



SPICe Briefing

Pàipear-ullachaidh SPICe

Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill

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This Bill would allow the Scottish Government to set up a scheme which could pay back costs to people who have paid healthcare companies to have transvaginal mesh removed privately. Some chose to do this following complications with surgery using mesh to treat Stress Urinary Incontinence or Pelvic Organ Prolapse. The costs reimbursed could include travel and accommodation costs paid in relation to their surgery.

TRANSVAGINAL MESH REMOVAL (COST REIMBURSEMENT) (SCOTLAND) BILL

EXPLANATORY NOTES

Under Rule 9.3.2A of the Parliament's Standing Orders, these Explanatory Notes are published in the Scottish Parliament on 23 June 2021.

Other accompanying documents are published separately:

Memorandum (SP Bill 3-EN);

Memorandum (SP Bill 3-PM);

Legislative Memorandum (SP Bill 3-DPM);

Bill 3-LC).

These documents have been prepared by the Scottish Government and the Scottish Ministers in order to assist in the debate on the Bill. They do not form part of the Bill and have no legal effect.

They are not meant to be construed in conjunction with the Bill. They are not, and are not meant to be, part of the Bill. So where a section, or a part of a section, does not have effect, none is given.

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Summary

The Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill was introduced in the Scottish Parliament on 23 June 2021. The Bill seeks to reimburse people who have paid for private surgery to remove transvaginal mesh from their body. The cost reimbursement is intended to include the costs of removal surgery and reasonable connected expenses. The Bill contains the following sections:

Section 1 empowers the Scottish Ministers to reimburse women for costs relating to transvaginal mesh removal surgery by putting in place a scheme for making reimbursement payments.

Section 1 defines “mesh removal surgery” and sets the criteria for mesh removal surgery which qualifies for reimbursement. The provision also sets out what reimbursable costs are incurred in relation to qualifying mesh removal surgery.

Section 2 makes further provision about the scheme of reimbursement payments. This includes provision on application procedures, administration, applicant requirements and review processes.

Sections 3, 4 and 5 include powers for the Scottish Ministers to make ancillary provisions, information on commencement and the short title.

Background

The Bill ¹ is made up of two main sections which cover:

- the power for Scottish Ministers to reimburse costs relating to the removal of transvaginal mesh
- provisions relating to administration, eligibility, time limits, [application](#) to the scheme and review of decisions.

The Bill doesn't cover any of the detail of the scheme, which will follow as secondary legislation, but it does say what provisions the scheme itself may make, such as about who might apply, about to whom payments can be made, and a date by which applications can be made.

The 'Final provisions', Section 3, cover the power to make regulations in relation to the Bill if required. The Bill and accompanying documents can be found on the bills and laws section of the Parliament's website.

What is transvaginal mesh?

Transvaginal tape (TVT) 'mesh', was used for [stress urinary incontinence \(SUI\)](#) and [pelvic organ prolapse and \(POP\)](#).

Surgical mesh made of synthetic materials, such as polypropylene, can be found in knitted mesh or non-knitted sheet forms.

The type most often used to treat pelvic floor disorders is made of the synthetic polypropylene. For pelvic organ prolapse repair, the mesh is placed to reinforce the weakened vaginal wall. This is different from the way it is used for stress urinary incontinence, in which a thin strip or tape is placed to support the urethra.

These non-absorbable materials will remain in the body permanently. Mesh made of these materials are used to provide permanent reinforcement and strength to the repair.

These two conditions, and their treatment with mesh, have been [the subject of much controversy](#) ², debate and a wide review. The [available evidence was summarised in chapter five of the Scottish Government's commissioned independent review](#) ³ of the use of transvaginal mesh implants. [New UK clinical guidelines were published in 2019](#) ⁴, which take account of possible complications by advising follow up after any surgery, and collecting data on any complications. [The concerns have not been limited to Scotland and have been raised internationally and elsewhere in the UK](#) ⁵.

What is the current situation on the use of transvaginal mesh?

Routine use of mesh for treatment of SUI and POP ceased in Scotland in 2014. This

suspension was tightened in 2018⁶ until a restricted use protocol was established, which halted certain procedures and allowed others in certain circumstances until new guidance was issued by NICE. A petition was lodged, Polypropylene Mesh Devices, PE 1517⁷, in 2014 and was active through to the end of parliamentary Session Five. The last submission in relation to the petition was a letter to the Committee from the then Cabinet Secretary, Jeane Freeman⁸, immediately prior to the 2021 pre-election recess. The letter set out the intention to introduce a new Bill to allow reimbursement.

Need for the Bill

The Bill could be seen as the end point in a campaign to highlight concerns and complications following surgery using polypropylene transvaginal mesh (TVM).

The Bill came about partly because of a campaign that started with the ⁷ petition presented to the Scottish Parliament Public Petitions Committee in 2014. The [petition](#) called for:

- a suspension in the use of Transvaginal Mesh (TVM)
- a full evaluation of safety concerns
- the introduction of fully informed consent throughout Scotland
- improved reporting of complications after surgery
- a national register of all TVM procedures which linked to international registers.

The [petition](#) ran for several years across two parliamentary sessions. The Committee published its report on 21 August 2018 ⁹.

The Policy Memorandum ¹⁰ describes, through the policy objectives of the bill (paras 4 - 14), the background to the Bill. It says that concerns of debilitating, severe and painful complications had been reported since the mid 2000s by women who had had transvaginal mesh implanted. For some, their own reports were not met with an understanding response by clinicians. Scepticism from clinicians about any links between the mesh and the symptoms reported, led the affected women to lose trust in the NHS. The experiences of women affected were reported in detail in the Independent Medicines and Medical Devices Review (the Cumberlege Report). ¹¹. The loss of trust meant that some of the women sought removal surgery outwith the NHS, from private providers in the UK and abroad, securing the funding through a range of means. There was no available referral route to independent providers.

The Scottish Government acknowledges this lack of trust and the reasons for it. They argue that the circumstances are exceptional and therefore reimbursement is justified.

There are now also specialist services established in Scotland and in England for women experiencing complications from mesh implant surgery who wish to have it removed.

The Scottish Government has taken the additional step in procuring the services of private providers to remove mesh from women who want it removed. Such women, who are resident in Scotland, will have the choice to have surgery outwith the NHS in Scotland, which will be funded by their home health board. The establishment of a specialist NHS service based in NHS Greater Glasgow and Clyde, and the option for referral to have surgery outwith the NHS do not form part of the Bill.

The Bill is required to enable a reimbursement scheme to be set up. [The mechanisms to allow patients to be referred outwith NHS Scotland for treatment](#), in circumstances where the NHS could not provide the treatment, have been in place for some considerable time.

Specialist mesh removal surgery service

Although specialist mesh removal services are not part of the Bill, their operation and delivery are clearly related to outcomes for women affected by transvaginal mesh.

Reference to the services are also made in the Policy Memorandum¹⁰. The Bill is only about reimbursement for retrospective treatment to remove vaginal mesh. The establishment of a specialist service was deemed necessary to support other women, who have not sought treatment privately, who wish to have their mesh removed.

Women will have a number of options for mesh removal surgery:

- a specialist centre in NHS Greater Glasgow and Clyde
- referral to NHS Specialist centres in England
- or referral to independent provision through Spire Healthcare in Bristol or to Dr. Veronikis, who is based at the Mercy Hospital, Missouri, US.

While the service in Scotland is available and taking referrals, it is not known how long women will have to wait, or the range of choices they will be given. The contracts and service level agreements have not yet been finalised for referrals to private services, although the procurement exercise was completed in summer 2021.

It is not clear what the criteria for referral will be to the service, nor how referral to services outside Scotland will operate in practice for women when they present with symptoms they think might be mesh-related.

What does the Bill do?

Section 1 - power to reimburse costs

This section covers the power to reimburse costs via a scheme. It defines what mesh removal surgery is, which restricts the scheme to cover surgery where mesh was implanted transvaginally only. It goes on to state that the surgery had to be undertaken outwith NHS Scotland, and that the person had to be ordinarily resident in Scotland at the time surgery was arranged. It also says that the scheme will specify a date by which surgery must have been arranged.

Subsection 4 covers definition of the costs within the scheme. It states that 'reasonable' costs in relation to travel, accommodation and subsistence will be covered as well as the cost of surgery itself. Subsection (4)(d) provides that any other costs, specified in the scheme will be covered.

Because the Bill will only apply in Scotland, the Scheme will only be available to those people who were ordinarily resident in Scotland at the time they arranged mesh removal surgery. It doesn't matter where the original surgery to implant mesh was carried out. ('Ordinary residence' is the term used to decide on eligibility to access NHS services in the UK, including Scotland ¹²). This means that:

- Those who have moved away from Scotland since removal surgery, will still be able to apply.
- The scheme will apparently *not* be open to women who were not resident in Scotland when they had mesh removal surgery, even if the mesh was originally inserted in Scotland. They might, once again, be resident in Scotland now, and have suffered complications from the original surgery.

Section 2 - Further provision about the scheme

This section covers more detail about the scheme and its administration and operation. The subsections suggest what provisions the scheme might make in relation to aspects such as:

- cut off date for applications
- evidence to be provided for reimbursement
- what if an application is refused – review process
- amount of reimbursement payments
- appointment of a person to administer the scheme on the Scottish Ministers' behalf
- if money is required to be repaid.

Section 3 - Ancillary provision

This allows Scottish Ministers to make a range of provisions they consider appropriate in connection with the Act, and may make regulations that modify the Act or that make different provision for different purposes. These purposes must be solely related to the reimbursement of costs related to qualifying mesh removal surgery.

Financial Memorandum

The Financial Memorandum (FM) ¹³ states that the overall expected total costs of the Bill will amount to £478,100. It also states that these costs are only likely to arise in 2022-23, depending on the Bill's passage through Parliament and when the Bill comes into force.

There are a number of assumptions made about both the administrative costs and the reimbursement costs.

The assumptions for the costs for administering the scheme are based on the costs associated with the Scottish Government Mesh Fund ¹⁴, which makes a one-off payment of £1,000 to women adversely affected by transvaginal mesh implants. The Fund is open to applications till June 2022. The costs for the year from July 2020 have totalled £33,100. The FM anticipates that these costs will be the same as those entailed in operating the reimbursement scheme. It is explained that this is because the number of women applying for reimbursement will be much lower than for the Mesh Fund, and is thought to only total around 20 women. So even though much more documentary evidence will be required for reimbursement, the lower numbers applying should, according to the FM, balance out the costs of administering the scheme.

Some of the women had mesh removal surgery a number of years ago, without any prospect of reimbursement, so ability to account for historical expenditure, or proof of how funding was raised, could be challenging.

Expected costs for the financial year 2022-23

Costs including administration and payment costs, based on 20 people applying for and receiving reimbursement. What the government expects to pay to cover all costs and payments related to the Bill

Costs	Financial Year: 2022-23
Reimbursement costs	£324,000 - £445,000
Administrative costs	£33,100
Total	£357,100 - £478,100

Financial Memorandum

The FM considers the 'margins of uncertainty', some of which match the submissions, such as the varied lengths of stay required for treatment/recuperation, different costs for flights, other, more expensive destinations, and clinical complexity. However, the highest estimate of the costs of the scheme are £891,000 - if 40 people were to come forward.

The length of the scheme will be of limited duration. This is linked to the operation of the new specialist service and option for treatment outwith Scotland and in the private sector. The cut off date for entry into private arrangements has been set at 12 July 2021, a few weeks after the introduction of the Bill (23 June 2021). This date (12 July) coincides with the announcement of the outcome of the procurement exercise carried out by the Scottish Government ¹⁵.

The date set for application to the scheme for reimbursement "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."

There is much uncertainty about the numbers who might be eligible, because of the lack of reporting of patient-reported outcomes ¹⁶ over the years. The Scottish Government acknowledge the uncertainty:

“ 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”

Scottish Parliament, Policy Memorandum

Key Issues raised about the Bill

The Health, Social Care and Sport Committee consulted on the Bill between September and October 2021¹⁷ ¹⁸. A number of questions and concerns were raised about the Bill.

- The Bill refers to reasonable costs, but it is unclear what ‘reasonable’ means. What if, for example, surgery was delayed because of newly-diagnosed issues or where post-operative complications occurred which required a longer stay, but were not related to the removal of the mesh?
- There are concerns from those who have already started on the process of seeking removal from private providers and are waiting. How might their surgery be affected by the specialist service procured by the Scottish Government which is contracting the same independent providers as the women are using?
- There are concerns around those who ‘crowdfunded’ for the costs of their treatment – should they still be able to apply for reimbursement or should those who donated apply for reimbursement? Also, would/should this means of raising the funding (i.e. from a crowdfunding platform) be deemed any different from raising money from friends and family?
- The cut-off dates for applying for reimbursement – might there be women who are not aware of the Bill, so do not apply within the timescale, but would otherwise be deemed eligible?
- The Bill only refers to direct costs of surgery and expenses:

“ The Bill does not address the additional costs incurred for persons accessing funding for mesh removal surgery. Applicants may have re-mortgaged their homes, taken bank loans, used credit cards with high interest rates, or borrowed from friends and families. The Bill does not refer to payment of such additional costs.”

Law Society of Scotland submission

- If surgery happened some time ago, receipts for accommodation, travel and subsistence may no longer exist, so how will expenses be eligible, even if proof of surgery is obtained?
- The Bill also does not consider whether the next of kin, in the case where someone has died, will be eligible to apply for reimbursement.
- The issue of residence was raised. Only those who were resident in Scotland when removal surgery was arranged/carried out will be eligible, regardless of where mesh was inserted. This could exclude women who had mesh fitted in Scotland, lived elsewhere when it was removed, but might now live once again in Scotland.
- Women affected by mesh or mesh removal might have ongoing associated costs. There is no provision for this in the Bill (although women will have access to specialist NHS services for ongoing issues).
- The Financial Memorandum bases assumptions on costs on around 20 women seeking reimbursement. It is not known how many women are affected by complications. If the number is significantly higher then both the administrative costs

and the reimbursement costs will be much higher than expected.

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