

TRANSVAGINAL MESH REMOVAL (COST REIMBURSEMENT) (SCOTLAND) BILL

[AS AMENDED AT STAGE 2]

REVISED EXPLANATORY NOTES

INTRODUCTION

1. As required under Rule 9.7.8A of the Parliament's Standing Orders, these Revised Explanatory Notes are published to accompany the Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill (which was introduced in the Scottish Parliament on 23 June 2021) as amended at Stage 2. Text has been added or amended as necessary to reflect amendments made to the Bill at Stage 2 and these changes are indicated by sideling in the right margin.
2. These Explanatory Notes have been prepared by the Scottish Government in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by the Parliament.
3. The Notes should be read in conjunction with the Bill. They are not, and are not meant to be, a comprehensive description of the Bill. So where a section, or a part of a section, does not seem to require any explanation or comment, none is given.

THE BILL: AN OVERVIEW

4. Transvaginal mesh was, until its use in Scotland was halted in 2018, often used to alleviate symptoms of stress urinary incontinence and pelvic organ prolapse. In some cases, complications associated with the use of transvaginal mesh may lead to a need to remove the mesh. Although removal surgery is available via the NHS in Scotland, a number of mesh recipients have, in recent years, chosen to arrange removal surgery privately. The Bill confers power for the Scottish Ministers to make payments (via a scheme) reimbursing certain costs incurred in relation to such privately-arranged surgery. Section 1 confers that power, and defines certain key terms used in doing so, while section 2 describes a number of more detailed issues that may be covered in the scheme.
5. Section 3 confers power on the Scottish Ministers to make ancillary provision in relation to the Bill, while section 4 provides for commencement and section 5 for the Bill's short title.

THE BILL: SECTION BY SECTION

Power to reimburse costs

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

6. Subsection (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 surgery.¹ Payments under the Bill may only be made in accordance with the scheme. Costs must already have been incurred in order to be covered by the scheme – the purpose of payments under the scheme is to reimburse costs, not pay costs in advance.

7. Subsection (2) defines “mesh removal surgery”. The definition describes aspects of both the original surgery during which synthetic mesh (also sometimes referred to as “tape” or “sling”) was implanted and the removal surgery.

8. Costs will be reimbursable under the scheme where the mesh was originally implanted for the purpose of treating stress urinary incontinence or pelvic organ prolapse. In addition, the original surgery must have inserted the mesh transvaginally, as described in subsection (2). The Bill does not cover cases in which the mesh was inserted abdominally.

9. The description of the removal surgery takes account of the fact that there are different approaches to surgery to remove transvaginal mesh – the mesh is sometimes removed in a single surgery, and sometimes over more than one surgery. Removal of the mesh may be the sole focus of a surgery – or it may also include elements aimed at treating the condition in relation to which the mesh was originally implanted. Sometimes the aim of the surgery will be to remove the mesh as fully as possible, in others the aim may be only to remove part of the mesh. Costs will be reimbursable under the scheme in all of these types of cases. In particular, in a case where mesh is removed in stages, costs in respect of each surgery will be reimbursable under the scheme.

10. Subsection (3) sets out additional conditions that require to be met in relation to the removal surgery in order for costs to be reimbursable under the scheme.

11. The first condition relates to how the mesh removal surgery was arranged – only surgery arranged other than by a health board is covered. In Scotland, all NHS health care of the type in question would be arranged by a health board.² Essentially, therefore, the effect of subsection (3)(a) in relation to persons resident in Scotland is that the mesh removal surgery must have been arranged privately by (or on behalf of) the person undergoing the mesh removal surgery. As it is not possible to make such arrangements with NHS providers, it follows that qualifying mesh removal surgery will also have been delivered privately.

¹ The power to make a scheme also includes power to revoke or amend the scheme – see section 6 of the Interpretation and Legislative Reform (Scotland) Act 2010.

² Defined in subsection (5) as a health board constituted under section 2(1)(a) of the National Health Service (Scotland) Act 1978 (that is, a territorial health board – such as NHS Lothian, NHS Grampian and so on).

12. The second condition relates to the place of residence of the person who underwent the mesh removal surgery. The person must have been ordinarily resident in Scotland when the mesh removal surgery was arranged or when the mesh which the removal surgery relates to was originally implanted. Some people will meet both of these criteria, but meeting one will be sufficient for the mesh removal surgery to qualify for reimbursement under the scheme. Where the person is ordinarily resident in Scotland at the time the mesh removal surgery is arranged, it does not matter whether the original surgery to implant the mesh was carried out by the NHS or a private health care provider, whether that surgery took place in Scotland or elsewhere or whether the mesh recipient was resident in Scotland at the time.

13. Finally, the mesh removal surgery must have been arranged by a date specified in the scheme (but the actual surgery does not need to have taken place by that date). The earliest date that may be so specified is the date the Bill receives Royal Assent.

14. It does not matter where the removal surgery took place. So costs are reimbursable under the scheme in relation to privately arranged surgery which took place elsewhere in the UK, or abroad, as well as in Scotland.

15. Subsection (4) describes the types of costs which will be reimbursable under the scheme. These are the cost of the mesh removal surgery itself and reasonable travel, accommodation and subsistence costs incurred by the person who underwent the surgery. Reasonable travel, accommodation and subsistence costs incurred by a person who travelled with the person who underwent the surgery in order to provide them with support are also reimbursable. Subsection (4)(d) allows other reimbursable costs to be specified in the scheme (for example, the scheme might specify that costs incurred in travelling for a consultation with the surgeon in advance of the surgery taking place are “costs incurred in connection with qualifying mesh removal surgery”).

Section 2: Further provision about the scheme

16. Subsection (1) sets out a non-exhaustive list of things that might be covered in the scheme.

17. The scheme may provide that an application must be submitted in order for costs to be reimbursed under the scheme (paragraph (a)). If applications are to be required in order for costs to be reimbursed, the scheme may also set out various other matters to do with applications, including a date before which applications must be submitted (so the scheme could have a “closing date”) (paragraph (b)), and stating how applications may be made (for example, whether they can be submitted online) (paragraph (d)).

18. The scheme may also specify the persons by whom applications should be made (paragraph (c)), and to whom payments may be made (paragraph (g)). 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 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 died.

19. 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.

20. Paragraph (f) allows the scheme to set out factors that may be taken into account in determining whether costs should be reimbursed, or the level of reimbursement. If, for example, fund-raising activities covered part of the cost of the surgery, the scheme could provide for the amount raised to be taken into account in determining how much the person should be reimbursed under the scheme.

21. Paragraphs (h) and (i) relate to reviews of decisions about the making of payments under the scheme. For example, the scheme could provide, under paragraph (i), that reviews provided for under paragraph (h) should be undertaken by a person who was not involved in the decision being reviewed.

22. Paragraph (j) allows the scheme to specify circumstances in which payments made under the scheme may require to be repaid.

23. Paragraph (k) allows the Scottish Ministers to appoint, in the scheme, another person to administer the scheme (including making the payments) on their behalf.

24. Subsection (2) requires the Scottish Ministers to lay a copy of the scheme before the Scottish Parliament and to publish the scheme. Both of these things must be done as soon as reasonably practicable after the scheme is made under section 1.

Final provisions

Section 3: Ancillary provision

25. This section allows the Scottish Ministers to make various types of ancillary provision if such provision turns out to be needed in order for the Bill to operate effectively. For example, if an NHS body is appointed to administer the scheme on Scottish Ministers' behalf by virtue of section 2(1)(k), it may be necessary to amend any enactment which specifies that body's functions to include reference to administering the scheme. Any such provision which is needed will be contained in regulations, which will be subject to the affirmative procedure if they amend an Act and negative procedure otherwise.³

Section 4: Commencement

26. The power conferred by section 3 to make ancillary provision will become exercisable on the day after Royal Assent. The scheme itself may not be made until at least two months have passed from the date of Royal Assent.

³ See sections 28 and 29 of the Interpretation and Legislative Reform (Scotland) Act 2010 for details of, respectively, the negative and affirmative procedures.

*This document relates to the Transvaginal Mesh Removal (Cost Reimbursement) (Scotland) Bill
as amended at Stage 2 (SP Bill 3A)*

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