not be processed, in favour of a licensed product, it is considered best practice to discuss this with the patients and the originating prescribing clinician.

Patient consent

“It is good practice to give as much information as patients or carers require or may see as relevant. (MHRA, 2009) This includes any known serious or common adverse reactions, to enable them to make an informed decision”

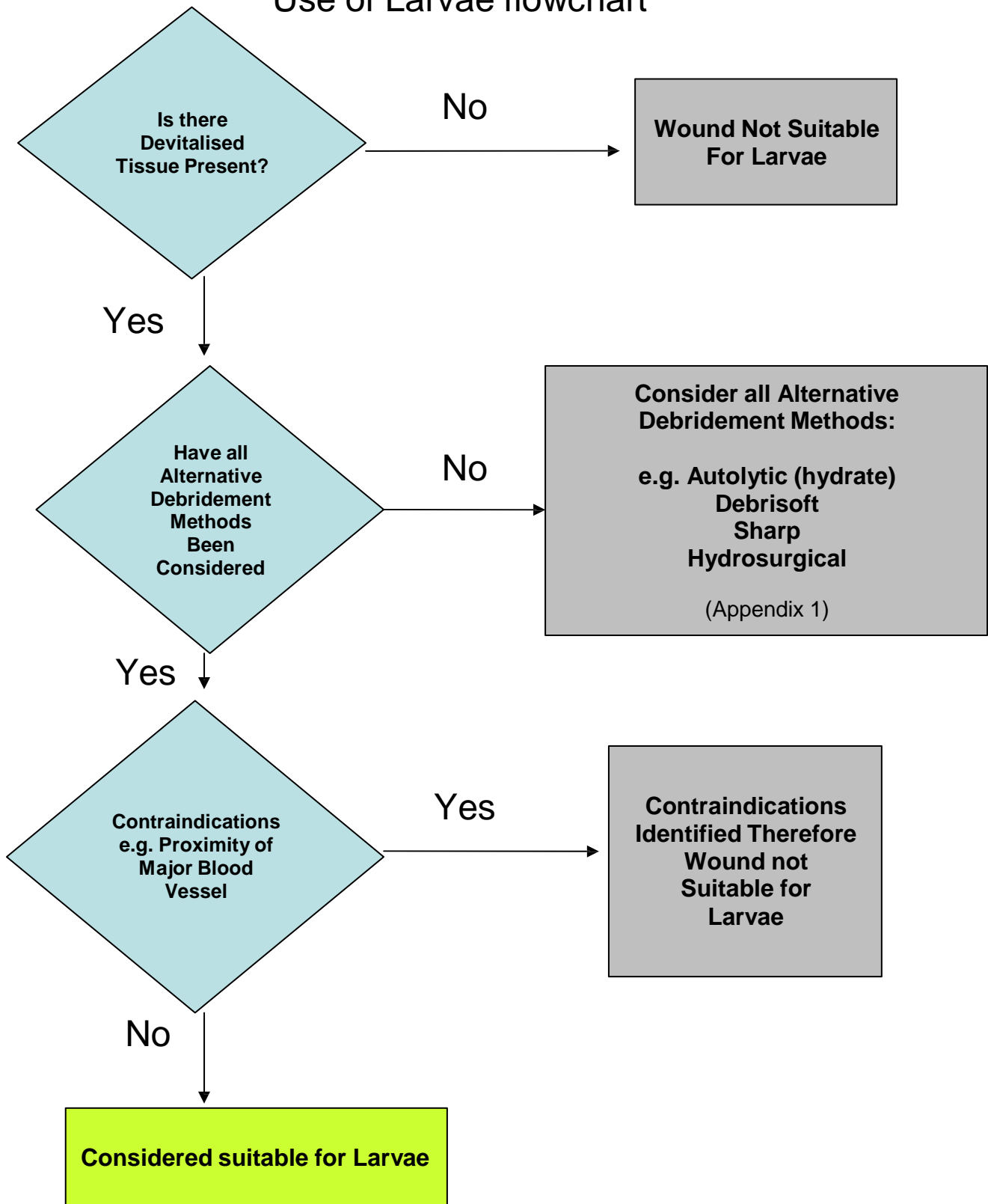
Completion of the unlicensed protocol form should be carried out which reflects that patient consent has taken place and rationale for use. This can be verbal or written.

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, Vascular Liaison Nurse, Podiatrist or Tissue Viability Nurse.

Use of Larvae flowchart



Presentation of larvae: two methods:

1. 'Free-range' larvae are presented in a small container with retention net to place over larvae when applied direct to wound bed. Tape is required to secure edges of net and a secondary NON occlusive dressing e.g. gauze to cover.
2. Bio Bag Application Pack, which contains larvae and can be placed directly on the wound. Sudocrem™ is supplied to protect peri-wound margins from enzymes produced by larvae. A secondary NON occlusive dressing e.g. gauze is required to cover.

Although 'free range' larvae offer a clinical advantage on deep wounds where undermining is apparent, the ease of application and removal of the Bio bag makes these dressings the product of choice for most users of sterile larvae. Both methods are effective in wound debridement.

Additional information on clinical management, patient information leaflets etc can be obtained from Biomonde <http://biomonde.com/en/> or further guidance on larval debridement link to http://www.welshwoundnetwork.org/files/6513/8632/3119/AWTVNFlarval_finalforweb_opt.pdf Clinicians are advised to access this for further information prior to use.

Acute Care Process for prescribing Larvae

Do not prescribe larvae direct from Biomonde

Process steps:

1. Larvae prescription form for the patients record (Appendix 2)
2. Larvae prescribed on prescription chart.
3. Complete Larvae Fax 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 is delivery date, place of delivery, an order number and what is needed.
Remaining information on form is for GGC internal use.
4. Deliver Proforma and a copy of the prescription form to your LOCAL hospital pharmacy department (local numbers on following page) Do **not** use fax number for PDC on order Proforma.
5. The pharmacy authorisation section will be signed following review of form to ensure that Unlicensed Medicine Documentation has been completed
6. Once this is complete your pharmacy department will fax 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.

Contact Fax Numbers for LOCAL pharmacy departments

Delivery of Larvae fax order proforma delivery and contact number for Local Pharmacy Departments.

Hospital Site	Larvae Fax Order Proforma Delivery	Telephone Number
BEATSON GARTNAVEL GENERAL	<ul style="list-style-type: none"> • Internal Mail • Hand Deliver 	0141 211 (5) 3315
INVERCLYDE	<ul style="list-style-type: none"> • Fax 01475 504930 • Internal Mail • Hand Deliver 	01475 504620
STOBHILL HOSPITAL GLASGOW ROYAL INFIRMARY	<ul style="list-style-type: none"> • Internal Mail • Hand Deliver 	Stobhill (satellite) 0141 211 (1) 1653 Royal 0141 (2) 211 5004
ROYAL ALEXANDRA HOSPITAL	<ul style="list-style-type: none"> • Pod System • Internal Mail • Hand Deliver 	0141 314 (0) 7070
QUEEN ELIZABETH UNIVERSITY HOSPITAL	<ul style="list-style-type: none"> • Pod System • Internal Mail • Hand Deliver 	0141 452 (8) 2957
VALE OF LEVEN	<ul style="list-style-type: none"> • Internal Mail • Hand Deliver 	01389 817540 87540

Action required on receipt of larvae:

1. Receiving areas must confirm receipt of larvae by faxing a copy of the delivery note (which will accompany the larvae) to PDC Reception on 0141 445 8758.
2. Queries should be directed to PDC Customer Services at 0141 347 8974.

Primary Care Process for Prescribing Larvae

Process for prescribing larvae through community pharmacist

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.
2. In order to ensure timely delivery and accurate order Biomonde must have information on the required delivery date, place of delivery, an order number and what is needed*.
3. Supplementary prescribers must have a completed Clinical Management Plan (CMP) and follow above steps. The CMP is retained in the patient's notes.
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.

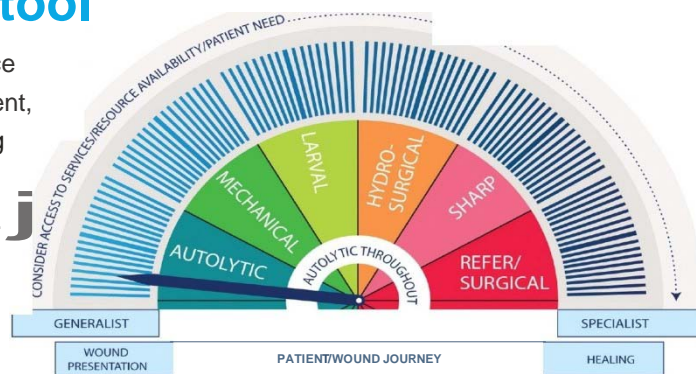
*It is essential that completed prescription details the delivery address as the health centre/clinic with post code and NOT patient home to ensure documentation is received and completed by health care professional.

Further reading and references:

1. All Wales Guidance for use of: larval debridement (2013)
http://www.welshwoundnetwork.org/files/6513/8632/3119/AWTVNFlarval_finalforweb_opt.pdf
2. Information on Use of Larvae: Biomonde - <http://biomonde.com/en/>
3. Wounds UK (2013) Guidelines for practice: Effective debridement in changing NHS: a UK consensus. London. Wounds UK http://www.wounds-uk.com/pdf/content_10761.pdf
4. Griffin J (2014) Wound Care: What nurses need to know about the application of larval therapy. Journal Community Nursing. Vo. 28, No 2, 58-62
<http://www.jcn.co.uk/files/downloads/articles/04-2014-what-nurses-need-to-know-about-the-application-of-larval-therapy.pdf>
5. National Institute for Health and Care Excellence (2015) Debrisoft monofilament debridement pad for use in acute or chronic wounds <https://www.nice.org.uk/guidance/mtg17/resources/the-debrisoft-monofilament-debridement-pad-for-use-in-acute-or-chronic-wounds-64371879418309>
6. Health Care Professions Council (HCPC) Standards of conduct, performance and ethics (2016): <http://www.hcpc-uk.org/aboutregistration/standards/standardsofconductperformanceandethics/>
7. Nursing & Midwifery Council. The Code: Professional standards of practice and behaviour for nurses and midwives (2015) <https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf>
8. Gov.Uk (2009) Off-label or unlicensed use of medicines: prescribers' responsibilities
<https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities>
9. Gov.UK (2015) Report a problem with a medicine or medical device ("Yellow Card")
<https://www.gov.uk/report-problem-medicine-medical-device>

Debridement selection tool

The aim of this tool is to aid the appropriate choice of 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.



Adapted from: Effective debridement In a changing NHS: a UK consensus. London: Wounds UK, 2013.

1. Key and Definitions*

A: Autolytic: The destruction of tissues or cells of an organism by hydration/donation action e.g. use of dressings such as hydrogels, hydrocolloids and hydrofibres.

M: Mechanical: Debriso is a monofilament fibre pad, which enables debridement and cleansing of wounds by rapidly removing wound debris, necrotic material, slough and exudate, as well as hyperkeratotic tissue from the surrounding skin e.g. removes and facilitates the removal of moist slough and debris.

L t Biobag® uses maggots to remove dead tissue and slough from the wound surface. Because of its selectivity for dead tissue, larval therapy is also known as bio surgery.

H: Hydrosurgical: Excises and evacuates necrotic tissue, bacteria and contaminants from wounds, using a razor-thin saline jet that spares viable tissue. Specialist use.

S: Sharp: A surgical procedure that uses scissors, scalpels and other sharp instruments to cut away or remove infected tissue. Specialist use.

E: Emollients

* Choice of debridement is based on clinical judgement and may require more than one method during the debridement process.

2. Assessment of the Wound

Sloughy wound

Thin, white, watery, mobile slough
Stringy, yellow, patchy slough
Yellow/thick tenacious slough
Thick, tenacious gum-like slough
Selected treatments

Tick if applicable

D

A

M

M

L

L

D

D

D

D

Specialist Use

H

H

H

D

S

S

D

Necrotic wound

Soft islands of necrosis
Soft, soggy necrosis
Black/brown eschar - loose at the edges
Hard, black/brown eschar - firmly fixed
Selected treatments

Tick if applicable

D

A

M

M

L

L

L

D

D

D

D

Specialist Use

H

H

D

S

D

3. Assessment of Periwound Skin

Periwound skin

Dry, scaly skin
Hyperkeratosis
Selected treatments

Tick if applicable

D

A

M

M

E

E

D

D

D

D

Specialist Use

D

D

- Remember debridement may remove not only surface contaminants, but also barriers to healing such as bacteria and dressing residue.
- Choose debridement method from above and apply the **SIMPLE** acronym to double check correct treatment choice (this should include both the cost of debridement and nursing time.)

t SIMPLE: Safe, Indicated, Measurable, Patient advantage, longevity, End point

M764 V1.1

Patient detail label

Hospital Site.....

Clinician using Larvae

.....

Consultant / Prescriber

.....

Clinical Rationale for using Larvae

What alternative treatments have been tried prior to Larvae choice, if any?

What is the reason for preferred used of Larvae/expected outcome?

Is the patient or those authorising treatment on patients behalf aware that this is an unlicensed medicine, rationale for use and have agreed to its initiation?

YES/NO

Larvae BioBag / Free range / Size and Qty requested?

Signature of clinician using

larvae.....Date.....

Signature of Consultant /

Prescriber.....Date.....

(Supplementary prescriber Clinical Management Plan to be placed in notes)

Note: Adverse reaction or incidents concerning use of Larvae should be reported through Yellow card System and <http://yellowcard.mhra.gov.uk/> and Datix
Individual patients should have the use of larvae thoroughly explained prior to use and the patient explanatory leaflet issued.

**LARVAE FAX ORDER PROFORMA: ON COMPLETION FORWARD TO LOCAL PHARMACY DEPARTMENT FOR
AUTHORISATION (local site fax numbers - refer to larvae guideline)**

Appendix 3

Purchase Order

To: CUSTOMER SERVICE

PHARMACY DISTRIBUTION CENTRE

Tel: 0141 347 8974

WARD/CLINIC ASCRIBE CODE:

PATIENT INITIALS: DELIVERY

DATE REQUIRED: PHARMACY

AUTH SIGNATURE:

YOUR FULL DELIVERY ADDRESS FOR THIS ORDER:

YOUR NAME

YOUR SIGNATURE

ZOOBIOTIC PRODUCT CODE	ASCRIBE NSV CODE	QTY	DESCRIPTION
BB50	PDC793M		BioBag 2.5cm x 4cm
BB100	PDC794N		Biobag 5cm x 4cm
BB200	PDC795O		Biobag 5cm x 6cm
BB300	PDC796P		Biobag 12cm x 6cm
BB400	PDC797Q		Biobag 10cm x 10cm
STKIT100	PDC405W		Larvae 100 & 30cm x 30cm NET KIT PACK
STKIT200	PDC406X		Larvae 200 & 30cm x 30cm NET KIT PACK
BTKIT100	PDC407Y		Larvae 100 with BOOT RETENSION NET KIT PACK
BTKIT200	PDC408Z		Larvae 200 with BOOT RETENSION NET KIT PACK
STVIAL100	PDC409A		Larvae 100 with RETENSION NET

TEL NO:

ZOOBIOTIC PRODUCT CODE	ASCRIBE NSV CODE	QTY	DESCRIPTION
STVIAL200	PDC410B		Larvae 200 with RETENSION NET
BTVIAL100	PDC411C		Larvae 100 with BOOT NET PACK
BTVIAL200	PDC412D		Larvae 200 with BOOT NET PACK

**** RECEIVING AREA MUST CONFIRM DELIVERY BY FAXING A COPY OF THE DELIVERY NOTE RECEIVED WITH LARVAE TO PDC (0141 445 8758)**