

TRANSVAGINAL MESH REMOVAL (COST REIMBURSEMENT) (SCOTLAND) BILL

POLICY MEMORANDUM

INTRODUCTION

1. As required under Rule 9.3.3 of the Parliament's Standing Orders, this Policy Memorandum is published to accompany the Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill introduced in the Scottish Parliament on 23 June 2021.

2. The following other accompanying documents are published separately:

- Explanatory Notes (SP Bill 3–EN);
- a Financial Memorandum (SP Bill 3–FM);
- a Delegated Powers Memorandum (SP Bill 3–DPM);
- statements on legislative competence by the Presiding Officer and the Scottish Government (SP 3–LC).

3. This Policy Memorandum has been prepared by the Scottish Government to set out the Government's policy behind the Bill. It does not form part of the Bill and has not been endorsed by the Parliament.

POLICY OBJECTIVES OF THE BILL

4. The purpose of the Bill is to give power to the Scottish Ministers to reimburse persons who have entered into arrangements privately and have paid to have transvaginal mesh removed from their body, in relation to the costs of removal surgery and also reasonable connected expenses.

5. 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.

6. 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 2018.¹ This halt remains in place.

7. 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.

8. The NHS has developed a number of services to assist people negatively affected by transvaginal mesh. These services now include a national specialist centre, located in NHS Greater Glasgow and Clyde (GGC). The specialist service assesses needs and, where appropriate, and subject to shared decision making and informed consent, performs mesh removal surgery. It has been an important part of this new service that it has been developed in ways that have drawn on patient feedback in the form of, for example, patient satisfaction surveys and the views of patient focus groups.

9. In July 2020, the Scottish Government also established a “mesh fund” to help those affected by transvaginal mesh complications.³ This fund allows eligible persons to claim a one-off £1,000 payment towards the costs associated with practical or emotional support, as they see appropriate.

10. It is intended that these new and improving specialist services, together with the support of the wider NHS locally will be effective in meeting the needs of those affected by mesh, both in terms of offering necessary health services and also in providing support in ways that are understanding and responsive to people’s wider needs. But the Scottish Government does also accept that the circumstances surrounding the use of transvaginal mesh, and particularly the experiences of those so badly affected, has in some cases led to a breakdown in trust in the NHS in Scotland, to the extent that some do not wish to be treated by it for mesh complications.

11. In the exceptional circumstances surrounding mesh, therefore, the Government has decided to offer those affected a wider range of service choices than would be normal in the provision of health services through the NHS. Complementing the new service in Glasgow, there will therefore be options for patients to receive mesh removal surgery in NHS centres in England and also the possibility of receiving surgery from independent providers commissioned by NHS Scotland. At the time of introduction of the Bill an NHS Scotland procurement process to secure services from

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

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

³ [Scottish Government Mesh Fund | National Services Scotland \(nhs.scot\)](https://www.nhs.uk/scotland/services/mesh-fund/)

independent providers is near conclusion. Applications have been received and considered, and it is hoped that the outcome of the exercise will be confirmed in the near future.

12. The Government hopes that the new NHS Scotland service, together with the options to receive treatment in the NHS outside Scotland, or from independent providers, will ensure that all patients have choice over their care, and thus will have access to treatment that meets their needs and, importantly, in which they can have confidence.

13. It is, however, in light of the additional steps being taken to provide more choice to persons in the future, that the Government considers that a very particular need for new legislation arises. Whilst NHS services have been available throughout, it is recognised that the breakdown of trust reported by a number of patients with mesh complications led them to seek mesh removal surgery outside the NHS and in some cases outside the UK, because they did not wish to undergo surgery in NHS Scotland. Given that, at that time, there was no NHS route to referral to an independent provider available, it is understood that a number of people instead sought and paid for private treatment in order to seek relief from the severe and painful complications they had endured.

14. The Scottish Government therefore considers, in light of all of these circumstances, that it is now reasonable and appropriate to reimburse persons who have entered into arrangements privately and have paid to have transvaginal mesh removed from their body. 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 and 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.

ELIGIBILITY CRITERIA AND PLANNED OPERATION OF THE SCHEME

15. The Bill gives the Scottish Ministers power to establish a scheme to allow applications to be made for reimbursement. If the Parliament approves the Bill and it is enacted, it is planned that reimbursement will be available to persons who arranged and paid for mesh removal surgery, carried out by an independent provider, and who were ordinarily resident in Scotland at the time the treatment was arranged. Those eligible to apply will be permitted to claim reimbursement of the costs associated with the removal treatment, as well as reasonable costs of travel, accommodation and subsistence for the person concerned and for a person who has travelled to support the person having the treatment.

16. 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.

17. It is planned that the administrative scheme proposed under the Bill will be of limited duration. This is because, as noted in paragraph 11 above, a procurement process is near conclusion, the aim of which is to allow mesh removal treatment by independent providers to be made available through the NHS in the future, so avoiding the need for people to make their own private arrangements or spend their own money. The date by which private arrangements must have been entered into in order to qualify for reimbursement under the scheme will be determined

once that process is complete, having regard to the date on which private treatment first becomes available for arranging through the NHS (as a result of that procurement process). The date by which applications must be made under the scheme will be determined so that sufficient time is available after the scheme becomes operational for all those potentially eligible for reimbursement to make an application. The Government will take steps to raise awareness of the scheme amongst those who are potentially eligible, and more generally the scheme will be laid before the Parliament and published.

18. The intention is that the scheme will be administered through an NHS body, for example, NHS National Services Scotland. Detailed eligibility criteria and the documentary evidence that will have to be provided to the scheme administrators to support an application will be set out in the scheme documentation.

ALTERNATIVE APPROACHES

19. As part of the Bill development process, alternative approaches were considered in the context of the policy objectives outlined above. Consideration was given in particular to the extension administratively of the present Scottish Government mesh fund, but it was not considered that the statutory base of that scheme could be relied upon to authorise a scheme of reimbursement, and – in line with the requirements of the Scottish Public Finance Manual – it was concluded that specific legislative authority was required.

20. If legislation is not introduced into the Parliament it is considered that there does not exist appropriate statutory authority to make the payments contemplated. However, this would of course involve those who had previously arranged and paid for private mesh removal carrying a financial burden privately for treatment that others will shortly be able to access, free of charge, via the NHS. The Scottish Government does not therefore view the status quo as a viable option.

21. When considering the definition of “mesh removal surgery” it was considered reasonable to limit this to the two procedures which are subject to the “halt” put in place in September 2018. The Chief Medical Officer’s position on the use of mesh in other procedures was also set out in this correspondence, with a high vigilance scrutiny protocol required in some cases or no change in practice in others.

CONSULTATION

22. In view of the very narrow circumstances that the Bill is intended to address and (relative to overall levels of expenditure) the very limited financial implications, it is not planned to conduct a consultation on this Bill. The Government is also mindful that consultation of the kind normally undertaken would necessarily bring further delay in offering appropriate recompense to the people affected and their families, and hopes that the Parliament will agree that it is desirable in these circumstances to avoid further delay or anxiety for those affected. 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 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 Alliance⁴ as well as in ministerial correspondence and in the Parliament.

23. Whilst a full consultation is not intended, 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 set up.

EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT ETC.

Equal opportunities

24. The public sector equality duty requires public bodies to have due regard to the need to eliminate discrimination, advance equality of opportunity and to foster good relations between different people when carrying out their activities.

25. An Equality Impact Assessment has been published on the Scottish Government website to coincide with the introduction of this Bill. The evidence base for the following protected characteristics was reviewed and assessed: age, disability, sex, pregnancy and maternity, gender reassignment, sexual orientation, race, religion and belief, and marriage and civil partnership. It has been determined that the Bill does not have a disproportionate positive or negative impact on any of the protected characteristics. However, the assessment has informed the policy and mitigations that can be made to ensure that the objective is met, for example, an application system will need to be developed which accounts for those with limited access or difficulty using the internet. A Fairer Scotland Duty Assessment has not been carried out as the introduction of this Bill does not constitute a strategic decision.

Human rights

26. A full Human Rights Impact Assessment has not been carried out. However, due consideration has been given to the European Convention on Human Rights (ECHR) and the Scottish Government is satisfied that the Bill is ECHR compliant.

27. Full consideration will be given to the relevant eligibility criteria and the duration of the scheme. The scheme will require the provision of information and evidence in support of applications. Sufficient safeguards will be in place to ensure that any interference with the right to privacy is proportionate, is ECHR compliant and that the applicant's right to privacy is protected.

28. ECHR obligations require that eligibility must link rationally to the overall purpose of the scheme and that decisions to include or exclude any particular group are proportionate. An Equality Impact Assessment has been carried out and the Scottish Government is satisfied that the introduction of this Bill does not create unlawful discrimination, harassment and/or victimisation. This is compliant with Article 14 of the ECHR (the prohibition of discrimination).

⁴ 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.

Island communities

29. The Bill applies equally to all communities across Scotland. Thus, if a person meets the eligibility criteria for reimbursement, their geographical location within Scotland is irrelevant. On this basis, an Islands Communities Impact Assessment has not been carried out.

Local government

30. The Bill does not impose any statutory duties on local government and is not considered to directly or indirectly impact local government.

Sustainable development

31. The Bill supports the United Nations Sustainable Development Goals (SDG), specifically:

- SDG 3: Good health and well-being – the Bill will have a positive impact on achieving wider policy objectives to ensure that all people with transvaginal mesh complications get the treatment and care that they need.

Strategic Environmental Assessment

32. The Bill is exempt from strategic environment assessment under section (4)(3)(b) of the Environment Assessment (Scotland) Act 2005 as it relates to financial and budgetary plans.

Business and regulatory impact assessment

33. An assessment of the business and regulatory impact has been undertaken and has been published on the Scottish Government website to coincide with the introduction of this Bill. The Bill does not impose any new costs on businesses or otherwise have any regulatory impact in the private sector.

This document relates to the Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill (SP Bill 3) as introduced in the Scottish Parliament on 23 June 2021

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