ABHI

HealthTech for Life

ABHI Discussion Document: Local Medical Device Formularies - Supporting Personalised Care and Patient Access

Introduction

We support the development of a framework for the creation of local medical device formularies, but would not support the imposition of a central list of named products. The framework should focus on enabling safe, effective, and equitable care, while upholding the core principles of local clinical judgment, patient-centred decision-making, product choice and access to innovation. We welcome national efforts to reduce unwarranted variation, but this is not the same as enforcing uniformity. Formularies should ensure consistency in standards of care, not uniformity of a truncated range of products, ensuring they are tools to enhance health outcomes, not instruments that constrain clinical judgement.

Many of the products indicated as in scope of the initiative (i.e. those listed in Part IX) are, in the main, highly personalised products that need to respond to the very significant diversity found in clinical presentation, individuals' anatomy and social environment.

Local Clinical Decision-Making Must Drive Formulary Development

Formularies must respect the clinical expertise of those closest to patients, particularly in community and primary care, where decisions about prescribable medical devices are most often made.
We strongly advocate for:

- Local teams retaining the authority to select the most appropriate product for the individual patient.
- Flexible mechanisms for off-formulary use where clinically justified.
- Avoiding blanket or nationally-imposed restrictions that fail to account for real-world patient variation.

One Size Does Not Fit All: The Need for Personalised Medical Devices

In many areas, such as stoma care, continence care, and intermittent catheterisation, the products used are highly individualised. Attempting to categorise or reduce these products into standardised groups for cost comparison ignores clinical reality. Such complexity cannot be captured by top-down, cost-based categorisation models.
HealthTech therefore differs from pharmaceuticals. While medicines follow clear sequencing (first to third-line), personalised medical devices require tailored matching to individual anatomy, conditions, and preferences.
For example, in stoma care alone, there are three peristomal body profiles (inward, outward, and regular) each of which can vary across 216 individual profiles, resulting in over 648 permutations when factoring in output types. A single product portfolio can comprise several hundred SKUs, each addressing specific clinical needs and anatomical differences. In wound care the journey to healing is complex and variable requiring access to a range of dressings types to address different stages of tissue management.
If this variety is reduced to a single "reference product" per category, many patients risk receiving inappropriate solutions, leading to complications, poor adherence, and diminished quality of life.

Why Formularies Must Reflect More Than Just Price

Reforms currently underway, such as the NICE Late-Stage Assessments (LSAs) and Part IX Drug Tariff changes, risk encouraging budget holders to reduce formularies to the cheapest products per category, based on superficial evidence of equivalence.

- LSAs have, to date, shown limited understanding of how nuanced and individualised device use is.

- Part IX reforms should not result in blanket substitutions at a local formulary level, especially when products are not functionally interchangeable. A list of categories for national reimbursement (ie Part IX) has a different purpose to a local formulary.
- The combination of these policies may embolden those far removed from the point of care to override specialist recommendations, with patients left to fight for access.
- There must be a balance between standardisation at a local level and flexibility to address complex and atypical needs.
- Formularies should be living tools, updated based on patient outcomes, satisfaction, and service data. Data should be routinely and consistently captured, with a nationally defined minimum dataset, to enable an evidence-based approach to formulary development and update.
- Resource and support needs to be made available to ensure that formularies are administered effectively and updated on a timely basis.

A critical element of any formulary is training and education that runs alongside the choice of product. This supports high standard of care and consistent and appropriate use of products. Ensuring compliance with formulary, which will be best supported at a local level, will help deliver evidence-based and cost-effective care.

Aligning with Broader Policy

Previous work[1] has shown that the cost of product is a small element within the overall cost of treatment, which is primarily driven by clinical resource. Formulary development must therefore be rooted in value-based principles:

- Value must be measured not only in cost savings, but in patient outcomes, clinical time saved, and quality of life. This needs to be supported by a clear value assessment methodology applicable to the community setting, in turn supported by robust data collection.
- The Life Sciences Sector Plan[2] commits to making the UK an outstanding place in which to start, grow, scale, and invest. Formularies should incentivise participation in evidence generation and innovation adoption.
- The MedTech Strategy[3] sets out the need for the UK health system to access innovative Medical Technologies. This requirement should cascade down through Part IX into local formularies.
- A review of formulary development is an opportunity to think broadly about how the shifts from hospital to community and analogue to digital can be supported. For example consideration should be given to the prescribing of digital tools and digital therapeutics.

Collaboration and Shared Evidence Are Essential

The system should support shared learning and clarity:

- We welcome initiatives from Professional Bodies, such as the ASCN's Evidence-Based Stoma Care Pathway, which aims to guide appropriate product use over the patient's life course, formulary development should be guided by these types of initiatives as well as any national workstreams such as GIRFT.

[1] Guest JF, Fuller GW, Vowden P. Cohort study evaluating the burden of wounds to the UK's National Health Service in 2017/2018: update from 2012/2013. BMJ Open. 2020 Dec 22;10(12):e045253. doi: 10.1136/bmjopen-2020-045253. PMID: 33371051; PMCID: PMC7757484.
[2] https://assets.publishing.service.gov.uk/media/687653fb55c4bd0544dcaeb1/Life_Sciences_Sector_Plan.pdf
[3] https://www.gov.uk/government/publications/medical-technology-strategy

- PrescQIPP's guidance, which builds on NICE's work, is a valuable tool but must be used alongside frontline clinical input.
- Guidance must ensure Shared Decision Making is embedded and supported across settings.
- Suppliers of products in Part IX provide significant support around their product offerings, including product training, patient education materials, audit programmes, patient helplines and clinical support services.

Addressing System Friction and Supporting the Patient Voice

Local formulary development should be a multidisciplinary activity across the relevant geographic and organisational footprints.

We urge the system to:

- Commit to joined up working across providers, commissioners, and pharmacies.
- Provide clear processes for reconciling specialist recommendations with local formularies.
- Invest in communication, education, and transparency, so patients understand their options and rights, enabling informed input.

Call for Broader Engagement and Inclusive Evidence Gathering

As work progresses on formularies and tariff reform, engagement must be broad-based:

- Include voices from patient groups, charities, clinical associations, Industry, and specialist nurses.
- We recommend working closely with the Professional Bodies such as Tissue Society of Tissue Viability Nurses, Association of Stoma Care Nurses, British Association of Urological Nurses and others.
- Ensure engagement mechanisms are inclusive and two-way, co-developing not just guidance but practical, patient-centred solutions.

Summary

Medical device formularies should enhance care, not limit it. Reform presents a chance to improve outcomes, reduce variation, and modernise prescribing. But this must be done with care: honouring clinical judgment, empowering patients, and avoiding simplistic cost-cutting that could harm those who rely on these essential products.

Industry is keen to work collaboratively to ensure that future frameworks for device access are safe, inclusive, innovative, and value-based.

Annex A: Summary of best practice based on a review of PrescQIPP and Wounds UK Formulary Guidance

- Embed structured assessments into formulary decision-making.
- Provide mechanisms for exceptions based on individual needs.
- Involve patients in shared decision-making and education.
- Establish a multidisciplinary formulary development group.
- Include patient/carer voices, especially those with lived experience.
- Use co-production methods to build legitimacy and buy-in.
- Define clear inclusion criteria for the formulary.
- Ensure each product has demonstrable safety, usability, and evidence-based benefit.
- Evaluate real-world performance over theoretical claims.
- Develop a standardised list of recommended products by category.
- Provide a robust, auditable process for non-formulary use.
- Train staff on when and how to apply flexibility appropriately.
- Define clear Terms of Reference for the formulary group.
- Include mechanisms for feedback, incident reporting, and product complaints.
- Set a review cycle (e.g. every 1–2 years or sooner if needed).
- Deliver training to prescribers and frontline staff.
- Provide accessible, patient-friendly information on product use and rationale.
- Engage suppliers for training on correct product application.
- Track prescribing patterns, product use, and clinical outcomes (e.g. CAUTI rates).
- Use data to inform formulary updates and training priorities.
- Incorporate PROMs where possible.
- Consider the needs of diverse populations (e.g. physical disability, cultural preferences, language needs).
- Ensure formulary products are accessible in all care settings.
- Monitor for disparities in product access or outcomes.