

**CONSULTATION ON**

**PROPOSED CHANGE TO THE NORTHERN IRELAND**

**DRUG TARIFF FOR WOUND CARE MANAGEMENT PRODUCTS**

**MARCH 2016**

**CONSULTATION ON PROPOSED CHANGE TO THE NORTHERN IRELAND DRUG TARIFF FOR WOUND CARE MANAGEMENT PRODUCTS**
**Introduction**

1. The Department of Health, Social Services and Public Safety has a statutory responsibility under Regulation 9 of the Pharmaceutical Services Regulations (Northern Ireland) 1997 to compile and publish a Drug Tariff for Northern Ireland[[1]](#footnote-1) (‘the Drug Tariff’).
2. This consultation relates specifically to the publication of Part III (g) and (h) of the Drug Tariff which sets out the list of wound care products which can be prescribed in primary care in Northern Ireland, together with the reimbursement prices paid to community pharmacy contractors for items dispensed against a health service prescription. Wound care products not included within Part III (g) and (h) of the Tariff may not be prescribed in primary care in Northern Ireland and suppliers are under no obligation to supply any such product.

**Current arrangements**

1. The Northern Ireland Wound Care Formulary was introduced in Northern Ireland on 1 April 2007 and revised in April 2011[[2]](#footnote-2). It provides guidance on wound dressings which may be prescribed to patients by health professionals in primary and secondary care and approximately 255,000 prescription items for wound care products were dispensed by community pharmacists in 2014 at a cost of £6.2 m.
2. The choice of dressing for inclusion in the Northern Ireland formulary has been supported by a rigorous process based on the scoring of evidence submitted by the manufacturer, literature searches, risk assessment of product presentation and a budget impact assessment
3. Since 2007, only products selected for the Wound Care Formulary are included within the Northern Ireland Drug Tariff. No other wound care management products can currently be prescribed, except in exceptional circumstances, for example, if a patient were to have an allergy to a listed dressing. In those circumstances, supply of a dressing not listed in the Drug Tariff can be arranged through a nominated HSC Trust Pharmacy Department by way of an exception protocol.[[3]](#footnote-3) During pre-consultation discussions some stakeholders suggested difficulties being reported in obtaining products through the exception protocol. That has not been raised, however, as a major issue by Tissue Viability Nurses (TVNs) who play an important role in the treatment and management of complex wounds.
4. A review of arrangements for populating Part III (g) and (h) of the Northern Ireland Drug Tariff is being undertaken and this consultation document sets out options which been informed by views gathered from stakeholders during a pre-consultation process. Views are welcome on the proposals and we would encourage you to submit your opinions.
5. Whilst the consultation is ongoing, and until new arrangements are in place for populating the Northern Ireland Drug Tariff with wound care products, the reimbursement prices for wound care products has been maintained as listed within the January 2016 Northern Ireland Drug Tariff.
6. A separate tender exercise to procure wound care products for secondary care has also recently been initiated. That exercise will conclude with defining a list of wound care products that will be available in secondary care. The scope of that tender competition does not extend to primary care.

**Options for changes to the Northern Ireland Drug Tariff**

1. This section sets out three options for populating the Northern Ireland Drug Tariff for wound care products.

Option 1 – Do nothing

1. Continuing with the status quo would mean maintaining the list of wound care products and prices in Part III (g) and (h) of the Northern Ireland Drug Tariff as currently listed in the January 2016 Drug Tariff. Arrangements for the alternative/exception protocol which ensure that patients have access to any products not listed on the Drug Tariff would also be maintained.
2. This option would provide continuity for health professionals and Tissue Viability Nurses (TVNs), in particular, who are familiar with the products currently listed in the Tariff. Patients would also likely welcome consistency in presentation and availability of wound care products. However, there would not be the scope to update the list of available wound care products and provide access to any new or innovative products.
3. Maintaining the current arrangements would also mean that there would not be any mechanism for changing reimbursement prices from those listed in the January 2016 Drug Tariff.

Option 2 – Populate the Northern Ireland Drug Tariff with Part IXA of the England & Wales Drug Tariff.

1. Under this option, the Northern Ireland Drug Tariff would be populated with wound care management products currently listed within Part IXA of the England & Wales Drug Tariff. Details of the products which would be included within the Northern Ireland Drug Tariff, based on the current version of the England & Wales Drug Tariff, are available from: [www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx)
2. Any future changes to the list of products or reimbursement prices within the England & Wales Drug Tariff would be automatically replicated within the Northern Ireland Drug Tariff. This option would bring wound care management products into line with the Department’s extant policy position of aligning reimbursement prices from the England & Wales Drug Tariff for drugs.
3. Replicating Part IXA of the England & Wales Drug Tariff would also expand the list of wound care products available for prescribing and dispensing in Northern Ireland. This could be considered beneficial to patients in that prescribers would have access to a much enhanced suite of wound care products.
4. There are, however, a small number of products which are currently included within the Wound Care Formulary, and the Northern Ireland Drug Tariff, that are not listed on the England & Wales Drug Tariff; the list of products is at Appendix 1. Overall, however, it is a relatively small number of products involved with 4,311 items dispensed in 2014. That is in the context of approximately 255,000 prescription items for wound care products dispensed by community pharmacists in that year.
5. If this option was adopted, arrangements could be put in place to ensure that patients would have access to products that would not be available following the adoption of an England & Wales Drug Tariff. In some cases, that could mean the provision of alternative sizes or similar products.
6. It is anticipated that there would be additional costs to the health service if the reimbursement prices within the England & Wales Drug Tariff were adopted for wound care management products. For example, on an analysis of wound care products dispensed in primary care in 2014, it is estimated that costs to the HSC could increase by approximately 20% if the same product is prescribed and community pharmacists were reimbursed in line with the current prices in the England & Wales Drug Tariff. However, following the consultation process and changes to the Northern Ireland Drug Tariff, the HSC Board would consider appointing a Panel for Prescribing Advice (PPA) to consider the evidence base and develop a revised non-mandatory formulary of first and second line choices for wound care.

Option 3 – Apply the STEPSelect selection methodology to populate the Northern Ireland Drug Tariff

1. Under this option a selection methodology would be adopted to select wound care products for inclusion within the Northern Ireland Drug Tariff. The main driver is that selection on the basis of evidenced quality and safety will ultimately drive economy. It is therefore proposed to deploy the STEPSelect methodology (Safe Therapeutic Economic Pharmaceutical Selection) to identify those wound care products that are clinically effective, safe and cost efficient.
2. The STEPSelect methodology is well established and considers, in the first instance, the clinical features of health technologies. At a further stage of the evaluation, product quality and fitness for purpose are assessed (the so-called risk assessment stage) as well as the budget impact of a health technology. Detail on how the STEPSelect process would be applied is provided at Appendix B. Views are also welcome on any other alternative selection methodologies.
3. When a list of suitable products has been identified by applying the STEPSelect methodology, it is proposed that reimbursement prices would be adopted from the England & Wales Drug Tariff. Any future changes to the reimbursement prices within the England & Wales Drug Tariff would be automatically reflected in the Northern Ireland Drug Tariff.
4. Where products are identified through the STEPSelect process but not listed in the England & Wales Drug Tariff, the reimbursement price will be the list price offered by the manufacturer/wholesaler. In relation to new products, these can be considered for addition to the Drug Tariff, based on the evidence provided, and this aspect will be undertaken on a regular dynamic basis. This appraisal will also be taken with regard to any new relevant evidence for escalating products on the Drug Tariff.
5. It would also be proposed to maintain the arrangements for the alternative/exception protocol to ensure that patients have access to any products not on the Drug Tariff. However, the list of products available through the protocol would be reviewed following the outcome of the STEPSelect process.
6. It is not possible to assess the overall budgetary impact of this option in advance of the STEPSelect process. However, the STEPSelect process is designed to deliver value for money within a professional and tested framework that supports medicines optimisation.

**Analysis of options**

1. Maintaining the current arrangements (Option 1) is not feasible on the basis that the current list of wound care products has not been updated in five years and therefore does not take into account changes in the market and newer clinical and cost effective products. On this basis, there would be resistance from stakeholders if the current list of wound care products and reimbursement prices was maintained as listed in the January 2016 Drug Tariff.
2. Option 2 would address the issue of having a mechanism in place for updating reimbursement prices to pharmacy contractors. Putting in place a mechanism to provide a link between the Northern Ireland Drug Tariff and England & Wales Drug Tariff would provide a basis for maintaining a current Tariff for wound care products. It would also ensure that any new products included within the England & Wales Drug Tariff would automatically be available in Northern Ireland. While this option could eventually be linked with a Northern Ireland Wound Care Formulary, such a Formulary would be guidance to prescribers. As a result, the most cost effective and clinically effective wound care products might not be delivered through this option.
3. Option 3 is the Department’s preferred option as the STEPSelect process offers a transparent and defensible approach to the selection of wound care products that are clinically effective, safe and cost efficient. The process is also underpinned by active engagement with wound care manufactures and wholesalers and healthcare professionals. Importantly, there would be flexibility to accommodate new products whilst ensuring product selection that takes account of the overall financial envelope. This option also supports a pricing strategy which is consistent across the UK and therefore supports sound budget impact assessment.

**Equality and Human Rights Considerations**

1. In accordance with guidance produced by the Equality Commission for Northern Ireland and in keeping with Regulation 75 of the Northern Ireland Act 1998, the proposed changes to the Northern Ireland Drug Tariff set out in this document have been equality screened and a preliminary decision has been taken that a full EQIA is not required.
2. The Department has also considered the policy from a Human Rights perspective and has provisionally concluded that this policy will not engage any of the rights.

**Summary**

1. Maintaining the current arrangements for populating the Northern Ireland Drug Tariff for wound care products is not sustainable and so alternative arrangements need to be established. This consultation document sets out a preferred option of applying the STEPSelect methodology and views are sought on the proposal.

**Responses**

1. Details about how to respond are set out in the Consultation Response Questionnaire.

**Medicines Policy Group
DHSSPS**

 **Appendix 1**

**Wound care management products currently available in Northern Ireland but not on the England & Wales Drug Tariff**

|  |  |
| --- | --- |
| **Product** | **Size** |
| **Dressings** |  |
| Duoderm Extra Thin  | 3.8x4.4cm |
| 5cmx20cm |
| Foam Wound Filler | 10x12.5cm |
| Gauze Rolls (Kerlix Amd) | 11.4x3.7m |
| Gauze Wound Filler | 15x17cm |
| Na Ultra | 19cmx19cm |
| Opsite Transparent Film Spray | 100ml |
| Pharmapad | 10cmx10cm |
| 10cmx20cm |
| 5cmx5cm |
| Tegaderm Film | 10cmx12cm |
| 20cmx30cm |
| 4.4x4.4cm |
| **TNP Products** |  |
| V.A.C Via Canister Kit | 250ml |
| V.A.C Via Dressing Kit | Medium |
| Infov. A.C. Canister With Gel | 500ml |
| Renasys Large Drapes | 20cmx30cm |
| **Larvae**  |  |
| Larvae Biobag Bb100 | 4cm x 5cm |
| Larvae Biobag Bb100Ind | 4cm x 5cm |
| Larvae Biobag Bb100Nonkit | 4cm x 5cm |
| Larvae Biobag Bb200 | 5cm x 6cm |
| Larvae Biobag Bb200Ind | 5cm x 6cm |
| Larvae Biobag Bb200Nonkit | 5cm x 6cm |
| Larvae Biobag Bb300 | 6cmx12cm |
| Larvae Biobag Bb400 | 10cmx10cm |
| Larvae Biobag Bb400Ind | 10cmx10cm |
| Larvae Biobag Bb400Nonkit | 10cmx10cm |
| Larvae Biobag Bb50 | 2.5cmx4cm |
| Larvae Biobag Bb50Ind | 2.5cmx4cm |
| Larvae Biobag Bb50Nonkit | 2.5cmx4cm |
| Larvae Fnet30 Flat Net | 30cmx30cm |
|  |  |
|  |  |
|  |  |

**Appendix 2**

**STEPSelect METHODOLOGY**

STEPSelect (Safe Therapeutic Economic Pharmaceutical Selection) is a tool for the rational, safe, evidence-based, cost-effective selection and procurement of medicines and medical devices within a comprehensive professional framework with the aim of comprehensive medicines optimisation. It is one of the most key components of the integrated medicines management (IMM) system developed in Northern Ireland. STEPSelect is a unique tool in which better quality of care is achieved, patient safety is improved and cost savings are based on a clinician driven safety and quality based approach to product selection. It is important to take into account that medicines optimisation needs both a clinical and a pharmaceutical aspect.

The STEPSelect approach is well accepted by both prescribers and pharmacists because of the fact that product selection is based on quality aspects, such as efficacy, documented effects on end-points, safety, tolerability and ease of use. It follows four distinct stages:

**Stage 1 Clinical Evaluation**

* Literature evidence is compiled to produce a comprehensive document
* Additional literature is also included based on evidence supplied by manufacturer
* Scores are assigned to each product and relative weights to each selection criteria

**Stage 2 Safety and Risk Assessment**

* Product samples are obtained from industries
* Assessment is undertaken with regard to packaging and labelling of product
* Products are then scored

**Stage 3 Budget Impact Analysis**

* Annual usage data is obtained to allow comparison of products in the same class

**Stage 4 Guidance**

* Guidance is produced which informs the service of products most suitable to meet patient needs.

**Maintenance of Product List**

New products will be assessed on an on-going basis for addition to the list as appropriate. New evidence for products not on the Drug Tariff will also be reviewed in this way.

1. The Northern Ireland Drug Tariff is available from: <http://www.hscbusiness.hscni.net/services/2034.htm> [↑](#footnote-ref-1)
2. Available from <http://niformulary.hscni.net/Formulary/Adult/WoundSection/Pages/default.aspx> [↑](#footnote-ref-2)
3. Detail on the protocol is available from: [niformulary.hscni.net/Formulary/Adult/WoundSection/ExceptionProtocol/Pages/default.aspx](http://niformulary.hscni.net/Formulary/Adult/WoundSection/ExceptionProtocol/Pages/default.aspx) [↑](#footnote-ref-3)