329 | June 2023 | 2.0

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Appliance Formulary Development

£868 million annually is spent on prescribed appliances in England, Scotland, Wales and the Isle of Man (NHSBSA April 2022 to March 2023) and Public Health Scotland (March 2022 to February 2023).

Local wound care, continence and stoma formularies provide a means of improving the clinical appropriateness and cost-effectiveness of appliances prescribed or supplied by the NHS, and they can help to reduce waste by ensuring that the correct products are prescribed in appropriate quantities. This bulletin aims to support appliance formulary development and maintenance.

Tools to support this process are also available as attachments.

Recommendations

- Develop local appliance formularies for wound care, continence and stoma care that reflect local needs, reduce variation in prescribing and support the selection of appropriate, cost-effective products.
- Recognise that, although there is overlap in how such appliance formularies may be developed, the clinical areas they cover are distinct and different approaches may be needed.
- Assemble a formulary decision-making group with a locally defined mix of members who have the range of skills and expertise needed to undertake all necessary activities.
- Implement a whole systems approach to formulary development, rather than producing a simple list of medicines or appliances.
- Include clinical groups and networks, patients or patient representative groups, local people and communities, product manufacturers where appropriate, and other relevant decision-making groups in local formulary stakeholder engagement.
- When calculating the cost of appliances, consider all aspects of the patient pathway and not simply the unit cost of the product alone.
- Regularly update, review and maintain local formularies to ensure they meet the needs of patients.
- Define how formulary adherence and other indicators will be monitored, and the frequency of monitoring.
- Practices should review how appliances are managed within their repeat prescribing system and make improvements where change is needed.
- Organisations contemplating procuring appliances via a non-prescription route must consider a number of factors in assessing its cost-effectiveness. These include the impact on patients, potential need to go out to tender, the implications for local community pharmacies, VAT implications, ordering, delivery, storage and monitoring.
- Organisations who have (or are considering having) a manufacturer-sponsored continence or stoma nurse working locally should ensure that the agreement does not promote conflicts of interest that could lead to poor practice. For example, the specialist nurse should not be required to recommend the sponsor's products in preference to other clinically appropriate appliances and the arrangement should not require that patients are recommended to use a particular dispensing service.

Background

The National Institute for Health and Care Excellence (NICE) defines a local formulary as 'the output of processes to support the managed introduction, utilisation or withdrawal of healthcare treatments within a health economy, service or organisation'.[1]

NICE states that the benefits of local formularies may include:[1]

- Improving patient outcomes by optimising the use of medicines.
- Supporting the inclusion of patient factors in decisions about medicines.
- Improving local care pathways.
- Improving collaboration between health professionals and commissioners.
- Improving quality by reducing inappropriate variations in clinical care.
- Improving quality through access to cost-effective medicines.
- Supporting the supply of medicines across a local health economy.
- Supporting financial management and expenditure on medicines across health communities.
- Supporting prescribers to follow guidance published by professional regulatory bodies in relation to medicines and prescribing.

The term 'medicine', used by NICE, includes all healthcare treatments that may be considered in local formularies. Examples include wound care products and appliances.[1]

Some of the challenges in developing appliance formularies can differ from those faced when compiling a formulary for other medicines. For example, the quality of the evidence required for approval of medical devices is generally lower than that required for other medicines, resulting in poor quality randomised controlled trials in this area.[2]

In relation to advanced wound dressings and antimicrobial dressings for chronic wounds, NICE states:[2]

"When a specific dressing cannot be adequately justified on clinical grounds, it would seem appropriate for NHS healthcare professionals to routinely choose the least costly dressing of the type that meets the required characteristics appropriate for the type of wound and its stage of healing (for example, size, adhesion, conformability and fluid handling properties). The frequency of dressing change needs to be carefully considered and should be appropriate for the wound and dressing type. Patients should be assessed regularly. Prescribing the minimum quantity of dressings necessary to meet a person's needs can avoid wastage and stockpiling."

In Northern Ireland (NI), the Health and Social Care Board (HSCB) and Public Health Agency (PHA) Process for Developing Prescribing Guidance and Formulary Chapters is in line with the NICE good practice guidance. The main difference is that the scope of the NI Formulary is to provide advice on first and second choice medicines, whereas the scope of local formularies in England is broader and therefore some recommendations are not applicable to the NI Formulary.[3]

NHS Scotland aims to standardise their approach to formulary development and use with a single national formulary (SNF), utilising the "Once for Scotland" approach.[4]

The process of developing and updating local formularies

A best practice statement from Wound Care Alliance UK aims to guide nurses, doctors, pharmacists and procurement officers within NHS Trusts in the development of a wound dressings formulary to ensure that a fair and equitable process is followed, avoiding the undue influence of industry.[5]

It states that "an identifiable process which is fair and impartial must be employed by a trust/health board when selecting products, taking into consideration a variety of expertise and clinical knowledge. It must also be recognised that a wound dressings formulary should be dynamic."[5]

It also advises that regular audit is needed to monitor which products are being used, in what quantities and whether their use is appropriate.[5] Furthermore, an ongoing educational programme is recommended alongside the formulary to ensure that the use of all included products is optimised for the benefit of both patients and healthcare professionals.[5]

This process can also be applied to the development of other appliance formularies e.g. stoma, continence.

NICE makes recommendations including the following in terms of developing and updating local formularies:[1]

1. **Understand and utilise relationships with other decision-making bodies**
   Local formulary decision-making groups rarely operate in isolation. Collaborating with other regional decision-making groups, where possible, can avoid duplication and variation in patient care, and support the development of local integrated care pathways across primary and secondary care.
2. **Ensure that the scope of the local formulary is appropriate**
   This should include consultation with all locally defined stakeholders. The size of the population, the treatments included, and the organisations adopting the formulary must be considered.
3. **Ensure that the local formulary decision-making group is effective and representative**
   A locally defined mix of members from partner organisations and key stakeholders should be included. The group must have the range of skills and expertise needed to undertake all necessary activities.
4. **Gain sufficient stakeholder engagement**
   This should include clinical groups and networks, patients or patient representative groups, local people and communities, product manufacturers where appropriate, and other relevant decision-making groups.
5. **Include processes for the adoption of medicines recommended by NICE technology appraisal guidance**
   When there is no NICE technology appraisal for a product (as is usually the case for wound care, continence and stoma products) use NICE guidelines and advice, and other sources of high-quality information produced by national and regional horizon scanning organisations, if available.
6. **Implement robust and transparent processes for selecting medicines to be considered for inclusion in the local formulary**
   When considering the cost of appliances, it is important to consider all aspects of the patient pathway and not simply the unit cost of the product alone.
7. **Clearly define and consistently apply standard criteria for decision-making**
   A robust and transparent process is needed for adopting, removing or updating products in a formulary. Horizon scanning should be in place to proactively identify new relevant products and publications.
8. **Ensure that high quality evidence and information gathering takes place**
   The relative lack of national guidance in these areas means that local critical appraisal and evaluation of products is likely to be needed for many appliances. The decision-making group should include people with the skills to search, appraise and interpret the literature alongside appropriate specialist practitioners who can use their knowledge and expertise to advise on and evaluate products.
9. **Incorporate new information from regulatory authorities**
   Medicines safety advice from regulatory authorities should be incorporated routinely into the local formulary. For example, Alerts, recalls and safety information: drugs and medical devices from the Medicines and Healthcare products Regulatory Agency.

10. Assess the financial and commissioning impact when making decisions

Local formulary decisions should be aligned within the framework of clinical commissioning. Organisations should also consider addressing barriers that may delay the speed of adoption of appliances into the formulary.

11. Use formally documented principles to guide deliberation

This includes mission statements, terms of reference, decision criteria, and legal and ethical frameworks. How local formulary decision-making groups reach their final decisions should be explicitly determined.

12. Ensure appropriate documentation

The deliberations and actions from local formulary decision-making group meetings, the outcomes of decisions, the rationale for each decision and all formulary policies should be appropriately documented.

13. Develop decision outputs to support local formulary decisions

Decisions should be made and published in a timely manner, to prevent delays to patients accessing treatment.

14. Communicate and disseminate information about the local formulary

Local formulary information should be published online, in a clear, simple and transparent way, so that patients, the public and stakeholders can easily understand it. This includes formulary policies, minutes of meetings and decision outcomes. Platforms such as www.netformulary.co.uk and the MicroGuide app can be used and formularies can be added to GP prescribing systems to provide support at the point of prescribing. PrescQIPP bulletin 271 Medicines formulary and share care guidance development across integrated care systems (ICS) provides further information.

15. Establish a robust and transparent process for reconsidering and appealing local formulary decisions

The criteria for a health professional to request a reconsideration of, or appeal a decision made by the local formulary decision-making group should be clearly defined.

16. Regularly review and update the local formulary

A robust and transparent process for reviewing and updating the local formulary should be established, including in response to NICE technology appraisal recommendations, new evidence/products, new safety information; in response to appeals, requests for review or the identification of errors; and structured review in accordance with a rolling schedule.

Patient scenario

The importance of embedding robust pathways as a means of improving clinical outcomes, people's experience and the financial cost of care is highlighted by the NHS RightCare programme.[6] The published resources include a long-term-condition scenario on wound care.[7]

This scenario uses a fictional patient, Betty, to examine a wound care pathway for venous leg ulcers, comparing a suboptimal but typical scenario against an ideal care pathway:

In the suboptimal pathway, there was a long delay in the recognition of Betty's leg wound as a venous leg ulcer. It took several months for an appropriate diagnosis to be made, which was followed by a wait of several more months for a Doppler scan and a full assessment. Betty's wound became very distressing. Many weeks of pain culminated in a five-day hospital stay for cellulitis. It ultimately took two years to heal Betty's ulcer using a reduced compression system that she could tolerate.[7]

In marked contrast, the optimal pathway describes Betty's rapid referral on to a lower leg wound pathway developed by the commissioner. Within eight weeks her leg was completely healed.[7]

A financial analysis gave the estimated costs of Betty's management via both the suboptimal and optimal pathways as £5,673 and £505, respectively.[7] In the suboptimal scenario, dressings represented

£1,353 (24%) of the total costs versus £88 (17%) in the optimal pathway. Clinical time represented 38% of the total costs in both the pathways £2,139 versus £195.[7]

This scenario illustrates (among other things) how important it is to have an agreed, evidence-based formulary, which is embedded in the local practice of healthcare providers.

Repeat prescribing process

A robust local formulary is a key element of a number of other strategies, such as managing the process for generating repeat prescriptions, in order to optimise appliance prescribing and reduce waste.

A practice process underpinned by a robust policy is essential for practices to ensure that repeat prescription requests for appliances are dealt with efficiently and safely.

Practices should consider how they can incorporate measures that help to prevent avoidable waste such as over-ordering and stockpiling into their repeat prescribing process.[8]

This may include the use of acute prescriptions for certain appliances in order to prompt regular review and prevent waste. This may be particularly useful when the treatment is subject to change, or a suitable product choice has not yet been established.

Dispensing appliance contractors

There can be significant problems related to dispensing appliance contractors ordering prescriptions on behalf of patients, such as over-ordering quantities or ordering too early, which can lead to considerable wastage.[9] Consequently, it is recommended that prescriptions for appliances should only be issued at the request of the patient or their carer and they should not be accepted from a dispensing appliance contractor.

Except in an emergency, retrospective prescriptions should not be issued and the dispensing appliance contractor must receive the prescription prior to the delivery of items.[9] In an emergency, the prescriber must be contacted by the patient, stoma nurse, appliance contractor or their agent, requesting their permission to supply appliances in advance of receipt of the prescription.[9]

It is strongly recommended that GP practices have their own agreed protocol for how to deal with dispensing appliance contractors.

Procurement of appliances and service redesign

Historically, dressings have been prescribed in primary care on prescriptions for individual patients. Increasingly, organisations have been looking at whether this is the most cost-effective and patient-centred approach.[10] This has resulted in a number of alternative procurement options arising.

These include organisations purchasing dressings directly, either in house via the organisation's centralised ordering portal,[10] or via online ordering portals provided by the NHS Supply Chain[11] or wound care product manufacturers.[12]

However, there are a number of issues that organisations considering the procurement of appliances via the non-prescription route must consider. They include the potential need to go out to tender,[13] the implications for local community pharmacies, VAT implications (VAT will be applicable to products obtained through alternative routes),[14] ordering, delivery, storage and monitoring.

In Scotland, a specified list of stoma appliances dictates those items that may be ordered by authorised prescribers on the appropriate lists of the Health Board and indicates the specifications and reimbursement prices which shall apply to the stoma services contractors (community pharmacy contractors and dispensing appliance contractors) who are authorised to dispense these products.[15]

Some areas have looked for new ways to commission and deliver wound care, continence and stoma services. Many of the new models have a common aspect of moving away from prescribing by GPs,

who often have limited knowledge of the appliances they are being asked to prescribe. Increasingly, the responsibility for providing or prescribing these appliances is shifting to health professionals (often nurses) with greater expertise in the particular area of practice.

Organisations that have (or are considering) a manufacturer-sponsored continence/stoma nurse working locally should ensure that the specialist nurse is not required to recommend the sponsor's products in preference to other clinically appropriate appliances or withhold information about other products. Furthermore, the arrangement should not require that patients are recommended to use a particular dispensing service.

Monitoring spend

The charts below show spend and items for wound care, continence and stoma products between 2017/18 to 2022/23 in England, Wales and the Isle of Man.

Figure 1. Total cost for wound care, continence and stoma products prescribed on the NHS

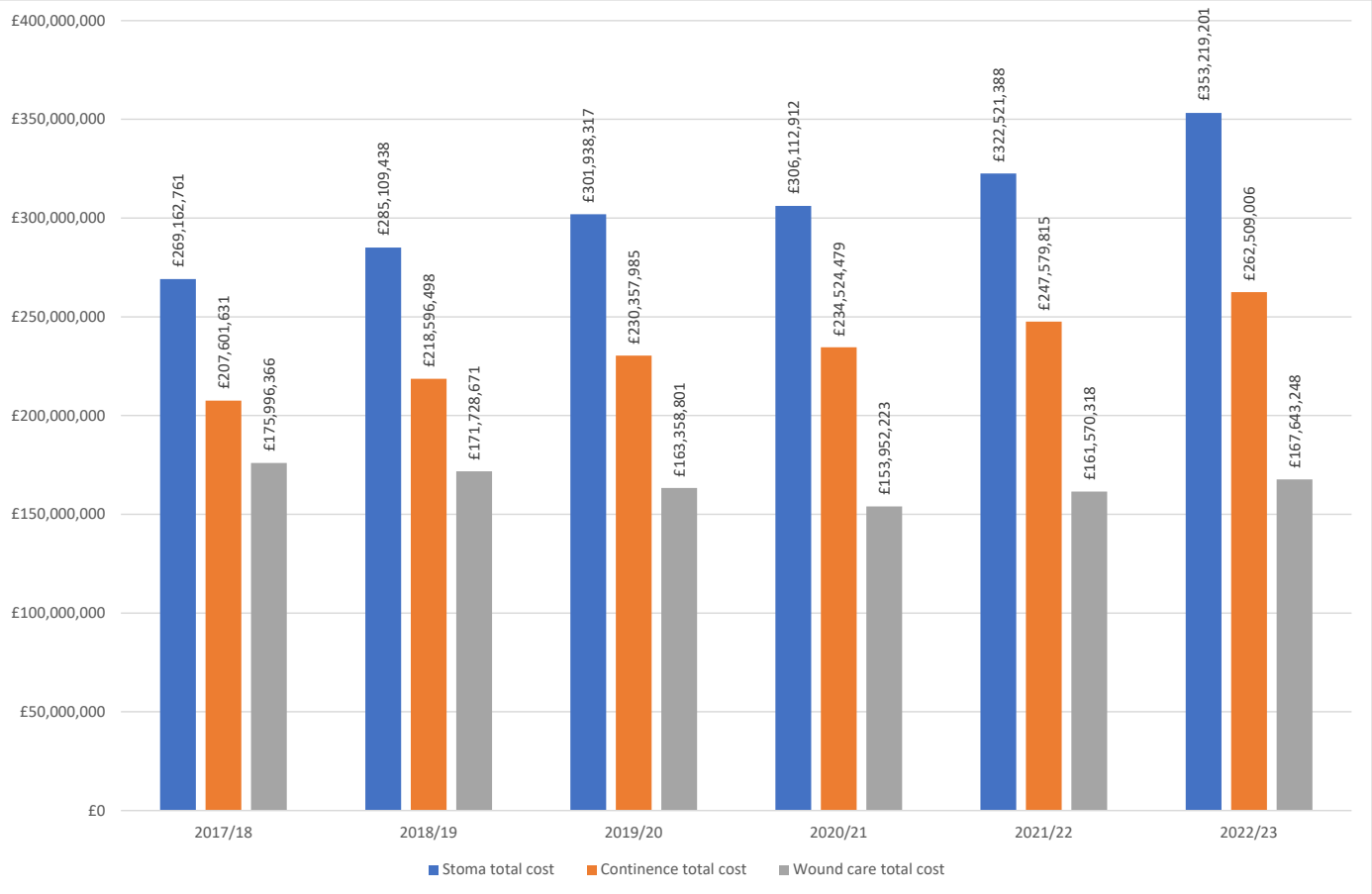
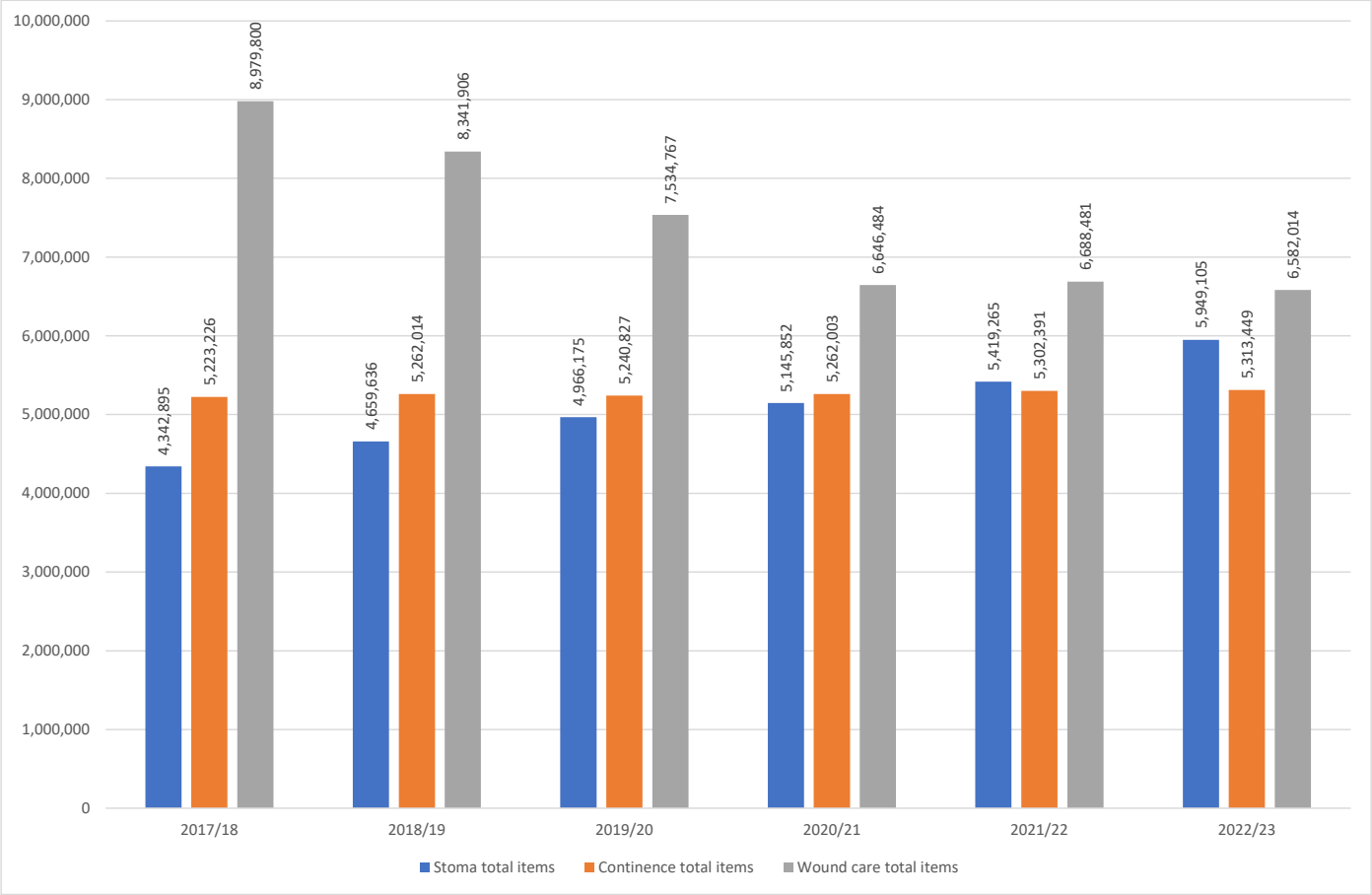


Figure 2. Total items for wound care, continence and stoma products prescribed on the NHS



Please note: These graphs only include items that were prescribed on an FP10/WP10 and not items supplied via any other alternative route.

In terms of the trends illustrated by these graphs, it can be seen that the total cost and total items for both stoma and continence appliances increased from 2017-2023. However, both the total cost and total items for wound care appliances showed a decreasing trend, with the exception of a slight increase in total items in 2021/22 for wound care products, compared with the previous year, but this was still down from the year before.

This may reflect work that areas have already undertaken in managing the use of wound care products. It may also represent a switch to non-prescription procurement in some areas, which would not be represented by these figures.

PrescQIPP subscribers can find information about local and national spend in these areas in the data section of the PrescQIPP website. https://www.prescqipp.info/our-resources/data-and-analysis/clinical-snapshots/

The National Wound Care Strategy Programme are developing a range of resources to help healthcare professionals deliver better wound care and help patients and carers understand what good looks like. Resources are published on their website as they become available. https://www.nationalwoundcarestrategy.net/

Summary

Local wound care, continence and stoma formularies can support the optimisation of appliance use, as well as their financial management across health communities.[1] Formularies are often a key component of other strategies for improving the clinical and cost-effectiveness of appliance use, such as strengthening repeat prescribing processes and redesigning services. Their development requires sustained collaborative working across professional and organisational boundaries.[1] Using a whole systems approach by integrating formularies with robust local pathways can provide a means of improving clinical outcomes, people's experience and the financial cost of care.

Additional resources

- An example of a wound dressings audit and a wound care product evaluation form that could be adapted for local use: Best Practice Statement. Development of a Formulary. Wounds UK, Aberdeen, 2008. https://www.wounds-uk.com/resources/details/best-practice-statement-development-formulary
- PrescQIPP continence and stoma resources. https://www.prescqipp.info/our-resources/webkits/continence-and-stoma/
- PrescQIPP wound management products and elasticated garments resources. https://www.prescqipp.info/our-resources/webkits/wound-care/
- PrescQIPP. Bulletin 292. Repeat prescriptions. Version 2.0. July 2021. https://www.prescqipp.info/our-resources/bulletins/bulletin-292-repeat-prescriptions/.
- PrescQIPP. Care homes resources. https://www.prescqipp.info/our-resources/webkits/care-homes/
- PrescQIPP Bulletin 273: Commissioning - Medicines in service redesign. Version 2.0. September 2020. https://www.prescqipp.info/our-resources/bulletins/bulletin-273-commissioning-medicines-in-service-redesign/
- PrescQIPP subscribers in England, Wales and Isle of Man can find information about local and national spend in the areas of continence, stoma and wound care products in the clinical snapshots data section of the PrescQIPP website.

References

1. NICE. Developing and updating local formularies. Medicines practice guideline [MPG1]. Published March 2014. Last updated October 2015. https://www.nice.org.uk/guidance/mpg1
2. NICE. Chronic wounds: advanced wound dressings and antimicrobial dressings. Evidence summary [ESMPB2]. Published March 2016. https://www.nice.org.uk/advice/esmpb2/chapter/Full-evidence-summary-medicines-and-prescribing-briefing
3. Health and Social Care Board and Public Health Agency. HSCB and PHA Process for Developing Prescribing Guidance and Formulary Chapters. March 2016. https://niformulary.hscni.net/about-us/development-and-review-of-the-formulary/
4. Scottish Government. Review of Access to New Medicines. Published December 2016. https://www.gov.scot/publications/review-access-new-medicines/pages/13/
5. Best Practice Statement. Development of a Formulary. Wounds UK, Aberdeen, 2008. https://www.wounds-uk.com/resources/details/best-practice-statement-development-formulary
6. NHS England. RightCare. Last accessed 11/05/2023. https://www.england.nhs.uk/rightcare/
7. NHS England. RightCare scenarios. Wound care. January 2017. https://www.england.nhs.uk/rightcare/scenarios/
8. PrescQIPP. Bulletin 292. Repeat Prescriptions. Version 2.0. July 2021. https://www.prescqipp.info/our-resources/bulletins/bulletin-292-repeat-prescriptions/

9. Morley NV. Consultation document on the arrangements for paying appliance contractors. An independent response on behalf of the agency appliance contractors. August 2003. https://www.sehd.scot.nhs.uk/appliance_contractors/consultation_responses/mrpharms.PDF
10. NHS England. The Atlas of Shared Learning. Case study: Procuring for effective wound management. November 2018. https://www.england.nhs.uk/atlas_case_study/procuring-for-effective-wound-management/
11. NHS Supply Chain. General wound care contract. Reference: 2020/S 222-547347. Start Date: 14 March 2022. Expiry Date: 31 January 2024. https://www.supplychain.nhs.uk/product-information/contract-launch-brief/general-wound-care/
12. Legg D, Parker J. Developing criteria for wound dressing selection. Primary Care Nursing Review (PCNR). Issue 11. Accessed 11/05/2023. https://pcnr.co.uk/articles/313/developing-criteria-for-wound-dressing-selection.
13. Health and Social Care Act 2012. UK Public General Acts 2012 c. 7. Part 3, chapter 2, section 75. https://www.legislation.gov.uk/ukpga/2012/7/section/75/enacted
14. HM Revenue and Customs. Guidance: Health professionals and pharmaceutical products (VAT Notice 701/57). How to account for VAT on goods and services provided by registered health professionals, including doctors, dentists, nurses and pharmacists. Published July 2014, last updated March 2022. https://www.gov.uk/guidance/health-professionals-pharmaceutical-products-and-vat-notice-70157
15. Public Health Scotland. Stoma Supplies. Prescribing and Medicines. Accessed 11/05/2023. https://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Stoma-Supplies/

Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-329-appliance-formulary-development/
Implementation tools	

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