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Health, Social Care and Sport Committee

Stage 1 Report on the Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill



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Contents

Summary of recommendations	1
Introduction	5
Overview of scrutiny and purpose of the Bill	5
Background to the Bill	7
Consideration by other Committees	9
Policy and Financial Memorandums	10
Policy Memorandum	10
Financial Memorandum	10
Principles behind the Bill	11
Section 1: Power for Scottish Ministers to reimburse costs relating to the removal of transvaginal mesh	11
Qualifying mesh removal surgery	11
Costs associated with reimbursement	13
Costs associated with administration of scheme	15
Section 2: Further provisions about the scheme	16
Deadline for applications	16
Who can apply for reimbursement	17
Evidence of expenditure	18
Decisions on whether reimbursement is paid	18
Sections 3 and 4: Ancillary provision and Commencement	20
Further Considerations	20
Inequality	20
Specialist mesh removal services in Scotland	21
Committee's findings on the Bill	23
Annexe A - Minutes of meeting	24
Annexe B - Evidence	25
Written evidence	25
Official reports of meetings	25

Health, Social Care and Sport Committee

To consider and report on matters falling within the responsibility of the Cabinet Secretary for Health and Social Care and matters relating to drugs policy.



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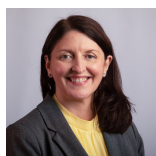
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Summary of recommendations

Committee Findings

The Committee is content to support the general principles of the Bill and recommends to the Parliament that they be agreed to.

The Committee draws the Scottish Government's attention to the various recommendations it has made about the details of the scheme. To ensure these recommendations are satisfactorily addressed, it further requests that the regulations setting out the details of the scheme are made subject to a procedure that will enable them to undergo full and proper scrutiny prior to their entry into force.

Principles behind the Bill

The Committee considers the key principle of the Bill is to ensure fairness and parity of treatment for all individuals in relation to transvaginal mesh removal services in Scotland. The Committee is committed to ensuring fairness is achieved within the Bill and the resulting scheme for reimbursement. The Committee further believes there are specific issues raised during evidence that need more clarity to ensure this is achieved.

Qualifying mesh removal surgery

The Committee believes that, to adhere to the principles of fairness and equity of treatment, greater clarity is needed around the residency criteria set out in the Bill. Specifically, the Committee believes there is a strong case for individuals who had their original mesh implant surgery undertaken by NHS Scotland but who were not ordinarily resident in Scotland at the time their mesh removal surgery was arranged to also qualify for reimbursement under the terms of the Bill. The Committee supports a widening of the eligibility criteria in such cases, provided those individuals have not already claimed for reimbursement of these costs elsewhere.

In accordance with the commitments made by the Cabinet Secretary when giving evidence, the Committee calls on the Scottish Government, in bringing forward regulations under section 3 of the Bill, to demonstrate appropriate flexibility in the definition of "making an arrangement" for mesh removal surgery".

We further call on the Scottish Government, in bringing forward those same regulations, to address the potential time gap in eligibility for reimbursement between the proposed cut-off date of 12 July 2021 and the actual date when contracts with independent providers of mesh removal surgery are ultimately concluded.

Costs associated with reimbursement

The Committee notes the Cabinet Secretary's commitment to take a flexible approach in determining what costs will be reimbursed under the Bill. To provide clarity for the individuals concerned and the scheme administrators, in bringing forward the details of the scheme in regulations, the Committee calls on the Scottish Government to outline in much greater detail the categories of costs that will be covered but equally to set out the flexible approach to be taken in processing individual cases.

Costs associated with administration of scheme

The Committee notes the uncertainty around how many individuals will ultimately apply for reimbursement under the scheme. The Committee strongly urges the Scottish Government to review costs to administer the scheme to ensure NHS NSS has sufficient resource to manage the scheme effectively without causing undue stress and anxiety to its workforce.

Deadline for applications

Ensuring all those who are entitled to reimbursement are aware of the reimbursement scheme and the deadline for making an application is crucial. Given there is no clear indication in the Bill documentation of how many individuals are likely to be affected, the Committee asks the Scottish Government to set out how it will ensure anyone that could be eligible is made aware of the scheme well in advance of the deadline for applications.

Who can apply for reimbursement

The Committee is concerned that there is no clear indication in the Bill whether crowdfunding or family donations will be eligible for reimbursement. The Committee would welcome further clarity on the approach to treatment of such alternative avenues for sourcing funding for mesh removal surgery, including reference to any duties or obligations related to the management of public finances that may have informed the Scottish Government's approach in this area.

Evidence of expenditure

The Committee reiterates its view that the details of the scheme to be brought forward via regulations needs to include a clear explanation of a flexible approach to reimbursement that takes account of individual circumstances, as committed to by the Cabinet Secretary and Scottish Government officials while giving evidence.

Decisions on whether reimbursement is paid

The Committee is of the view that individuals should be entitled to reimbursement where they have had any form of private mesh removal surgery, whether that surgery was successful or not.

The Committee expects the scheme to detail the criteria for reimbursement, which should include clinical input to support scheme administrators. However, the Committee understands there should be a balance between ensuring the surgery has led to positive and lasting outcomes and not causing additional stress and anxiety to individuals by creating an onerous or difficult application process. The Committee looks forward to seeing detail of how this can be achieved in the final scheme, as well as the processes to be put in place for reviewing and challenging such decisions.

Ensuring individuals affected by transvaginal mesh have positive and lasting outcomes must remain a key priority. The Committee welcomes further detail from the Scottish Government on additional work to ensure those individuals who have paid for private removal surgery and are reimbursed under the Bill, have timely access to post-operative support.

Ancillary provision

The Committee is aware that many of the specific issues it has raised about the operation of the scheme will be addressed in implementing regulations to be submitted to the Parliament for scrutiny in the form of subordinate legislation. The Committee believes that these regulations must therefore be subject to a procedure that will enable an appropriate level of scrutiny to take place.

Inequality

The Committee supports the principles of fairness, equity and parity which, in its view, underpin the Bill. However, it is concerned there may be additional considerations surrounding and included within the Bill that could give rise to inequality. To address these concerns, the Committee considers it is vitally important that any individual who has experienced complications due to transvaginal mesh has their case reviewed and receives appropriate treatment as quickly as practically possible via the complex mesh national surgical service.

Specialist mesh removal services in Scotland

The Committee would welcome further detail from the Scottish Government on campaigns to publicise the complex mesh national surgical service, training for primary care staff on mesh complications and person-centred approaches for supporting individuals through treatment including pre and post-operative support. To this end, the Committee will continue to take an active interest in the operation of the complex mesh

national surgical service and intends to take further evidence on this topic in the course of 2022.

Introduction

Overview of scrutiny and purpose of the Bill

1. The Scottish Government introduced the [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill](#) on 23 June 2021. The Bill was introduced by the Cabinet Secretary for Health and Social Care, Humza Yousaf MSP. The Health, Social Care and Sport Committee was designated as the lead Committee by the Parliamentary Bureau for Stage 1 scrutiny of the Bill. It was referred to the Committee the same day by correspondence.
2. The policy memorandum notes the main policy objective 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.
3. To achieve this, the Bill contains the following sections:
 - Section 1 empowers the Scottish Ministers to reimburse relevant persons for costs relating to transvaginal mesh removal surgery by putting in place a scheme for the making of such 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 and applicant requirements and review processes.
 - Section 3 confers power on the Scottish Ministers to make ancillary provision in relation to the Bill.
 - Section 4 provides for commencement, and
 - Section 5 sets out the short title of the Bill.
4. The Scottish Government published the following documents in relation to the Bill:
 - [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill](#) ¹
 - [Policy Memorandum](#) ²
 - [Explanatory Notes](#) ³
 - [Financial Memorandum](#) ⁴
 - [Statements on Legislative Competence](#) ⁵
 - [Delegated Powers Memorandum](#) ⁶

- Business and regulatory impact assessment ⁷
 - Equality impact assessment ⁸
 - Fairer Scotland Duty - Assessment Not Required Declaration ⁹
5. The Presiding Officer decided under Rule 9.12 of Standing Orders that a financial resolution was required for this Billⁱ.
 6. The Committee issued a call for written views on the Bill on 1 September 2021, which ran until 13 October 2021 and received 15 submissions ¹⁰ .
 7. The call for written views asked five questions:
 - Do you support the aims of the Bill?
 - Would you like to see any changes to the Bill? If so, what?
 - Can you see any issues with implementation of the Bill or the way the costs will be reimbursed?
 - Does the Bill adequately address how reimbursement will be administered? Does it take account of how finance to pay for treatment was raised (for example, via ‘crowdfunding’)?
 - Do you think that the costs as set in the Financial Memorandum are a reasonable estimate?
 - Do you have any other comments on the provisions set out in the Bill?
 8. Individuals who have been affected by transvaginal mesh in Scotland were able to provide additional, confidential information to the Committee through the written call for views if they wished to do so.
 9. In his letter of 24 June 2021 to the Committee, the Cabinet Secretary expressed his desire for a quick timetable for the passage of the Bill stating “In order to allow those affected to be reimbursed with the minimum of delay, our hope is that the Bill will receive Royal Assent as quickly as possible.¹¹”
 10. The Committee has been keen to ensure an appropriate balance between enabling effective scrutiny of the Bill, while not unduly delaying reimbursement to those affected. At its meeting on 31 August 2021, the Committee agreed to work to an expedited timescale. Scrutiny of the Bill at Stage 1 took place on 26 October and 2 November 2021.
 11. As part of its Stage 1 scrutiny, the Committee held an informal meeting on 26 October 2021 with individuals affected by transvaginal mesh in Scotland who have experience of travelling outwith Scotland for mesh removal surgery. This session,

ⁱ The financial resolution procedure is a means of giving extra control to the Scottish Government over Bills with certain financial implications. For more information see - [Annex P - Financial Resolutions - Parliamentary Business : Scottish Parliament](#)

supported by the Health and Social Care Alliance (the ALLIANCE), provided an opportunity to hear first-hand accounts of individual experiences and views on what should be included in the Bill. The Committee then held a formal session with the Scottish Government Bill team on the same date, focusing on the Bill's provisions.

12. On 2 November 2021, the Committee held a formal session with the clinical lead of the Complex Mesh National Surgical Service, representatives from NHS Greater Glasgow and Clyde, and NHS National Services Scotlandⁱⁱ. This session focused on the Complex Mesh National Surgical Service, the referral process for future mesh removal services outside NHS Scotland, as well as eligibility and the intended administration of the scheme as described in Section 2 of the Bill. The Committee then took evidence from the Cabinet Secretary for Health and Social Care on the same day.
13. The Committee thanks everyone who provided evidence as part of our consideration of the general principles of this Bill. It would particularly like to thank those who attended the informal group meeting on 26 October 2021, providing insight into their personal experiences of travelling outwith Scotland for removal surgery. A list of all written evidence can be found in Annexe B.

Background to the Bill

14. Transvaginal mesh is a medical device which was in routine use only from the early - mid 2000s in NHS Scotland. It was vaginally implanted in a surgical procedure to alleviate symptoms of stress urinary incontinence and pelvic organ prolapse. The mesh was intended to reinforce weakened tissue in a woman's pelvic area ¹².
15. NHS Scotland formally halted the use of transvaginal mesh for stress urinary incontinence and pelvic organ prolapse in September 2018. This followed concerns about the impact of the use of mesh and evidence of complications experienced by patients who had transvaginal mesh implanted.
16. A number of individuals reported that their experiences of complications and side effects were not taken seriously by the NHS. It is not clear from the documentation accompanying the Bill what provisions or policy NHS Scotland had in place at that time for treating individuals reporting complications from transvaginal mesh. These individuals reported losing faith and trust in NHS Scotland to the extent that some did not wish to be treated by the NHS for mesh complications. At that time, while there was a route to refer patients for NHS services between Scotland and England, there was no referral option to independent providers. In the absence of such a referral route some individuals chose to seek out and pay for mesh removal surgery themselves via private treatment.
17. The policy memorandum ¹³ details a number of services currently in development or that have already been introduced to support individuals affected by transvaginal mesh in Scotland going forward:

ii National Services Division (NSD), a division within NHS National Services Scotland (NSS), are the commissioners of the Complex Mesh National Surgical Service on behalf of NHS Scotland and commission this service from NHS Greater Glasgow and Clyde.

- Introduction of a national specialist centre, located in NHS Greater Glasgow and Clyde to perform mesh removal surgery.
 - Options for patients to receive mesh removal surgery from independent providers commissioned by NHS Scotland, in cases where there has been a breakdown in trust and do not want to be treated by the NHS in Scotland.
 - A mesh fund to help those affected by transvaginal mesh complications.
18. The Scottish Government notes that in the future individuals in the same circumstances and with the same preferences as those who have previously sought private treatment will have the option of having comparable treatment arranged and paid for by the NHS. As such, this Bill is retrospective seeking to reimburse individuals who have already entered into arrangements privately and have paid to have transvaginal mesh removed from their body.

Consideration by other Committees

19. The Finance and Public Administration (FPA) Committee issued a call for views on the estimated financial implications of the Bill, receiving 2 responses by their closing date of 15 October 2021¹⁴. The FPA Committee agreed to take no specific action in relation to scrutiny of the Bill.

20. The Delegated Powers and Law Reform (DPLR) Committee considered the delegated powers in the Bill at its meeting on 28 September 2021. The DPLR Committee considered the two delegated powers in the Bill:

- Section 1(1) – Power for Scottish Ministers to reimburse costs relating to the removal of transvaginal mesh; and
- Section 3(1) – Power to make ancillary provision in relation to the Bill

It determined that it did not need to draw the attention of the Parliament to the delegated powers in either of the provisions.

21. The DPLR Committee published its report on the Bill on 5 October 2021¹⁵.

Policy and Financial Memorandums

22. The lead committee is required to report on the Financial Memorandum and Policy Memorandum, which accompany the Bill.

Policy Memorandum

23. The Committee has no specific concerns it wishes to bring to the attention of the Parliament. It is content the information contained has been sufficient to aid our scrutiny of the Bill at this stage.

Financial Memorandum

24. The Financial Memorandum which accompanies the Bill states that anticipated costs of the Bill will be between £357,100 and £478,100. This is to include reimbursement costs of £324,000 to £445,000 and administrative costs of £33,100¹⁶.
25. The Committee took evidence on concerns around financial implications of the Bill and is content the projections detailed in the financial memorandum¹⁷ appear to be reasonable. We have set out a number of concerns in this report under Section 1. However, the Committee does not consider any reassessment of estimates is required as a consequence of these concerns.

Principles behind the Bill

26. All respondents to our call for views were in favour of the policy objective of the Bill and supported the need to reimburse individuals who have entered into arrangements privately and have paid to have transvaginal mesh removed from their body.

27. The Committee considers the key principle of the Bill is to ensure fairness and parity of treatment for all individuals in relation to transvaginal mesh removal services in Scotland. The Committee is committed to ensuring fairness is achieved within the Bill and the resulting scheme for reimbursement. The Committee further believes there are specific issues raised during evidence that need more clarity to ensure this is achieved.

Section 1: Power for Scottish Ministers to reimburse costs relating to the removal of transvaginal mesh

28. Section 1 empowers Scottish Ministers to make a scheme under which they will be able to make payments reimbursing costs incurred in connection with qualifying mesh removal surgeryⁱⁱⁱ 18 . It also defines mesh removal surgery, sets out the eligibility criteria for applying for reimbursement under the scheme, and the costs to be reimbursed.

Qualifying mesh removal surgery

29. Alongside other criteria, subsection 3 stipulates that mesh removal surgery can only be defined as “qualifying” for reimbursement under the scheme if it is in relation to a person who was, at the time the surgery was arranged, ordinarily resident in Scotland. This criterion applies irrespective of where the mesh was originally inserted.

30. The Committee received evidence which expressed specific concerns about the residency requirements as set out in the Bill 19 . This evidence points out that, as the Bill is currently drafted, individuals who were not resident in Scotland at the time of their original surgery, but who lived here when their mesh removal surgery was arranged would be eligible for reimbursement. In contrast, it further points out that patients who were resident in Scotland at the time of their original surgery, but who lived elsewhere when they arranged mesh removal surgery would not be eligible.

31. Greig Chalmers, Head of the Chief Medical Officer’s Policy Division in the Scottish Government told the Committee the Scottish Government has not received any correspondence from individuals in the situation described above; that is individuals

ⁱⁱⁱ The explanatory notes also detail that the power to make a scheme also includes power to revoke or amend the scheme under section 6 of the Interpretation and Legislative Reform (Scotland) Act 2010.

who were not ordinarily resident in Scotland when their mesh removal surgery was arranged²⁰ .

32. Subsection 3 also stipulates that mesh removal surgery is eligible for reimbursement if it was arranged before a date to be specified in the scheme. The Committee has established this date is likely to be 12 July 2021. This date was chosen as the cut-off date as this is when it was announced that an alternative route for mesh removal service will be in place. The Cabinet Secretary noted:
- ” In all the communications that have followed from 12 July, we have been keen to say to the women that we are working as hard as we possibly can with those independent providers to finalise the contracts and to put the appropriate pathways in place and, if they can hold off from arranging any surgery with independent providers until the scheme is in place, that would be favourable²¹ .
33. Many people told the Committee the introduction of the Bill has caused confusion and concern for individuals who are in the process of arranging private mesh removal surgery or who are awaiting surgery, having already made arrangements. Disruptions due to travel restrictions and additional requirements imposed by the COVID-19 pandemic have added to these concerns. These individuals, self-named as the "in-betweeners" are seeking reassurance their costs will be reimbursed if the Bill is passed. The Committee recognises this may only affect a small number of individuals, who may have received confirmation of surgery after this date.
34. The Cabinet Secretary announced the outcome of the NSS procurement exercise to allow individuals to receive mesh removal surgery from independent providers commissioned by NHS Scotland on 12 July 2021.²² During evidence, he further noted the detailed arrangements are now being finalised with the independent providers which will ensure the appropriate pathways are in place for future treatment options²³ .
35. The Cabinet Secretary went on to clarify it is the Scottish Government's intention that anyone who made their own arrangements for treatment outside of the NHS on or before the announcement on 12 July 2021, will be able to apply for reimbursement, regardless of whether or not that treatment has already been carried out. Anyone seeking transvaginal mesh removal outwith NHS Scotland after that announcement was made, would not be eligible for reimbursement under the Bill.
36. As it stands, the Committee notes there is a gap between the 12 July, when the outcome of the procurement exercise was announced, and when the contracts are established and pathways open for referrals. At the time of writing, these contracts have yet to be concluded.
37. The Committee acknowledges the Cabinet Secretary agreed to consider flexibility for the small number of individuals who may have entered into private arrangements within this gap²⁴ . However, the Cabinet Secretary noted concerns of changing the date in case that led to an increase of individuals subsequently arranging private mesh removal surgery instead of utilising the new pathways set up for referral, which includes pre and post-operative care.²⁵ The Cabinet Secretary acknowledged Members' concerns about the “in-betweeners” and

showed a willingness to address this issue during the passage of the Bill.

38. The Committee notes the Cabinet Secretary also acknowledged clarity is needed on what constitutes making an arrangement²⁶ and indicated his willingness to be flexible in determining how precisely this is defined.

39. The Committee believes that, to adhere to the principles of fairness and equity of treatment, greater clarity is needed around the residency criteria set out in the Bill. Specifically, the Committee believes there is a strong case for individuals who had their original mesh implant surgery undertaken by NHS Scotland but who were not ordinarily resident in Scotland at the time their mesh removal surgery was arranged to also qualify for reimbursement under the terms of the Bill. The Committee supports a widening of the eligibility criteria in such cases, provided those individuals have not already claimed for reimbursement of these costs elsewhere.

40. In accordance with the commitments made by the Cabinet Secretary when giving evidence, the Committee calls on the Scottish Government, in bringing forward regulations under section 3 of the Bill, to demonstrate appropriate flexibility in the definition of “making an arrangement” for mesh removal surgery”.

41. We further call on the Scottish Government, in bringing forward those same regulations, to address the potential time gap in eligibility for reimbursement between the proposed cut-off date of 12 July 2021 and the actual date when contracts with independent providers of mesh removal surgery are ultimately concluded.

Costs associated with reimbursement

42. Subsection 4 stipulates the following costs incurred in relation to qualifying mesh removal surgery will be reimbursable under the Bill:

” (a) the cost of the qualifying mesh removal surgery, as charged to or in respect of the person who underwent the surgery,

(b) reasonable costs incurred by— (i) that person, and (ii) one other person who was supporting that person, in travelling to and from the place where the surgery took place,

(c) reasonable accommodation and subsistence costs incurred by those persons while at that place, and

(d) any other costs specified as such in the scheme.

43. The Financial Memorandum²⁷ states that reimbursement costs are based on the following assumptions:

- Treatment costs will be in the region of £15,000 per patient.
- Accommodation, flights, meals and other transport costs will range from £1,188 to £7,268.

The Financial Memorandum further notes these are illustrative and it is likely the amount reimbursed will be based on the actual costs incurred, and evidenced by receipts provided by applicants.

44. The Committee received evidence from a number of individuals and organisations that the use of the word 'reasonable' in the Bill in connection with reimbursable expenses was vague, unhelpful and required further clarification. NHS National Services Scotland noted in its submission ²⁸ :
- ” What is reasonable to one might not necessarily be reasonable to the Scheme Administrator. Without this clarity additional stress and anxiety may be experienced by both patient and administrators.
45. The Law Society of Scotland also noted:
- ” Such ambiguity may encourage a lack of trust, which is unhelpful when dealing with persons already negatively impacted by transvaginal mesh and their dealings with NHSS.
46. The Scottish Government advised there was no intention for a specific cap on costs for the cost of the removal surgery and that it "might look to set out what would be considered reasonable by way of accommodation and travel costs and so on" ²⁹ .
47. Individuals told the Committee they'd like more clarity on what would be included. During the informal meeting with individuals on 26 October 2021, individuals told the Committee they felt the following costs should be included, in addition to the costs set out in the Bill:
- Pre and post-operative appointments and support in addition to removal surgery, including ongoing mental health support, physiotherapy and pain relief;
 - Insurance to travel outwith the UK;
 - Expenses for a travel companion - all individuals agreed it would be impossible to travel and have surgery without a companion;
 - Incidentals such expenses as taxis, pharmacy costs and pain relief;
 - Additional travel expenses during COVID, such as emergency visa and embassy related costs;
 - Additional costs such as loan, credit card or mortgage interest rates.
48. The Committee heard that some individuals may have had mesh removal surgery a number of years ago, at a time when they had no expectation there would be any prospect of having their costs reimbursed in the future. On this basis, they argued this could make it challenging to account for incidental expenditure where no receipts or record of payment had been kept.

49. The Committee notes that, responding to questions on these matters, the Scottish Government gave assurances that its intention is that expenses for a travel companion will be included for reimbursement. It further gave assurances there will be a standard approach to the assessment of applications to the scheme which ensures individuals are fairly reimbursed for reasonable expenses in cases where no receipts or record of payment has been kept.³⁰

50. The Committee notes the Cabinet Secretary's commitment to take a flexible approach in determining what costs will be reimbursed under the Bill. To provide clarity for the individuals concerned and the scheme administrators, in bringing forward the details of the scheme in regulations, the Committee calls on the Scottish Government to outline in much greater detail the categories of costs that will be covered but equally to set out the flexible approach to be taken in processing individual cases.

Costs associated with administration of scheme

51. Costs for administering the scheme are based on the costs associated with the Scottish Government Mesh Fund³¹, which made a one-off payment of £1000 to individuals adversely affected by transvaginal mesh implants. Yearly administrative costs associated with the mesh fund, launched in July 2020, have totalled £33,100.

52. The Financial Memorandum anticipates that as a similar form of administration is required for the reimbursement scheme, similar costs can be assumed. It goes on to note that, while the mesh fund will have received more applications than are anticipated to be received by the reimbursement scheme, comparatively greater documentary evidence is likely to be submitted to the reimbursement scheme and senior overview is likely to be necessary³².

53. There is uncertainty about the numbers of individuals who might apply under the scheme. The Financial Memorandum notes there is no firm data available on the number of individuals eligible for reimbursement, but goes on to note informal estimates indicate this may be as few as 20 individuals³³.

54. In many instances, individuals affected by transvaginal mesh implants have sought private treatment through Spire Healthcare in Bristol, under care of Professor Hashim, and Vaginal Surgery & Urogynecology in the USA, under care of Dr Veronikis. The Committee wrote to Professor Hashim and Dr Veronikis requesting further indications of how many individuals affected by transvaginal mesh have travelled to them for mesh removal surgery and how many have so far entered into private arrangements with them for future mesh removal surgery. The Committee received a response from Professor Hashim, who said three individuals have travelled to him to date for mesh removal surgery³⁴. Professor Hashim told the Committee that no further individuals from Scotland have entered into private arrangements with him for future mesh removal surgery. The Committee did not receive a response from Dr Veronikis.

55. The Committee notes there might be a much higher number of applicants to the

scheme than this estimate suggests, which could impact on both the costs as set out in the financial memorandum and the costs to administer the scheme. While the Committee is satisfied there is sufficient additional resource detailed in the financial memorandum for reimbursement should more individuals come forward, it has concerns about the implications this might have for the administration of the scheme.

56. NHS National Services Scotland (NSS) has expressed concern that the costs of administering the scheme are too low. In written evidence it said its experience has:

” “shown that to manage this level of reimbursement package appropriately, additional resources will be required...The previous solution and resourcing has proved insufficient and put excessive requirements on wider management to check detail. This led to increased stress and anxiety in the workforce”

57. During oral evidence Paul Hornby, head of strategic sourcing and commercial in national procurement at NHS National Services Scotland, noted:

” I am not sure whether additional resources are required. We are at the stage of getting the bill through, of understanding the number of payments that will be made, and the level of detail of the scheme. If NSS is appointed to administer the scheme, we will then have to resource it accordingly³⁵ .

58. The Committee notes the uncertainty around how many individuals will ultimately apply for reimbursement under the scheme. The Committee strongly urges the Scottish Government to review costs to administer the scheme to ensure NHS NSS has sufficient resource to manage the scheme effectively without causing undue stress and anxiety to its workforce.

Section 2: Further provisions about the scheme

59. Section 2 sets out a list of further provisions that might be addressed by the scheme, such as a deadline for applications, evidence to be provided for reimbursement, the review process and the amount of reimbursement payments. It also states Scottish Ministers must lay a copy of the scheme before the Scottish Parliament as soon as reasonably practicable after making a scheme under Section 1.

Deadline for applications

60. The deadline for applying for reimbursement is due to be set out within the scheme. The explanatory notes set out that the date set for application to the scheme for reimbursement “will be determined so sufficient time is available after the scheme becomes operational for all those potentially eligible for reimbursement to make an application³⁶”.

61. However, in its submission, the Law Society of Scotland argues the Bill should have a clearly defined time period of application. It notes there could be individuals (or executors or funders) who do not become aware of the scheme within the

timescales set but would otherwise be eligible³⁷ .

62. Giving evidence to the Committee, the Cabinet Secretary acknowledged the importance of publicising and raising awareness of the reimbursement scheme. Scottish Government officials explained there were plans in place to undertake engagement work to ensure individuals were aware of the scheme and their likely eligibility for reimbursement.³⁸

63. Ensuring all those who are entitled to reimbursement are aware of the reimbursement scheme and the deadline for making an application is crucial. Given there is no clear indication in the Bill documentation of how many individuals are likely to be affected, the Committee asks the Scottish Government to set out how it will ensure anyone that could be eligible is made aware of the scheme well in advance of the deadline for applications.

Who can apply for reimbursement

64. A number of submissions expressed concern over who should or should not be able to receive reimbursement. There were concerns around eligibility for reimbursement for individuals who raised funds for surgery through third party fundraising platforms, such as crowdfunding. There were also concerns about how, in the event of an individual's death, family members or next of kin could be reimbursed.

65. The explanatory notes set out that the scheme may specify the persons who are eligible to apply to the scheme or to receive reimbursement from the scheme. It goes on to state:

” For example, the scheme could specify that a travelling companion may apply and be reimbursed separately from the person who underwent the surgery. These paragraphs [(Section 2 (1) (c) and (g)] would also allow the scheme to specify that an application could be made by the next of kin of the person who underwent the surgery, if that person has since died³⁹ .

66. A number of submissions expressed concern that those who had paid for their treatment via crowdfunding to cover expenses should not be reimbursed. Conversely, another submission argued there was little difference between crowdfunding via a platform and receiving donations from family and friends.
67. NHS National Services Scotland notes⁴⁰ that, in administering the scheme, there is no clarity with respect to its responsibility for determining whether or not money for treatment was raised through other avenues, such as crowdfunding or charitable donations. It goes on to note that if such alternative avenues of fundraising are deemed eligible for reimbursement, there should be clarity as to who is responsible for providing evidence of the source of finance used to pay for the mesh removal surgery.
68. The Cabinet Secretary acknowledged the complexities in balancing a flexible approach to reimbursement with public finance and funding obligations, particularly as this relates to crowdfunding and family donations⁴¹ .

69. The Committee is concerned that there is no clear indication in the Bill whether crowdfunding or family donations will be eligible for reimbursement. The Committee would welcome further clarity on the approach to treatment of such alternative avenues for sourcing funding for mesh removal surgery, including reference to any duties or obligations related to the management of public finances that may have informed the Scottish Government's approach in this area.

Evidence of expenditure

70. The Committee heard significant concerns the Bill and supporting documentation does not outline what will be required for reimbursement. For example, as previously highlighted, receipts for accommodation, travel and subsistence may no longer exist if surgery was some time ago.
71. The explanatory notes⁴² state:
- ” Paragraph (e) allows the scheme to make provision, for example, requiring receipts or invoices relating to the costs incurred to be provided with an application. The wording of this paragraph also allows information and evidence to be provided in relation to applications – so additional evidence could be requested after the application is submitted.
72. During the evidence session with the Scottish Government on 26 October, members of the Bill team noted "there is a plausible risk that someone will not have receipts for a taxi or for lunch, which is perfectly understandable" and acknowledged there will be a "standard approach, whereby a person will be fairly reimbursed for such reasonable expenses."⁴³
73. While the Committee appreciates this flexibility of approach, it is concerned the application process as set out in the Bill and accompanying explanatory notes has the potential to cause additional undue stress and anxiety for applicants. This is especially relevant given the often traumatic previous experiences of these individuals.

74. The Committee reiterates its view that the details of the scheme to be brought forward via regulations needs to include a clear explanation of a flexible approach to reimbursement that takes account of individual circumstances, as committed to by the Cabinet Secretary and Scottish Government officials while giving evidence.

Decisions on whether reimbursement is paid

75. The Law Society of Scotland highlighted a further issue in relation to reimbursement, where private removal surgery has not been fully or partially successful. It noted:

” Reimbursement should only be given if the treatment has been undertaken in an accredited mesh centre and there has been a positive outcome for the patient ⁴⁴ .

76. The Committee heard from individuals that follow-up care and ongoing access to post-operative care, including for example, mental health support, physical health support and physiotherapy was not easily accessible in Scotland for individuals returning home having undergone private removal surgery outside Scotland. One individual told the Committee they required pelvic health rehabilitation but, having opted to undergo private mesh removal surgery, were no longer recorded in the NHS Scotland system and needed to start the whole referral process again. Instead of receiving seamless, wraparound care, this will have necessitated additional waiting times and will have required individuals to explain their journey to new healthcare staff unfamiliar with their treatment history.
77. The Cabinet Secretary gave assurances to the Committee that, once the clinical pathway for referral is in place through the complex mesh national surgical service, the multidisciplinary team will consider each case on an individual basis and that this will take into account all aspects of pre and post-operative care ⁴⁵ . However, the Committee believes that there is an outstanding issue around fairness and access to these services for those individuals who receive reimbursement under the Bill.
78. Furthermore, the Bill documentation does not address the question raised by the Law Society of whether cases where private removal surgery has not been fully or partially successful will be reimbursed. This poses particular challenges since, in some cases, the definitive outcome of mesh removal surgery might not be known until weeks, months or even years after the surgery has taken place.
79. Problems with transvaginal mesh can occur immediately or may manifest over a longer time period. It is not unreasonable to assume any complications, or further support needed following mesh removal surgery could follow the same trajectory. Questions remain over how the scheme administrator will decide whether or not reimbursement will be paid, and if the scheme administrator will have access to the necessary clinical advice to support those decisions.
80. Section 2 of the Bill further sets out that the scheme will include detail of the review of where a decision has been made to refuse to make a reimbursement payment or around the amount of a reimbursement payment, and how those reviews should be undertaken.

81. The Committee is of the view that individuals should be entitled to reimbursement where they have had any form of private mesh removal surgery, whether that surgery was successful or not.

82. The Committee expects the scheme to detail the criteria for reimbursement, which should include clinical input to support scheme administrators. However, the Committee understands there should be a balance between ensuring the

surgery has led to positive and lasting outcomes and not causing additional stress and anxiety to individuals by creating an onerous or difficult application process. The Committee looks forward to seeing detail of how this can be achieved in the final scheme, as well as the processes to be put in place for reviewing and challenging such decisions.

83. Ensuring individuals affected by transvaginal mesh have positive and lasting outcomes must remain a key priority. The Committee welcomes further detail from the Scottish Government on additional work to ensure those individuals who have paid for private removal surgery and are reimbursed under the Bill, have timely access to post-operative support.

Sections 3 and 4: Ancillary provision and Commencement

84. Section 3 allows the Scottish Ministers to make various types of ancillary provision if these are needed in order for the Bill to operate effectively. The explanatory notes⁴⁶ state any such provision will be contained in regulations, which will be subject to the affirmative procedure if they amend an Act and negative procedure otherwise.
85. Section 4 notes the power to make ancillary provision, conferred by section 3, will become exercisable on the day after Royal Assent. This Section further sets out that Sections 1 and 2 come into force at the end of the period of two months beginning with the day of Royal Assent.
86. The Committee is also content with this arrangement, however, given the importance of the detail of the scheme think it important to have the opportunity to scrutinise the scheme further as previously set out in this report.

87. The Committee is aware that many of the specific issues it has raised about the operation of the scheme will be addressed in implementing regulations to be submitted to the Parliament for scrutiny in the form of subordinate legislation. The Committee believes that these regulations must therefore be subject to a procedure that will enable an appropriate level of scrutiny to take place.

Further Considerations

Inequality

88. The business and regulatory impact assessment forming part of the Bill documentation reported that the Bill:

” 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 options available to them, fully funded by the *NHS*.

89. In addition, there may be a number of individuals who did not seek private mesh removal surgery as they could not afford to spend around £20,000 up front. These individuals may not have access to personal funds, funds from family members or private loans. During evidence, the Cabinet Secretary noted that it would be reasonable for interest applied to any bank loan, that can be evidenced, to be eligible for reimbursement⁴⁷. The Committee heard evidence from individuals affected by transvaginal mesh in Scotland that loan interest rates and issues around accessibility to loans may have prevented some individuals undertaking mesh removal surgery.
90. However, evidence received by the Committee suggests that individuals without access to funds to be able to seek private treatment may have experienced the same breakdown in trust in NHS Scotland as those that were able to fund private treatment, but had no alternative pathway to seek to resolve their issues. This evidence suggests that such situations create an unfair disadvantage to certain individuals.
91. In this context, the Committee considers it is vitally important that any individual who has experienced complications due to transvaginal mesh can have their case reviewed and receive appropriate treatment as quickly as practically possible via the complex mesh national surgical service.
92. The Committee supports the principles of fairness, equity and parity which, in its view, underpin the Bill. However, it is concerned there may be additional considerations surrounding and included within the Bill that could give rise to inequality. To address these concerns, the Committee considers it is vitally important that any individual who has experienced complications due to transvaginal mesh has their case reviewed and receives appropriate treatment as quickly as practically possible via the complex mesh national surgical service.

Specialist mesh removal services in Scotland

93. The Committee has heard that in the future, individuals will have a number of options for mesh removal surgery, namely:
- the 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 Dr. Veronikis, who is based at the Mercy Hospital, Missouri, US.

94. However, questions remain over when these referral pathways will be in operation. The Committee welcomes the recognition from both the Scottish Government and the complex mesh national surgical service that a significant confidence issue with NHS Scotland services remains for individuals who have been harmed by mesh, some of whom have already been referred to the service or who are awaiting referral.
95. The Committee understands some of the individuals who have been harmed by mesh and have experienced a breakdown in trust in NHS Scotland's services are not convinced the complex mesh national surgical service meets patient's expectations or will provide the standard of care required. The Committee further heard during evidence that the service has long waiting times and NHS Greater Glasgow and Clyde is currently operating at 40 to 45 per cent of its pre-Covid level of elective activity, which has had an impact on mesh removal surgery⁴⁸.
96. It is not yet clear how many individuals will wish to make use of these services, although the Committee heard from Dr Jamieson, clinical lead for the service, that the numbers of individuals being referred and reviewed to the service are increasing:
- ” 64 women were reviewed by the MDT service in September, which is 26 more than were reviewed in August.
97. However, because the reporting of complications has not been clear cut, the numbers of individual affected by complications of transvaginal mesh and who may be seeking mesh removal services now or in the future are not known. One of the issues raised by individuals was that they were not believed when they reported symptoms, or that their symptoms were not linked by clinicians to complications arising from their mesh implant. Patient experience was not a feature of follow-up, or of early research, and the criteria for success or otherwise of the procedure was based only on whether the original issue of stress urinary incontinence or pelvic organ prolapse had been resolved.
98. The Committee recognises there could be individuals who are unaware of the new service, not realising (along with their clinicians or primary care teams) that symptoms they are experiencing are because of mesh. Work undertaken by The ALLIANCE highlight a wide range of symptoms, as well as pain, experienced by individuals, such as chronic fatigue, recurrent infections and autoimmune disorders⁴⁹.
99. The Committee would welcome further detail from the Scottish Government on campaigns to publicise the complex mesh national surgical service, training for primary care staff on mesh complications and person-centred approaches for supporting individuals through treatment including pre and post-operative support. To this end, the Committee will continue to take an active interest in the operation of the complex mesh national surgical service and intends to take further evidence on this topic in the course of 2022.

Committee's findings on the Bill

100. The role of the Committee at Stage 1 is to consider the general principles of the Bill.
101. The Committee supports the policy objective of the legislation and regards it as a necessary and important step forward in ensuring fairness and parity for individuals affected by transvaginal mesh and the breakdown of trust experienced during treatment by NHS Scotland.
102. There is a need to ensure individuals who are reimbursed under the Bill have continued access to post-operative support through the complex mesh national surgical service and this should include entitlement to their own choice of clinician, where appropriate.
103. While the Committee supports the Bill, it notes that getting the details of the scheme right will be crucial to its successful implementation and that these details are due to be set out in secondary legislation.

104. The Committee is content to support the general principles of the Bill and recommends to the Parliament that they be agreed to.

105. The Committee draws the Scottish Government's attention to the various recommendations it has made about the details of the scheme. To ensure these recommendations are satisfactorily addressed, it further requests that the regulations setting out the details of the scheme are made subject to a procedure that will enable them to undergo full and proper scrutiny prior to their entry into force.

Annexe A - Minutes of meeting

2nd Meeting, 2021 (Session 6) Tuesday 31 August 2021

Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill (in private): The Committee considered its approach to the scrutiny of the Bill at Stage 1 and agreed:

- To hold a call for views;
- Its approach to information gathering and briefings in preparation for consideration of the Bill; and
- The themes for each session it will hold on the Bill and its approach to witness selection.

8th Meeting, 2021 (Session 6) Tuesday 26 October 2021

Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: The Committee took evidence on the Bill at Stage 1 from—

- Individuals who have privately paid for transvaginal mesh removal surgery (in private)

and then from—

- The Scottish Government Bill Team

9th Meeting, 2021 (Session 6) Tuesday 2 November 2021

Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: The Committee took evidence on the Bill at Stage 1 from—

- NHS Greater Glasgow and Clyde, the Complex Mesh National Surgical Service and NHS National Services Scotland

and then from—

- the Cabinet Secretary for Health and Social Care.

11th Meeting, 2021 (Session 6) Tuesday 16 November 2021

Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill (in private): The Committee considered and agreed a draft Stage 1 report.

Annexe B - Evidence

Written evidence

- [Responses submitted to the Committee's call for views.](#)
- [Additional written evidence, where publishable, is available on the Health, Social Care and Sport Committee webpage.](#)

Official reports of meetings

- [Tuesday 26 October 2021- evidence from the Scottish Government](#)
- [Tuesday 2 November 2021 - evidence from stakeholders and then from the Scottish Government](#)

- 1 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill \(parliament.scot\)](#)
- 2 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Policy Memorandum](#)
- 3 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Explanatory notes](#)
- 4 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Financial Memorandum](#)
- 5 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Statements on Legislative Competence](#)
- 6 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Delegated Powers Memorandum](#)
- 7 [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: business and regulatory impact assessment](#)
- 8 [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: equality impact assessment](#)
- 9 [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: fairer Scotland duty assessment](#)
- 10 The Scottish Parliament, [Health, Social Care and Sport Committee Call for Views, 2019](#)
- 11 [Letter from the Cabinet Secretary for Health and Social Care to Convener](#)
- 12 [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: fairer Scotland duty assessment](#)
- 13 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Policy Memorandum](#)
- 14 The Scottish Parliament, [Finance and Public Administration Committee, The Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill Call for Views](#)
- 15 The Scottish Parliament, [Delegated Powers and Law Reform Committee Report, Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill : Stage 1 Report](#)
- 16 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Financial Memorandum](#)
- 17 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Financial Memorandum](#)
- 18 The Scottish Parliament, [Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill: Explanatory notes.](#)
- 19 [Response 1009236928 to Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill - Scottish Parliament - Citizen Space](#)

- 20 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 21 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 22 [Letter from Cabinet Secretary for Health and Social Care regarding the procurement exercise for mesh removal services. | Scottish Parliament Website](#)
- 23 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 24 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 25 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 26 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 27 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Financial Memorandum
- 28 [Response 1009236928 to Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill - Scottish Parliament - Citizen Space](#)
- 29 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 30 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 31 [The Scottish Government Mesh Fund | National Services Scotland \(nhs.scot\)](#)
- 32 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Financial Memorandum
- 33 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Financial Memorandum
- 34 [Letter from Professor Hashim Hashim in relation to the Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill - 19/10/21 | Scottish Parliament Website](#)
- 35 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 36 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Explanatory notes
- 37 [Response 21060865 to Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill - Scottish Parliament - Citizen Space](#)
- 38 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 39 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Explanatory notes
- 40 [Response 1009236928 to Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill - Scottish Parliament - Citizen Space](#)
- 41 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 42 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Explanatory notes

- 43 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 44 [Response 21060865 to Transvaginal Mesh Removal \(Cost Reimbursement\) \(Scotland\) Bill - Scottish Parliament - Citizen Space](#)
- 45 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 46 The Scottish Parliament, Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill: Explanatory notes
- 47 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 48 [Official Report - Parliamentary Business : Scottish Parliament](#)
- 49 [ALLIANCE-Mesh-Report-2019.pdf \(alliance-scotland.org.uk\)](#)

