

Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill

Business and Regulatory Impact Assessment

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Legislation introduced in order to reimburse persons who have paid for private transvaginal mesh removal surgery

1. Purpose and intended effect

1.1 Background

Prior to 2014, transvaginal mesh, a medical device, was in routine use in NHS Scotland, as well as in the rest of the UK and internationally. It was implanted into persons, vaginally, in a surgical procedure that had the aim of alleviating symptoms of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). The mesh is intended to reinforce weakened tissue in a person's bladder or pelvic area.

Concerns about the impact of the use of mesh began to emerge in the mid-2000s and strengthened over the years that followed. In light of concerning evidence of very painful and debilitating complications being experienced by patients who had had transvaginal mesh implanted, its use in the treatment of SUI and POP in NHS Scotland was formally halted in September 2018¹. This halt remains in place.

Work is underway in Scotland to improve the services available to those with transvaginal mesh complications; taking into account people's past experiences, listening to their concerns and taking action to reconcile these. The National Centre for mesh complications has been introduced in NHS Greater Glasgow and Clyde and additional pathways to NHS England as well as to an independent provider are being developed. This will ensure that everyone gets the treatment and care that they need.

The proposal for introducing this legislation is to allow those who have sought private treatment at their own expense to be reimbursed reasonable costs. The Government considers this step reasonable because it is simultaneously taking steps to secure that, in the future, persons in the same circumstances and with the same preferences will have the option of having comparable treatment arranged and paid for by the NHS. It seems to the Government unfair and unreasonable for persons who arranged such treatment prior to that option becoming available to have had to meet the financial costs themselves.

¹ [CMO\(2018\)10 - Transvaginal mesh \(scot.nhs.uk\)](#)
[CMO\(2018\)12 - Restricted Use Protocol for interventions to treat stress urinary incontinence and pelvic organ prolapse \(scot.nhs.uk\)](#)

1.2 Objective

Concerns about complications suffered by those who had had mesh implanted were also accompanied by concerns that reports of complications did not, in the view of a number of people, elicit from some clinicians an appropriately substantial or understanding response. The experiences of those affected were reported in considerable detail in the report of the Independent Medicines and Medical Devices Review (sometimes referred to as “the Cumberlege report”)². In a number of instances, people reported an impression that their experiences of painful complications and life changing side effects were not being taken seriously by the NHS. As a result of these experiences, significant numbers reported losing faith and trust in the NHS in this regard, and the Scottish Government does understand why those affected would have reacted this way in light of the experiences they report.

This legislation fits within wider Scottish Government policy in respect of transvaginal mesh, including the commitments set out in the 2021 election manifesto, where we are continuing to work to improve services for those experiencing complications.

This legislation is intended to ensure recompense for those affected, and this decision is reached in light of the accumulation of factors, including the physical and psychological harm caused by the presence of mesh, and the aforementioned issues of trust in the NHS.

1.3 Rationale for Government intervention

The Government wishes to legislate to ensure parity for those who have experienced transvaginal mesh complications.

2. Consultation

2.1 Within Government

The following government departments have been consulted in the preparation of this Business and Regulatory Impact Assessment (BRIA):

- Scottish Government Legal Directorate

2.2 Public Consultation

It is not proposed to conduct a full consultation on this Bill. The Government is mindful that consultation of the kind normally undertaken would necessarily bring further delay in offering appropriate recompense to the people affected and their families.

The Government has been involved in continual and detailed formal and informal discussions with persons affected by mesh, and with representative bodies. Ministers including the First Minister have also met with persons with mesh

² [the Independent Medicines and Medical Devices safety Review \(immdsreview.org.uk\)](https://immdsreview.org.uk)

complications and, during those meetings, the issue of reimbursement was raised. Similarly, it has been raised in patient engagement sessions held by the Health and Social Care Alliance³ as well as in ministerial correspondence and in the Parliament.

Whilst there will not be a full consultation, the Alliance will shortly host a focus group with those who have had private mesh removal to understand their views on how a scheme might work in practice. The feedback from this session will directly influence the scheme that is established.

2.3 Business

These proposals are expected to have minimal, if any impact on business.

3. Options

3.1 Option 1: Introduce the Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill.

Introduce legislation giving Ministers the power to reimburse people who have undergone transvaginal mesh removal surgery privately.

3.2 Option 2: Do nothing

Maintain the status quo whereby, Ministers do not have the power to reimburse people in this circumstance, and instead, the consideration of reimbursement falls to each NHS Scotland Health Board, where, broadly, the NHS will only meet the costs of the healthcare it commissions.

4. Benefits

Options	Positive Impact	Negative Impact
<u>Option 1</u>	This will allow people to reclaim costs of medical treatment and associated reasonable costs, which may be in the region of £19,000 per claimant. The group who are likely to benefit is very small, and may be fewer than 20.	This may be received poorly by those who did not arrange private treatment but consider that they would have done so, had they known that they would later be reimbursed. There is also the additional impact of Covid-19 which might have prevented some people travelling. That said, it is intended that people will, in the future, have equivalent treatment

³ The Alliance is the national third sector intermediary for a range of health and social care organisations. They are a strategic partner of the Scottish Government and have fed into several mesh policy developments including the development of the Complex Mesh Removal Service in NHS GGC and the Scottish Government mesh fund.

<u>Options</u>	<u>Positive Impact</u>	<u>Negative Impact</u>
		options available to them, fully funded by the NHS.
<u>Option 2</u>	<p>No legislative change would be required.</p> <p>There would be no diversion of funds (albeit very small indeed compared to available monies) to private persons.</p>	This specific group who have had private treatment will feel aggrieved that they are carrying a financial burden for private treatment, which may, in the future, be available to others, fully funded by the NHS.

5. Costs

<u>Options</u>	<u>Costs</u>
<u>Option 1</u>	<p>Whilst there is no firm data, informal liaison with interested parties suggests that there are likely to be a very limited number of persons potentially eligible for reimbursement, possibly as few as 20. Assuming 20 patients successfully apply for reimbursement, based on the per-patient estimates, the total cost of reimbursement could be expected to be in the region of £324,000 to £445,000.</p> <p>In addition, there will be a resource cost to cover the administration of the scheme which we will ask a body such as NHS National Services Scotland to undertake. Yearly administrative costs associated with the mesh fund, launched in July 2020, have totalled £33,100 and, on the basis that a similar form of administration is required for the reimbursement scheme, similar costs can be assumed.</p>
<u>Option 2</u>	There will be no costs involved.

6. Scottish Firms Impact Test

These proposals are not expected to have any impact on small firms.

7. Competition Assessment

These proposals are not expected to have any impact on competition.

8. Consumer Assessment

These proposals are not expected to have any impact on consumers.

9. Test run of business forms

This policy will not introduce any statutory business forms.

10. Digital Impact Test

These proposals are not expected to have any digital impact.

11. Legal Aid Impact Test

These proposals are not expected to have any impact on the legal aid budget.

12. Enforcement, sanctions and monitoring

It is planned that payments under the scheme will be administered through an NHS body, for example, NHS National Services Scotland. Arrangements will be in place under the scheme proposed under the Bill for applications to be invited, and for those applications to be considered and determined. There will also be arrangements made for the recovery of payments made in error or accidentally in excess. It is expected that the effective duration of the scheme will be limited, as will payments arising from it, as there is a limited number of persons potentially eligible and it is intended that in future, persons with equivalent medical needs will be offered surgery through the NHS or through private providers procured by the NHS.

13. Implementation and delivery plan

Based on our assumptions on the time needed for the Bill's Parliamentary passage, and as the scheme itself may not be made until two months after the date of Royal Assent, it is likely that a scheme of reimbursement will not be made until the financial year 2022-23.

14. Summary and recommendation

In summary, introducing legislation will ensure that people who have sought removal of transvaginal mesh privately can be recompensed for the costs they have incurred. It has been concluded that without legislation, the Scottish Ministers do not have the power to use public funds in this way, and as such, doing nothing would not achieve our objectives.

Although there are costs associated with legislation, these are justified in light of the additional pathways that, in the future, will be available for people wishing to seek mesh removal treatment outside of Scotland, or outside the NHS entirely. The intention is to provide some parity for those who have sought their own private treatment.

We therefore intend to proceed with the legislation Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill outlined in **Option 1**.

15. Declaration and publication

I have read the Business and Regulatory Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs. I am satisfied that business impact has been assessed with the support of businesses in Scotland.

Signed: Humza Yousaf

Date: 17 June 2021

Minister's name: Humza Yousaf

Minister's title: Cabinet Secretary for Health and Social Care

Scottish Government Contact point: David Bishop



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