SWL Wound Management Product Evaluation
Standard Operating procedure

Introduction

This document was developed by the SWL Wound Management Steering Group and provides a framework for evaluating wound management products for use in South West London. The aims are:

- To support clinical and cost-effective wound care for all patients within South West London.
- To provide robust evaluation tools to demonstrate clinical and cost effectiveness of wound management products.
- To demonstrate transparency in the decision making process of wound management product selection.
- To provide a consistent methodology of product evaluation for formulary development and management.

Wound Management Product Screening

- The product may be identified via new clinical evidence, literature, education, pricing or indicated by prescribing data. The SWL wound management steering group will decide upon a subgroup, which will screen products for subsequent evaluation areas. If identified by a member of the steering group, they will complete the screening form for the product (with suport from a pharmacist member if required).

- The initial screening tool (Appendix 1) will be used by the subgroup/individual to establish if:
    - There is evidence that the product may provide a clinical equivalence and cost advantage to a product already in use in South West London.
    - The product may be considered as an addition to the formulary to benefit patient care.

- The screening tool will also establish 'fitness for purpose' of the product:
    - Size/range available.
    - Recommended wear time.
    - Cost per day.
    - Quality – CE mark is mandatory.
    - Availability of product established i.e. drug tariff, NHS supply chain, direct from manufacturer.
    - Clinical evidence to support the effectiveness of the product.
    - Functionality of the product against screening criteria i.e. non-patient examination and handling of the product to mimic its use in the clinical situation.

- Depending on the outcome, the product will either be recommended to proceed to clinical evaluation in the nominated evaluation sites by the SWL Wound Management Steering group or the product will not be successful.

Wound Product Evaluation Following Screening

- The aim is to establish the clinical effectiveness of the product in clinical use.

- Process:
    - Clinical evaluation time period will be dependant upon wound care product and setting. Typically 4-8 weeks but can be up to 6 months if necessary.
    - A product range for evaluation will be allocated to one or more local care settings.
    - The site for evaluations and patient inclusion criteria will be agreed by the local subgroup. As part of good clinical practice all patients should be informed of the evaluation, and that feedback would be useful
    - The Wound Product Evaluation Tool (Appendix 2) will be completed at suitable intervals for the products evaluated.

- The subgroup will identify evaluation sites where there are clinicians who are sufficiently involved in wound care provision. Wherever possible, an even distribution of evaluation sites will be used to minimise any bias, however, this may not be practical depending upon the product category. Evaluation sites may include: acute hospitals, community hospitals, patient homes, NHS clinics, GP surgeries and care homes.

- Variations to the Process - Whilst the minimum number of evaluations that are performed is defined as 10, it is acknowledged that this is a subjective number agreed on which a decision regarding the evaluation of a product will be made. However, other variables that will need to be taken into account include:
    - The number of specialist sites suitable to evaluate the product
    - The availability of suitable wound types and/or wound characteristics (as assessed by the clinician performing the evaluation) that meet the criteria of indications for use of the product.

- Identifying Suitable Patients - When deciding to undertake a wound product evaluation, the clinician must ensure that they have selected a wound suitable for the product. Patients' views and opinions are valued and should be reported on the completed evaluation tool.

- During all the processes of wound evaluation codes of good practice relating to privacy, dignity, confidentiality, information sharing and capacity will be adhered to.
- Clinicians should ensure they are aware of any ethical considerations or diversity issues associated with the product that may be of relevance to inform the patients' decision making.

- Products for evaluation will be requested or prescribed as per local policy

- In addition to responsibilities above, manufacturing company representatives may be asked to support training on evaluation product use. Manufacturing company representatives are advised not to contact evaluation sites unless requested to do so for a specific purpose.

- The use of the evaluation wound product should be discontinued:
    - At the patient's request
    - If there is any deterioration and/or reaction that is attributed to the wound product, it should be stopped immediately and if appropriate, reported via The Suspected Adverse Drug Reactions MHRA (yellow card system) and an incident form completed.
    - If the wound product is found to be inferior to an existing product on the current wound formulary it must be discontinued, detailed on the evaluation form and an alternative product prescribed.
    - If the evaluation period has been completed the product used should be discontinued. However, if there are improved outcomes for the patient then the product can be continued, although further supplies must be prescribed and/or ordered in the usual manner for that service.
    - The products supplied for the purpose of the evaluation must not be used on any other than the identified patients.

Outcome and Decision-making

- All feedback regarding the evaluation and the completed evaluation forms should be given to the subgroup. The results will be correlated by the subgroup and discussed by the South West London wound management steering group. At no point should any separate manufacturing company evaluation tool be completed nor should any verbal feedback or a copy of the evaluation tool be given to the manufacturing company.

- The final decision rests with the South West London wound management steering group regarding the outcome of the evaluation. The evaluating subgroup can submit an opinion based upon the evaluations completed.

- The SWL wound management steering group will make a recommendation to South West London Joint Formulary Committee for ratification based upon the

clinical effectiveness, service provision and cost of the product, as to whether it will be included in the South West London Joint Formulary.

Document History

Version: V 2

Author: **South West London Wound Management Steering Group**

Approved by: SWL Integrated medicines optimisation committee (IMOC)

Approval date: **17/04/2024**

Review Date: 2 years from approval date or sooner where appropriate.

APPENDIX 1 - Wound Product Screening Tool

Date **Company**	
Product	**Potential Formulary Category**
Key Functions and Aim of Product (See Manufacturers Information Form)	
Quality Does the product carry a CE mark in accordance with the Medical Devices Directive (93/43 EC)? **Yes/No**	
Availability Drug Tariff† Available via hospital/pharmacy† Other†	
Education to use the product Is any training/ education required to support the use of the product? If so what level of support from the manufacturer is available? See manufacturers information form	

Fitness for Purpose of Wound Product	Details
Functionality (state e.g. adherence, absorption)	
Strength of Clinical Evidence Summary*	
Any special precautions/ethical considerations (e.g. any constituents derived from animal or blood products, latex or nuts)	
Size range available	
Recommended wear time	
Estimated cost per day (average cost of 7 days wear time using 10 x 10cm dressing if possible)	
Ease of use/handling	
Additional qualities depending on category (state)	

Is the product to proceed to patient evaluation? Yes/No

Rationale…….....

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***Hierarchy of evidence for use during screening process**

Levels of evidence for intervention studies (NICE 2008)

1++ High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1− Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++ High-quality systematic reviews of case–control or cohort studies; high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal

2+ Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2− Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal

3 Non-analytical studies (for example, case reports, case series)

4 Expert opinion, formal consensus

NICE (2008) Surgical site infection prevention and treatment of surgical site infection. National Collaborating Centre for Women's and Children's Health. Commissioned by the National Institute for Health and Clinical Excellence

APPENDIX 2 – Wound Management Product Evaluation Tool

On completion of evaluation send completed patient forms to:

Product:				
Evaluator:				
Organisation:				
Site/health centre/care home:				
Speciality:	Hospital nurse ☐ Community nurse ☐ Podiatrist ☐ TVN ☐ Practice nurse ☐ Nursing home ☐			
Date evaluation commenced:				
Clinical evaluation must be returned by:	**(Date of completion)**			
Size of dressing……. Adhesive ☐ Non Adhesive ☐				
Duration of wound:	Less than 2 weeks	☐	3 – 6 months	☐
	2 – 4 weeks	☐	6 – 12 months	☐
	1 – 2 months	☐	12 – 24 months	☐
	2 – 3 months	☐	Over 24 months	☐
Wound Type Pressure Ulcer ☐ Leg Ulcer ☐ Trauma ☐ Burn ☐ Fungating Lesion ☐ Surgical ☐ Diabetic Foot Ulcer ☐ Other ☐ state ……				

Compression in situ **Y/N**
Predominant Tissue Type (please indicate %) Necrotic …...% Slough ……% Granulating …...% Epithelialisation …...% Healed/Intact ……% Surrounding skin condition ……
Reason for using dressing (tick all applicable) Absorption ☐ Hydration ☐ Odour Control ☐ Minimise pain ☐ Non adherence ☐ Control bleeding ☐ Desloughing ☐ Protection ☐ Reduce bacterial load ☐ Other ☐ state……
Was the product used as: Primary ☐ or Secondary ☐ dressing?
Was the product used in combination with any other dressing? **Y / N** (If yes, please state)

Wound Care Product Evaluation Tool – to be completed at each dressing change

Please score the wound care product effectiveness using the following criteria:

0 =Does not do this at all, 1 = Partially does this, 2 =Mostly does this, 3 = Completely does this, N/A = not applicable.

Date of dressing change								
Absorbed exudate and locked it away from the surrounding skin								
Hydrated the wound bed								
Visual removal of slough								
Conformed to wound bed								
Controlled odour (where applicable)								
Controlled bleeding (where applicable)								
Surrounding skin remained healthy								
Pain on application (0-5)								
Pain on removal (0-5)								
Acceptable to patient								
Product met expected performance								

	Yes	No
Were the instructions for use clear/understandable?		
Was the dressing easy to apply?		
Did the dressing detach prematurely?		

Did the dressing need additional fixation?		
Did the dressing cause any skin damage on removal?		
Did the dressing need hydration to aid removal?		

Would you consider this product for inclusion in the wound formulary? Y/N

Reasons:

Would you recommend this product replace the existing product within its category in the wound formulary? Y/N

Reasons:

If the evaluation had to be discontinued please state date and reason why:

Evaluation completed by:

Designation: **Date evaluation completed:**

Appendix 3 - Wound Product Final Evaluation

Company	
Product	
	Comments
Summary of screening (Refer to Appendix 1)	
Summary of evaluation (Refer to Appendix 2)	
The above product has been evaluated with the recommendation that it **will** ☐ **will not** ☐ be included within the SWL Joint Formulary **Rationale:**	
Date: **Completed by SWL Wound Management Steering Group**	