

Larvae Therapy (*BioBag*®) (*TLS amber with shared care*)

Shared Care Guidelines: For the treatment of wounds with Larvae therapy

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Larvae therapy for wounds shared between the Tissue Viability specialist nurse and general practitioner (GP).

GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with the condition are under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the Larvae and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
<ol style="list-style-type: none"> 1 Initiate treatment 2 Discuss the benefits and side effects of treatment with the patient. 3 Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient. 4 Supply GP with summary within 14 days of a patient review 5 Monitor the patient throughout the treatment 6 Review the patient's condition and monitor response to treatment regularly where indicated. 7 Give advice to the GP on when to stop treatment. 8 Report adverse events to the MHRA. 9 Ensure that clear backup arrangements exist for GPs to obtain advice and support. 10 Provide training for community nursing staff to ensure that they are competent in assessing the wound for this therapy, applying, monitoring and removing the larvae.

General Practitioner responsibilities
<ol style="list-style-type: none"> 1 Reply to the request for shared care as soon as practicable. 2 Prescribe larvae at the quantity recommended. 3 Refer promptly to specialist when any loss of clinical efficacy is suspected (e.g. worsening of disease-related symptoms, new symptoms suggestive of disease recurrence or progression) or intolerance to therapy occurs. 4 Liaise with specialist for the following issues 5 Report to and seek advice from the specialist on any aspect of patient wound care that is of concern to the GP and may affect treatment. 6 Stop treatment on the advice of the specialist. 7 Report adverse events to the specialist and MHRA.

Patient's role
<ol style="list-style-type: none"> 1 Report to the specialist or GP if he or she does not have a clear understanding of the treatment. 2 Share any concerns in relation to treatment with medicine. 3 Report any adverse effects to the specialist or GP whilst taking the medicine.

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Email address:
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SUPPORTING INFORMATION

Summary of condition and licensed indications.

The medicine is indicated for:

- **Debridement of devitalized tissues i.e. slough or necrosis**

Treatment Aims (Therapeutic plan)

Larvae therapy involves the use of live, sterile larvae that actively cleanse and debride a wound containing devitalized tissue. The larvae are used in a bag, the product being called "BioBag". So locally, we no longer use "free range" larvae.

This is effective in debriding a wound bed usually within 3-5 days. More than one treatment may be required depending on the extent of the devitalized tissue. The treatment / therapy can be carried out in the patient's own home or in a care setting; this will depend on the site of the wound.

The larvae therapy can be applied by a specialist tissue viability nurse or by a community nurse who has undergone the appropriate training. The larvae produce enzymes which dissolve the devitalized tissue which is then ingested by the larvae (see appendix 2).

This treatment can carry out debridement quickly and efficiently, it can achieve equivalent debridement in 3-5 days compared to 4-6 weeks of using a hydrogel or other conventionally dressings. **Therefore the nursing visits are reduced and the patients' ultimate healing times are quicker.** There is evidence that infection can be resolved by using larvae therapy particularly as the devitalised tissue, which a growth medium for bacteria, is removed.

The care over the 3-5 days of treatment would be carried out by the community nursing team in a shared care arrangement to offer the patient support and secondary dressing change.

Treatment Schedule (including dosage and administration)

The sizes of the larvae Biobags are: 2.5x4cm; 4x5cm; 5x6cm; 6x12cm; 10x10cm

Further information can be found via this link for appendix 1: (<http://biomonde.com/en/hcp/product/biobag>).

Contra-indications and precautions for use

Contra-indications:

Patients on Warfarin
 Patients with malignant wounds
 Blind ended sinus
 Fistula
 Dry necrotic
 Wounds that contain major blood vessels
 Wounds that connect to any internal organs

Side-effects

On rare occasions the use of larvae has caused the wound to bleed. For this reason it is recommended that the dressing is inspected daily. If bleeding has occurred the larvae should be removed and the wound re-assessed.

Although some patients have stated that the use of larvae causes a reduction in wound pain, others have reported an increase in pain following their application. This seems to occur most commonly in patients who have wounds associated with ischaemia.

Monitoring

Parameter	Frequency of monitoring	Action (adjustment and referral back to hospital)
Change of secondary dressing	Daily	
If bleeding occurs	Patients advised to contact HCP in the event of a bleed	The HCP will remove larvae and stem bleeding with a haemostat i.e. Kaltostat

Drug Interactions

Nil

Cost

The sizes of the Biobags are: 2.5x4cm; 4x5cm; 5x6cm; 6x12cm; 10x10cm

The price for these sizes is as follows: £204.09; £234.78; £255.24; £285.93; £306.39
(see link for appendix 1 <http://biomonde.com/en/hcp/product/biobag>).

Ordering from Biomonde via FP10:
BioMonde Ltd.
Units 2–4 Dunraven Business Park
Coychurch Road
Bridgend
CF31 3BG
United Kingdom
Telephone: +44 (0) 845 230 1810
Email: enquiries@biomonde.com

References

- 1 Thomas S., Jones M, Shutler S, and Jones S (1996) Using larvae in modern wound management. *Journal of Wound Care* 5;(2) 60-69
- 2Graham, K (1997) The role of maggots in plastic surgery. *Paper presented to 2nd World Conference on Biosurgery*, Porthcawl
- 3 Sherman RA, Wyle F, Vulpe M (1995) Maggot therapy for treating pressure ulcers in spinal cord injury patients. *Journal of Spinal Cord Medicine* 18 :(2) 71-74.
- 4 Edwards J (1997) Larval therapy in burns. *Paper presented to 2nd World Conference on Biosurgery*, Porthcawl

Date of review

Decemeber 2019

Document details

Date originally prepared: 12.02.2009 By Gill Wicks. Updated
December 2017 by R Hobson & G Wicks.
Document identification: GWTVLarvae
Expected date for review: 12.2019

Appendix 1: See link: <http://biomonde.com/en/hcp/product/biobag>

Appendix 2

**Wiltshire Health & Care
Tissue Viability
Guidelines for Use of Larvae Therapy in Wound Management**

Sterile Larvae (Maggots)

Larvae therapy (also known as maggot therapy or Bio-therapy) has been used for many years, as long ago as the First World War, to debride wounds. This treatment has had a revival since the 1990's due to antibiotic resistance and the potential problems associated with surgical debridement.

Mode of Action

Sterile larvae (maggots) supplied for use in wound management are those of the common greenbottle, *Lucilia sericata*. When applied to the wound they are only about 2-3 mm long, but once in place they produce powerful proteolytic enzymes that degrade and liquefy necrotic tissue which they ingest as a source of nutrient. Healthy tissue is not affected by the maggots although their enzymes can cause excoriation or maceration. In sufficient numbers, maggots are able to eliminate a wide range of wound infections, including MRSA, due to the antimicrobial nature of their secretions and their ability to ingest and destroy bacteria as they pass through their gut. Maggots can help reduce wound malodour and there is evidence to suggest that their secretions stimulate the development of fibroblast cells.

Use of larvae Therapy

- i A full wound assessment must be completed and the choice of debridement method must be documented;
- ii the patient must be fully informed of the choices for debridement and must give informed consent to treatment;
- iii the nurse applying the larvae therapy must have attended a study day and be able to safely apply the therapy;
- iv wounds suitable for larvae therapy:
 - infected wounds
 - wet sloughy or necrotic wounds
 - all wounds types **except** for:
 - dry necrotic wounds
 - malignant wounds
 - fistulae or blind sinus
 - next to a natural orifice (except in a BioBag, see below)
 - wounds that contain major blood vessels
 - wounds that connect to any internal organs.

Warnings and precautions

On rare occasions the use of larvae has caused the wound to bleed. For this reason it is recommended that the dressing is inspected daily. If bleeding has occurred the larvae should be removed and the wound re-assessed.

Although some patients have stated that the use of larvae causes a reduction in wound pain, others have reported an increase in pain following their application. This seems to occur most commonly in patients who have wounds associated with ischaemia.

Ordering the larvae therapy

Larvae are available on FP10 or can be ordered directly from the company Biomonde. See appendix 1: (<http://biomonde.com/en/hcp/product/biobag>).

Locally, Larvae are used in a small fabric bag – 'BioBag'. These bags are placed directly onto the wound surface and can be used for wounds that are close to a natural orifice or in a cavity, as the larvae are contained.

- Check the viability of the larvae and report concerns to the BioMonde Customer Service team prior to application
- The larvae should be cream to beige in colour
- The larvae should be visibly moving however it is possible for them to be sluggish due to the effects of transportation
- Check the temperature strips in the box: do not expose the larvae to temperatures above 25C or below 6C.
- DO NOT REFRIGERATE. Store in the transport container in a cool room until use
- Use the product before the expiration date indicated on the packaging
- For best results apply on the day of delivery

This ESCA should be read in conjunction with the Summary of Product Characteristics (SPC)

Prepared by: Gill Wicks & R Hobson on behalf of NHS BaNES CCG. Update approved by BCAP PTC Jan 18

Application of sterile larvae

i Equipment required:

- wound dressing pack
- bag for disposal of existing wound dressing
- gloves
- hydrocolloid wafer - to form 'border' to wound
- sterile saline - to rinse larvae from container
- moist gauze pads - applied to outside of net to prevent desiccation of larvae
- absorbent pad to cover wound site - exudate production **always** increases with use of larvae.

ii Method:

- Remove existing dressing.
- Cleanse the wound with warm saline if there is any dressing residue present - very **important if the previous dressing was hydrogel**. If any gel remains on the wound, it may kill the larvae..
- Open dressing pack, sterile gauze, hydrocolloid and sterile net.
- Place hydrocolloid around wound like 'picture frame'; if wound is too large for hole to be cut in hydrocolloid then it may be cut into strips and applied to wound edges.
- Cut adhesive tape ready for application to net.

For BioBag;

- Prepare the wound as above with the hydrocolloid frame.
- Apply the BioBag to the wound and then cover with moistened gauze. The bags should be reviewed daily and removed for the wound (put onto sterile field). Wash the wound gently with sterile saline and then reapply the BioBag.
- The bag can be reapplied to wound for 4-5 days.

NB. Do not use film dressings or any dressing that may occlude the oxygen from the larvae or they will die.

Dressing removal:

- Place a yellow clinical waste disposal bag under the wound.
- Remove outer dressings, the BioBag and the hydrocolloid and dispose in clinical waste.
- If the free roaming larvae have been used, remove the outer dressings and then remove the hydrocolloid and net as one unit from the wound site from the top down. This way the larvae will collect at the bottom of the dressing and can be dropped into the yellow clinical bag for disposal. If there are any larvae remaining at the wound site they may be irrigated away using saline. There is no need to cleanse the wound after removal of the larvae. If the wound is debrided, treatment can be changed to conventional dressings. If there is any devitalised tissue remaining in the wound then a further application of larvae may be required.

Acknowledgements

These guidelines have been adapted from the original Wiltshire guidelines and the guidelines written by K Purser, TVSN, Royal United Hospital, Bath.

**Wiltshire Health & Care
Tissue Viability
Patient Information Sheet
The Role of Fly Larvae (Maggots) In Wound Management**

For hundreds of years it has been recognised that the larvae of certain types of flies can have a beneficial effect upon the healing of infected wounds. In the main these larvae found their way into the wound by accident, particularly under battlefield conditions, but it was recorded that when this occurred, the wounds tended to heal more quickly with less complications than comparable wounds that had not been similarly affected. As a result of these observations, in the 1930s larval therapy became very common, particularly in the USA where the larvae were produced commercially in large numbers for this purpose. With the introduction of modern drugs and dressings, however, this method of treatment gradually fell into disuse.

In recent years, for a number of reasons, the use of larvae is becoming popular once again; centers in the United Kingdom and America are using them for the treatment of 'mucky' or infected wounds. In these situations the larvae remove dead tissue and bacteria without damaging the healthy tissue beneath. It has also been suggested that the presence of the larvae may stimulate the wound to heal faster but this has not been confirmed.

The larvae we use have been specially bred to be 'germ free' so they cannot cause any infection. They will not burrow under our skin or penetrate into healthy tissue. You will probably not be aware of their presence although it is possible that you might experience some slight discomfort associated with a tickling sensation.

The potential benefits resulting from the use of larvae are:

- rapid removal of dead tissue
- prevention of infection
- control of odour.