Title: Reduced prescription charges for HRT patients in England IA No: 9592 RPC Reference No: Out of scope (not referred to RPC) Lead department or agency: Department of Health and Social Care (DHSC) Other departments or agencies: n/a	Impact Assessment (IA) Date: 06/02/2023 Stage: Final Impact Assessment Source of intervention: Domestic Type of measure: Secondary Legislation Contact for enquiries: carol.walker@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Out of scope

Preferred (or more likely) Option (in 2022/23 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£611m	-£23m	£2.8m	Exempt (non-qualifying)

What is the problem under consideration? Why is government action or intervention necessary?

Many women suffer adverse symptoms during the menopause but do not always get the treatment they need. The Government's Women's Health Strategy considers the various barriers that limit access to treatment and mentions in particular the high cost of prescriptions for hormone replacement therapy (HRT). One of the objectives set out in the strategy's 10-year ambition is to reduce the cost of HRT and thus improve access to treatment. Government is best placed to achieve these goals as prescription charges are set in legislation: reducing prescription costs for HRT requires a change in regulations.

What are the policy objectives of the action or intervention and the intended effects?

1. Reduce and remove financial barriers and thus improve uptake by lowering the cost to patients of HRT prescriptions.
2. Ensure that prescription charges are kept as simple and easy to operate as possible.
3. Ensure that the NHS continues to receive some revenue from HRT prescription charges to help maintain resilience of the service.

These objectives do conflict slightly and the policy aim is to achieve a balance between the three, with the emphasis on meeting the first objective without unduly harming the other two.

What policy options have been considered, including any alternatives to regulation?

Many factors affect uptake of HRT treatment, and this cost reduction reform should be seen in the context of multiple interventions being required to optimise access to HRT over time.

This IA compares two main options:

Option 1: Maintain the status quo, meaning that charges would remain at their current level, which can exceed £1,000 per patient while their symptoms persist. Stakeholders have argued strongly that this acts as a disincentive to get treatment.

Option 2 (preferred option): Introduce an HRT-specific pre-payment certificate (effectively a season ticket) which would cost £18.70 a year and cover all HRT medication. This will deliver significant savings to patients, while also meeting the other policy objectives. Its price would be set with reference to the standard prescription charge, (two standard prescription charges), which is subject to an annual review and possible uplift.

On cost reduction specifically, the option of making HRT free has been rejected (it fails to meet the third policy objective).

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** within 5 years.

Is this measure likely to impact on international trade and investment?		**No**		
Are any of these organisations in scope?	**Micro** **Yes**	**Small** **Yes**	**Medium** **Yes**	**Large** **Yes**
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** Nil	**Non-traded:** Nil	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Neil O'Brien Date: 17/02/2023

Summary: Analysis & Evidence

Policy Option 1

Description: Business as Usual (BAU) – counterfactual

FULL ECONOMIC ASSESSMENT

Price Base Year 2022/23	PV Base Year 2022/23	Time Period 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: £0

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

Option 1 is the counterfactual or Business as Usual (BAU). This is the option against which all other options will be assessed. The value of the BAU is set to zero and all costs and benefits reflected in other options calculated incrementally.

Although set to zero for appraisal purposes, the status quo option maintains prescription charges at a high level, discouraging patients from taking HRT. By extension, this means that levels of health and wellbeing are lower than they could be.

Other key non-monetised costs by 'main affected groups'

As above

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

Benefits are calculated incrementally in the proposed intervention, meaning benefits are set to zero in the BAU option.

The main benefits of maintaining the status quo are a higher level of revenue for the NHS (at the expense of patients paying more for their prescriptions) and avoiding the need to introduce new systems or charges. However, the lower level of health achieved may lead to these benefits being offset in the long run.

Other key non-monetised benefits by 'main affected groups'

As above

Key assumptions/sensitivities/risks **Discount rate (%)**

It is assumed that the current legislation would stay in place for the remainder of the appraisal period. Therefore, there is no change to cost or benefit under this option throughout the appraisal period.

The status quo also assumes that prescription charges would continue to rise over time in line with inflation (which has been normal practice, albeit with charges being frozen in 2022-23).

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: £0	Benefits: £0	Net: £0	£0

Summary: Analysis & Evidence

Policy Option 2

Description: Introducing an HRT specific PPC in England, which would allow patients to pay a single fee of £18.70 covering all HRT prescriptions procured within a year.

FULL ECONOMIC ASSESSMENT

Price Base Year 2022/23	PV Base Year 2022/23	Time Period 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: £19m	**High:** £2,487m	**Best Estimate:** £611m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.14m	Year 1	£71m	£648m
High	£0.14m		£90m	£827m
Best Estimate	**£0.14m**		**£80m**	**£738m**

Description and scale of key monetised costs by 'main affected groups' **i)** Existing patients who pay prescription charges and buy an HRT PPC will make a saving of £30 per person, totalling £9m/year, which translates into lost NHS revenue. **ii)** NHS BSA have already incurred £1.3m in sunk development costs. They will additionally incur delivery and operating costs of c.£1.4m per year. The NHS will also have to provide extra HRT healthcare, estimated to cost £5.8m per year. All these translate into an opportunity cost of c.£76m (range £67m-£85m) per year (the value of QALYs foregone, due to the reduction in NHS revenue). **iii)** New patients will purchase the HRT PPC at a cost of £18.70, amounting to £1.8m (range £1.2m-£2.4m) . **iv)** Pharmacists will incur a cost of £2.8m (range £2.6m-£3m) per year due to potentially having to perform extra checks for the new HRT PPCs.

Other key non-monetised costs by 'main affected groups'

Familiarisation costs for patients, pharmacists and GPs (these are expected to be small relative to other costs).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	-		£73m	£667m
High	-		£361m	£3,314m
Best Estimate	-		**£148m**	**£1,348m**

Description and scale of key monetised benefits by 'main affected groups'

i) Health gains from using HRT – monetary value of £56m-£334m (best estimate £125m) per year. ii) Monetised QALY gain of £8.4m (range £5.6m-£11.2m) per year from extra NHS revenue from new HRT patients. iii) Financial savings incurred by existing patients due to paying less, totalling £9m per year. iv) Wider societal benefits in the form of reduced sickness absence cost (valued at £48.87 per person), amounting to £4.7m (range £3m-£6.3m) per year.

Other key non-monetised benefits by 'main affected groups'

Some patients may currently take less effective treatment for their menopausal symptoms than HRT (e.g. antidepressants). If the cost reduction encourages them to start HRT, they may stop using other less suitable medicines and thus make a saving. There could also be other labour market cost reductions such as a decrease in women reducing working hours or women losing out on promotion opportunities due to symptoms.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5 & 1.5

- From 64,000 to 130,000 (best estimate 100,000) patients will take up HRT as a result of this reform. This is based on estimates of demand elasticity. While increased uptake is expected, evidence on the size of effect is of lower quality, being quite old and/or not limited to HRT specifically.
- Patients starting HRT treatment are assumed to gain between 0.012 and 0.037 QALYs per year during treatment. The precise amount is uncertain and depends on both severity of symptoms and the degree to which symptoms are mitigated already without HRT use.
- Patients are assumed to minimise their costs. Individual savings will depend on numbers of prescriptions including non-HRT items and whether patients qualify for existing exemptions.
- The value of the sickness absence cost per woman is supported by limited evidence
- The uptake increase may not occur immediately, and health benefits may not be fully gained within a year of starting HRT

The high medium and low scenarios are based on upper, central and lower estimates of QALY gain and elasticity (the two most significant variables). Other parameters are less influential and explored through sensitivity analysis.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: Out of Scope
Costs: £2.8m	**Benefits:£0**	**Net: -£2.8m**	

Evidence Base

1. The problem under consideration

1. The government published its Women's Health Strategy for England in July 2022. It sets out ambitions and actions to improve the health and wellbeing of women and girls in England. Women's Health Strategy for England - GOV.UK (www.gov.uk)

2. In the strategy's public call for evidence, which ran from March to June 2021, 48% of respondents asked for the menopause and its treatments to be considered in future service planning. Many expressed concerns about the accessibility of Hormonal Replacement Therapy (HRT) and the barriers that can prevent some women getting the care they need. These concerns are long-standing and had already been raised prior to their inclusion within the strategy document.

3. Many factors affect access to HRT including patient awareness, a reluctance to discuss a traditionally taboo subject, concerns about potential side effects, prompt diagnosis and adequate availability of treatment. A multi-dimensional approach, as proposed in the strategy, is required to address these issues.

4. One barrier to access, often cited by campaigners, is the cost to patients of obtaining HRT on the NHS. Around 90% of NHS prescriptions are issued free in England, but for HRT the figure is only 60%, because age-based exemptions are less likely to apply. HRT prescriptions cost £9.35 each, but many women need combination therapies which can cost £18.70 per month. Given that HRT is a long-term treatment (up to 15 years for some women) the total lifetime cost can exceed £1,000. This can deter some patients from starting or maintaining a course of treatment.

5. Carolyn Harris MP has led a campaign to improve access to HRT and she said in a parliamentary debate on 29 October 2021: *"We also desperately need to look at prescription charges for HRT in England and at what we can do to ensure that the cost is not a barrier to women accessing it. The menopause does not discriminate, so the cost to treat it should not either. There are women struggling to find almost £20 a month, and … we must ensure that those women who need it are not denied HRT because of financial restraints."*

6. The government agreed that where cost was a barrier, that barrier should be removed and accordingly, the government announced in October 2021 plans to reduce the cost of HRT prescriptions for menopausal women.

7. This commitment was reiterated in the Women's Health Strategy for England, which the ambition that "All menopausal women for whom HRT is suitable are able to access HRT and at a reduced cost".

8. This IA focuses on the cost element of this ambition, while recognising that any proposal to reduce cost should be seen in the context of the wider aims in the women's health strategy to ensure all women can access the menopause-related healthcare and other support that they need.

2. Policy objective

9. The main policy objective is to

- reduce and remove financial barriers and thus improve uptake by reducing the cost of HRT prescription charges.

10. In doing this, there are two further considerations:

    - ensure that prescription charges are kept as simple and easy to operate as possible;
    - ensure that the NHS continues to receive some revenue from HRT patients, to help maintain the resilience of the service.

11. These three objectives do conflict to some extent, such that a balance needs to be struck between raising revenue, reducing charges and keeping the system simple. The proposed intervention seeks to achieve an appropriate balance.

3. Description of current situation and proposed intervention

3.1. Business as Usual (BAU)

12. Unless exempt (because of age, low income or having certain conditions such as cancer), patients in England are charged for NHS prescriptions. The charge is typically £9.35 per item, but some HRT medicines attract a double charge of £18.70. These charges are levied each time a prescription is issued, usually monthly or quarterly, which can lead to significant costs over time. Charges tend to increase each year in line with inflation (although, exceptionally, they were frozen in 2022-23).

13. Patients can choose to buy a standard Pre-Payment Certificate (PPC) which acts as a season ticket. This costs £108.10 for a year, or £30.25 for 3 months, and entitles the patient to free prescriptions (of any kind) for that period. Awareness of these PPCs is variable and not all patients take advantage of the savings, but many do.

14. There is no special process for users of HRT, so they will incur the full current charges unless they are exempt (which means around 40% will be charged and 60% will be exempt).

15. Maintaining the status quo does not address the main policy objective of reducing costs and any resultant barriers to access. It is thus rejected as a suitable option but provides the baseline against which other options can be measured.

3.2. Introduce an HRT specific PPC (proposed intervention)

16. The proposal is to reduce the cost of HRT to a maximum of £18.70 per year, compared with the current maximum of £108.10 for standard PPC users or more for some pay-as-you-go users. This amount has been set to align with the current monthly charge for a combination therapy, which is twice the single item fee of £9.35. This alignment is expected to be preserved, such that any future changes in standard fees would also apply to HRT.

17. The amount itself has been chosen because it achieves a balance between delivering significant savings for many patients, while also preserving some revenue for the NHS. It also conveniently aligns with current per item charges, which makes the system easier to understand, rather than introducing a completely different scale of fees.

18. Administratively, the most efficient mechanism for delivering this change within the current system is to introduce an HRT-specific PPC, costing £18.70 and allowing free HRT prescriptions for 12 months. This ensures that patients only pay once for the year, while avoiding any need to record total usage to date, or similar data.

19. The new HRT PPC will be made available online via the NHS Business Service Authority (NHSBSA) website, by telephone, or in person via select pharmacies that already sell the standard PPC. It will be non-refundable and patients with existing standard PPCs will be advised to wait until their existing PPC expires before purchasing a HRT PPC. All current exemptions will continue to apply.

20. Implementing this option will require amendments to the following regulations:

    - the National Health Service (Charges for Drugs and Appliances) Regulations 2015, (the Charges Regulations);
    - the National Health Service (General Medical Services Contracts) Regulations 2015 (the GMS Regulations)
    - the National Health Service (Personal Medical Services Agreements) Regulations 2015 (the PMS Regulations)
    - the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (the PLP Regulations).

21. This option meets all three policy objectives of reducing costs and improving access, while maintaining some NHS revenue and delivering those outcomes in an administratively efficient manner. It is the preferred way forward.

3.3. Definition of HRT

22. Hormonal Replacement Therapy covers a multitude of different products, strengths, methods of administration and combinations of those therapies. The legislation will specify the exact rules for determining which prescriptions can be obtained with an HRT PPC, and which cannot.

23. For the purposes of this ex-ante impact assessment, the analysis assumes the following inclusions, which are HRT medicines licensed for the treatment of menopause symptoms. It is possible that some differences may emerge in the detailed scheme rules and in any case the qualifying list will be regularly reviewed in future as new products are developed and licensed.

Table 1. HRT definition based on the British National Formulary (BNF)[1]

BNF code	Description	Assumption
060401	Female sex hormones and their modulators	All of sub-paragraph 0604011 is in scope. Utrogestan 100mg from sub-paragraph 0604012 is also in scope. Others are out of scope.
060402	Male sex hormones and antagonists	Out of scope
060403	Anabolic steroids	Out of scope

[1] https://bnf.nice.org.uk/

070201	Preparations for vaginal and vulval changes	In scope
070202	Vaginal and vulval infections	Out of scope

24. This definition of HRT ensures that all the main products are included, but it excludes (for example) any use of testosterone, alternative therapies and steroids. This is judged reasonable for economic appraisal purposes but as stated may not mirror the final list as set out in detail in the legislation and/or associated guidance.

25. The effect of any deviations from the above definition will be mitigated in so far as some patients taking excluded products may also be taking ones which are in scope, and thus those people will be considered in the analysis anyway.

3.4. Options around price-setting

26. In principle there are many different prices which could be charged for the HRT PPC. Higher charges would generate more revenue but reduce the uptake effect and health gains. Lower charges would achieve the opposite. A balance needs to be struck.

27. It would be possible to charge different rates according to circumstances (for example the price might be means-tested). But we retain a policy objective of keeping the system simple, both to administer and for patients to understand. It is advantageous to link the price charged to wider prescription charge fees, both to keep the variety of different fees as low as possible, and to facilitate any annual revision of fees in future.

28. The proposed fee of £18.70 is chosen as an appropriate balance between these policy objectives. It is also designed to avoid any short-term increase in fees which might deter patients. At present a common scenario for a first prescription would be a combined treatment containing both oestrogen and progestogen, which often costs double the single fee – in other words £18.70. A higher charge than that would lead to more being paid initially than under the status quo, whereas a lower charge would fail the objective of maintaining some revenue for the NHS and funding administration of the PPC scheme.

29. This impact assessment presents analysis for the status quo and for the main proposed charge of £18.70 and also discusses why making HRT free would not be appropriate. Other prices have been considered within DHSC but rejected for the reasons explained above.

3.5. Rejected alternative options

Making all HRT prescriptions free

30. This option would remove all financial barriers to access, would maximise the benefit to patients, and would also be easy to implement administratively. However, it fails to maintain any amount of revenue to help the NHS operate the system, which in the current financial environment is problematic and fails to meet the third policy objective.

31. Given that the preferred option already delivers a significant cost saving, and that existing exemptions (e.g. for low-income patients on benefits) will be maintained, the marginal additional benefit of free charges over and above the preferred option is reduced, while the loss of NHS revenue is increased. This makes the free charge option unattractive, and it is rejected accordingly.

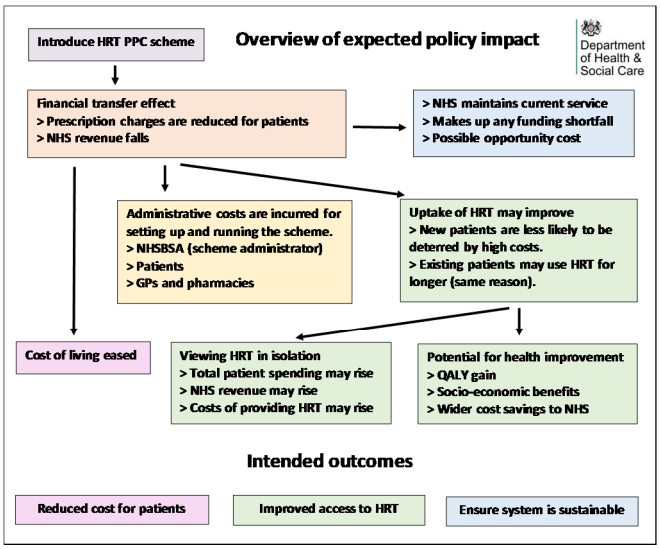
Tackling barriers to HRT access in some other way, non-financially

32. HRT access is being tackled on several fronts, as explained in the Women's Health Strategy. There is no suggestion that non-financial activity (such as improving awareness) should be ignored. On the contrary, such activity is essential. However, this impact assessment focuses on the specific objective of reducing costs to patients. The reform will combine with other initiatives to impact women's health, and the analysis acknowledges that any quantification of benefits should be seen in that wider context.

4. Expected impacts

33. This policy has three main impacts:
    - a financial transfer from the NHS to patients,
    - some administrative costs to both the NHS supply chain and businesses, and
    - an improvement in health (with consequential social and economic benefits).
34. The diagram below presents a high-level overview of how these three effects will arise.

Fig.1. Expected policy impacts



35. The largest of these impacts is expected to be the improvement in health. Existing research and NICE guidance demonstrate that HRT therapy provides significant short and longer-term benefits for those that use it.

36. While the policy is expected to be beneficial in economic terms (the health gains outweighing any opportunity costs to the NHS) on an individual basis, the total impact depends on how many patients increase their use of HRT. This is very difficult to predict accurately even though the logic, that a price reduction will increase demand, is based on sound economic theory and feedback from stakeholders. The above diagram is designed to give an overview of the main consequences arising from the HRT PPC. It is not intended to convey a detailed account of all the influences and interactions that might arise in the complex HRT space. The later section on monitoring and evaluation discusses additional detail to help understand the logical relationships and thus inform evaluation.

5. Interaction with other policies

37. The HRT PPC reform should not be viewed in isolation: as explained it forms one part of a wider strategy to improve women's health. However, it is difficult to isolate the effects of different influences accurately, or to determine in advance how well different initiatives will synergise. The objectives of the Women's Health Strategy are set to be achieved over ten years which means that different elements will take effect at different times - this adds additional complexity.

38. In principle, option one (the status quo option) takes account of both other interventions and wider developments and events. The IA uses a price elasticity approach to estimate the effect of price reductions relative to that baseline, and this approach is helped by the HRT PPC being introduced early and because its effects are expected to arise relatively quickly after implementation.

39. The analysis also makes assumptions about the HRT PPC being sufficiently publicised so that all those who might benefit have the opportunity to do so. This awareness is likely to be easier to achieve amongst existing patients who are familiar with the system. New patients may be more difficult to reach, although even at this early stage, information about the PPC has been widely discussed in both traditional and social media.

40. People who do not currently use HRT will make their decisions based on several factors. Price reform will influence some but not all of these and therefore may affect a different subpopulation compared to other interventions. This provides additional reassurance that the approach taken is reasonable in the circumstances.

41. Reasons for not taking HRT might include but are not limited to:
    a) lack of awareness about the menopause or the treatments available
    b) lack of funds / cost concerns
    c) worried about side effects of HRT
    d) previous bad experience with HRT (medical side effects, administrative issues etc.)
    e) previous bad experience by proxy (e.g. friend had a bad experience)
    f) medically not suitable for HRT
    g) apathy – not enough time, not prioritised
    h) symptoms not severe enough to merit treatment
    i) forgets to take HRT / doesn't follow advice given
    j) too ill (physically or mentally) to seek the care they need
    k) short-term UK resident
    l) takes HRT but prefers to source it privately

42. Inevitably, these factors will combine to help each individual make a decision. Although a full segmentation of patient types is not available, it is possible to consider different levels of willingness to adopt, or refrain from, HRT. For example:
    a) strongly in favour – very keen to use HRT
    b) moderately in favour – will use with little persuasion but may be some minor barriers
    c) neutral – may well adopt HRT if encouraged
    d) leaning against – reluctant to use, multiple barriers to overcome, but could be encouraged
    e) strongly against – very resistant to adopt
    f) medically unsuitable for HRT

43. The HRT PPC will tackle the cost concern and may also indirectly improve awareness. It will not address other barriers on its own. However, both the main effects and the impact of other considerations should be implicitly reflected in the evidence about price elasticity and contribute to its relatively inelastic nature. Many of the reasons for adopting HRT or not will also apply to prescriptions more generally, such that more generic evidence remains relevant albeit not perfect. While the wider complexity does create uncertainty, the proposed approach remains valid and is proportionate.

6. Summary of costs and benefits

44. By convention, the costs and benefits of option 1 (maintaining the status quo) are defined as zero, with the costs and benefits of the preferred option 2 (introducing an HRT PPC) expressed relative to that baseline.

45. The impacts assessed are:
    a) Financial transfer effect – existing patients save money and NHS revenue falls by the same amount.
    b) Uptake effect – financial barriers are removed for new and existing patients to take up HRT and/or (where clinically appropriate) to increase their use (e.g. taking HRT for longer).
    c) Health impact – increased uptake will deliver health gains to those affected.
    d) Opportunity cost – the monies saved by patients may generate wider benefits for them, but the NHS loses any benefits that would have accrued previously. In practice, this results in a net health loss which partially offsets the health gain in (c) above.
    e) Administrative cost – introduction and maintenance of the HRT PPC will create costs for the NHS, businesses such as pharmacies, and patients.
    f) Wider business and societal impacts – such as any consequences for sickness absence, employee efficiency and welfare, social care etc.

46. The table below summarises the monetised and non-monetised costs and benefits as taken into account for the best-estimate scenario. Detailed explanations of how these were quantified and then monetised are provided in the next section.

Table 2. Summary of cost-benefit analysis for option 2 (Central best estimate)

	Further Details	Typical annual cost Year 1 = 2023/24 *
PATIENT NUMBERS		
Existing number of HRT patients	Based on NHS BSA data for 2021/22 (the most recent full year available). Numbers have been rising and the possibility of further rises during 2023/24 is considered in sensitivity analysis.	1,700,000
Existing patients making savings	Based on analysis of combined HRT and non-HRT related items usage, 18% of existing patients could make a saving under the new policy. Others may already be exempt or have other conditions which make an existing standard PPC a better option than an HRT one.	300,000
New patients due to price reduction	Price Elasticity of Demand = -0.15 (based on literature review) % change in price = -38% % change in demand = % change in price x PED = 5.7%	100,000
BENEFITS		
B1) Savings benefits for existing patients	£30 average saving per existing patient who benefits (DHSC analysis)	£9,000,000
QALYs due to HRT uptake	QALY gain per patient starting HRT = 0.01856 (based on evidence in NICE guidance)	1,791
B2) Monetised QALYs gained	£70,000 per QALY (societal value)	£125,390,000
B3) Reduction in sickness absence cost	Sickness absence saving = £48.87 per new HRT patient (based on literature review)	£4,720,000
NHS revenue gained from new patients	Each new patient purchases an HRT PPC at £18.70	£1,800,000
B4) Monetised QALYs gained from extra NHS revenue	NHS spends £15,000 to gain a QALY valued at £70,000	£8,420,000
B5) Patient savings on unsuitable current treatment	Some patients may currently take unsuitable treatment for their menopausal symptoms (e.g. antidepressants). If the cost reduction encourages them to start HRT, they will stop using the other unsuitable medicines.	unmonetised
B6) Further labour market cost reductions	Decrease in, for e.g., symptom-related lateness to work, women reducing their working hours, or women losing out on promotion opportunities due to symptoms	unmonetised
Total Monetised Health Related Benefits (B2+B4)		£133,820,000
Total Monetised Non-Health Related Benefits (B1+B3)		£13,720,000

TOTAL BENEFITS		£147,530,000

COSTS		
C1) Financial cost to new patients	All new patients will pay £18.70 for an HRT PPC	-£1,800,000
Lost revenue to the NHS in prescription charges	Equivalent to the savings for existing patients	-£9,000,000
Cost to the NHS for providing extra HRT care	Average net ingredient cost per HRT patient = £60 (NHS BSA data)	-£5,790,000
Delivery cost for NHS BSA	£1m in Year 0 (sunk) Followed by c.£110,000 in Year 1 (provided by NHS BSA)	-£110,000
Operating cost for NHS BSA	c.£190,000 in Year 0 (sunk) £2.1m in Y1 Followed by an average of £1m each year (provided by NHS BSA)	-£2,060,000
Optimism bias adjustment to total NHS BSA costs	25% increase in total NHS BSA costs	-£540,000
Total financial cost to the NHS	The sum of the four NHS costs above	-£17,510,000
C2) Opportunity cost	Value of QALYs forgone due to lost NHS revenue	-£81,720,000
C3) Cost for pharmacists	Internal DHSC estimate accounting for pharmacists having to contact GPs and perform manual checks. Estimate includes a 25% increase in costs to account for optimism bias	-£2,820,000
C4) Cost of familiarisation with new policy	For patients, GPs, and pharmacists	unmonetised
Total Monetised Health Related Costs (C2)		-£81,720,000
Total Monetised Non-Health Related Costs (C1+C3)		-£4,620,000
TOTAL COSTS		-£86,340,000

NET BENEFITS	(including first year one-off costs)	£61,190,000

NET PRESENT VALUE for 10-years	**£610,540,000**

The net present value has been calculated by applying a discount rate of 1.5% to health-related costs and benefits and a discount rate of 3.5% to non-health related costs and benefits.
The net benefit is lower in the first year because of one-off set-up costs. Later years are not reduced in the same way and the net benefit rises to around £68m instead of £61m.

** unless otherwise specified, all patient numbers, costs and benefits remain constant across the 10-year period*

** numbers may not add up due to rounding (to the nearest 10,000)*

7. Methodology for quantifying and monetising costs and benefit

7.1. Benefit B1 – monetary savings for existing patients

7.1.1. Estimating the amount of savings per person based on existing HRT patients

47. Patients must decide in advance whether to buy a PPC, based on their best estimate of future medical needs. Some patients may not, with hindsight, select the cheapest option but for costing purposes we assume that they would.

48. We assume that a patient:
    a) pays for their prescriptions;
    b) receives H chargeable HRT-related items per year;
    c) receives N chargeable non-HRT-related items per year;
    d) predicts their prescription usage accurately;
    e) is aware of all payment options; and
    f) will pay using the cheapest option.

49. We use the following parameters:
    a) a single prescription costs £9.35 (higher charges are discussed later);
    b) an HRT pre-payment certificate (HPPC) costs £18.70;
    c) a standard (3 or 12 month) pre-payment certificate (SPPC) costs £108.10 per year or £30.25 per quarter.

50. On this basis, a patient will benefit from an HPPC if:
    a) $H > 2$, so that an HPPC is cheaper than paying for HRT singly; and
    b) $N < 10$, because if $N \geq 10$ a SPPC would be a better option than an HPPC, and thus no change from the status quo.

51. For patients who meet these two criteria, the savings are summarised in Table 2 below.

Table 3. Savings for patients benefitting from an HRT PPC

	Current charge	Proposed charge	Saving
If (H + N) < 12	(H + N) x 9.35	18.7 + (N x 9.35)	(H – 2) x 9.35
If (H + N) ≥ 12	108.10	18.7 + (N x 9.35)	89.40 – (N x 9.35)

52. The full table of savings is as follows. For example, a patient paying for 6 HRT and 6 non-HRT prescriptions per year would currently buy a SPPC for £108.10. In future they would pay just £18.70 for the HRT items, plus 6 x £9.35 = £56.10 for the rest. The total of £74.80 is a saving of £33.30.

Table 4. Annual savings for different prescribing levels (£ per patient)

H↓ N→	0	1	2	3	4	5	6	7	8	9
3	-9.35	-9.35	-9.35	-9.35	-9.35	-9.35	-9.35	-9.35	-9.35	-5.25
4	-18.70	-18.70	-18.70	-18.70	-18.70	-18.70	-18.70	-18.70	-14.60	-5.25
5	-28.05	-28.05	-28.05	-28.05	-28.05	-28.05	-28.05	-23.95	-14.60	-5.25
6	-37.40	-37.40	-37.40	-37.40	-37.40	-37.40	-33.30	-23.95	-14.60	-5.25
7	-46.75	-46.75	-46.75	-46.75	-46.75	-42.65	-33.30	-23.95	-14.60	-5.25
8	-56.10	-56.10	-56.10	-56.10	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
9	-65.45	-65.45	-65.45	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
10	-74.80	-74.80	-70.70	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
11	-84.15	-80.05	-70.70	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
12 or more	-89.40	-80.05	-70.70	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25

53. The NHS Business Service Authority (NHSBSA) monitors prescriptions and has provided data for 2021/22 on the numbers of patients paying individual charges, as follows:

Table 5. Numbers of patients paying individual charges

H↓	N →	0	1	2	3	4	5	6	7	8	9
3		27,180	11,899	8,583	6,799	5,564	4,612	4,346	3,630	2,894	2,258
4		31,426	12,931	9,011	6,549	5,818	4,869	4,796	3,661	2,848	2,231
5		15,531	6,748	4,769	3,438	2,889	2,620	2,423	2,052	1,578	1,276
6		9,753	4,412	3,040	2,379	1,887	1,497	1,582	1,254	994	709
7		5,564	2,545	1,816	1,338	1,129	910	970	749	576	488
8		5,186	2,338	1,502	1,157	944	718	655	600	443	361
9		3,024	1,384	945	721	576	478	402	363	287	211
10		2,493	1,096	716	514	408	353	302	266	199	170
11		1,484	722	460	342	276	220	207	136	124	97
12 or more		3,727	1,541	1,037	779	573	422	426	355	261	230

54. For clarity, this table only counts patients expected to save money. Many more will have values of H and N outside the tabulated range, implying that they would not benefit from an HPPC.

Estimated savings to patients (if currently paying individually)

55. These two tables can be multiplied together to give the total change in charges, assuming everyone follows their optimal strategy before and after the introduction of an HPPC. The result is that around 290,000 patients who currently pay individual charges might save a collective total of £7.5 million per year.

Numbers of patients paying with a standard PPC

56. The above tables cover only those patients who paid for prescriptions individually. Over 30,000 patients who paid for prescriptions using a SPPC might also save money.

57. The analysis here is less certain, because it is not always clear whether patients are using quarterly or annual SPPCs, and hence how much they are paying now. Some patients may prefer to buy one or more quarterly SPPCs, which cost £30.25, rather than an annual one. HRT itself is normally a longer-term treatment, but not all patients continue with treatment.

58. We assume the following purchasing behaviour, which is intended to be a plausible approximation of real life.

Table 6. Patients' purchasing behaviour

No. of prescriptions bought during the year (H + N)	Cost if bought individually (£)	Assumed SPPC purchases	Assumed SPPC charges (£)
12+	112.20 or more	1 x annual	108.10
10-11	93.50 – 102.85	3 x quarterly	90.75
7-9	65.45 – 84.15	2 x quarterly	60.50
0-6	0.00 – 56.10	1 x quarterly	30.25

59. Following a similar approach to those paying individually, the number of patients and their estimated savings are as follows:

Table 7. Count of patients using standard PPCs

H↓ N→	0	1	2	3	4	5	6	7	8	9
3	1,407	940	988	981	915	888	965	831	847	794
4	1,089	657	761	668	816	687	702	628	657	639
5	503	311	305	311	335	367	391	355	355	317
6	496	284	265	296	281	301	318	248	282	264
7	298	148	144	147	184	176	179	178	190	189
8	315	124	143	149	168	172	147	158	150	165
9	239	106	86	119	89	87	106	92	108	108
10	199	109	81	61	70	101	92	86	89	96
11	134	56	62	59	62	63	71	80	60	55
12 or more	892	427	301	237	244	232	256	258	280	248

Table 8. Potential change in charges for patients using standard PPCs

H↓ N→	0	1	2	3	4	5	6	7	8	9
3	-11.55	-2.20	0.00	0.00	0.00	0.00	0.00	-6.60	0.00	-5.25
4	-11.55	-2.20	0.00	0.00	-4.40	0.00	-15.95	-6.60	-14.60	-5.25
5	-11.55	-2.20	0.00	-13.75	-4.40	-25.30	-15.95	-23.95	-14.60	-5.25
6	-11.55	-2.20	-23.10	-13.75	-34.65	-25.30	-33.30	-23.95	-14.60	-5.25
7	-11.55	-32.45	-23.10	-44.00	-34.65	-42.65	-33.30	-23.95	-14.60	-5.25
8	-41.80	-32.45	-53.35	-44.00	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
9	-41.80	-62.70	-53.35	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
10	-72.05	-62.70	-70.70	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
11	-72.05	-80.05	-70.70	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25
12	-89.40	-80.05	-70.70	-61.35	-52.00	-42.65	-33.30	-23.95	-14.60	-5.25

60. For example, a patient with 8H + 2N is assumed to buy three quarterly SPPCs over the year, costing £90.75 in total. Under the new rules, they could pay £18.70 for an HPPC plus a further £18.70 for their non-HRT medication. Total saving = £90.75 - £37.40 = £53.35.

61. Multiplying the preceding tables together, around 33,000 patients who currently use SPPCs might save a collective total of £0.6 million under the proposed regime. These figures are indicative.

Effect of some HRT prescriptions being charged at double (or triple) rate

62. Some HRT products attract a double prescription charge of £18.70 instead of £9.35. The current effect of this is to increase charges for low-volume users, and to lower the number of items needed to make a SPPC worthwhile.

63. Under the proposals for an HPPC, patients who pay for double rate items may make additional savings on top of those identified in the main analysis:
    a) Anyone paying individually for double rate items will save an additional £9.35 for each item beyond the first, by buying an HPPC.

b) Some patients using a SPPC to pay for double rate items may save more. For example, someone with six single rate items could cut costs from £56.10 to £18.70, but someone with six double rate items could switch from a SPPC to an HPPC and cut costs from £108.10 to £18.70.

64. The exact savings will depend on individual circumstances and the precise levels of HRT and non-HRT prescriptions used by that individual. Tentatively, we estimate around 50,000 patients might attain extra savings because of double-charged items, and the associated extra saving might be around £1 million (£20 per person). These patients are the same as those already counted, so it is only the extra money that changes.

7.1.2. Overall estimated savings to patients

65. Total number of HRT patients in 2021/22 = 1.7 million
    - this number may have increased slightly during 2022/23, but we do not yet have sufficient data to complete a more recent appraisal.

66. Number of patients making savings = 0.3 million (18%)
    - of whom 290,000 currently pay individually and 33,000 currently pay using a PPC, but some may use both so the rounded figure of 0.3 million is used as a conservative total estimate. Of those, 50,000 may save extra because of double-charged items

67. Total amount saved by existing patients = £9 million
    - comprising £7.5m for individual charge-payers, £0.6m for SPPC users and £1m for double-charged item users. These groups may overlap but the savings are cumulative.

68. Average (mean) savings per person per year = £9m / 0.3m = £30.
    - actual savings will vary according to individual circumstances.

7.1.3. Uncertainties around the level of patient savings

69. The above estimates are uncertain and rely on assumptions about patient behaviour. The most significant assumptions and their impacts are:

Patient awareness of the new charges

70. The analysis assumes that all patients who would benefit from an HPPC would be made aware of it and would be willing and able to take advantage. If any patients were not, then the impacts would be reduced proportionately. For example, if 25% of those eligible to save money were unaware, the savings could fall from £9 million to £6.75 million per year. In practice, one might expect awareness to be lower initially and then improve over time.

Any overspending under the current rules is ignored

71. The analysis assumes that patients are currently paying the minimum they can. In practice some may be paying more than that through a lack of awareness, uncertainty over treatment needs or other reasons. The proposed policy, particularly if it included education and improved awareness, might help patients reduce such overspending, as well as delivering the main savings associated with cheaper charges. The effect of this

would be to increase the potential reduction in patient spending / NHS revenue compared with the status quo, although arguably it is not directly attributable to the reduction in charges.

Patients using a combination of standard PPCs and individual charges

72. Some patients may use a combination of payment methods during the year. However, the analysis considers each category separately and may underestimate savings compared with a more holistic view. For example, a patient who currently buys 4H under a SPPC and 4H individually would be modelled under the new charges as paying £18.70 twice (because an HPPC saves money in each case) but in practice they would only need to buy one.

Past prescribing is assumed to be a good guide to the future

73. The modelling assumes that prescribing patterns in 2021/22 will continue (apart from any change caused directly by cheaper HRT charges). This isn't unreasonable, although patterns of health and care can of course change over time.

7.2. Assessing the effect of the price reduction on uptake

7.2.1. Barriers to taking HRT

74. Patients face several barriers in getting HRT, apart from cost, such as lack of awareness about the menopause or the treatments available, lack of awareness among healthcare professionals meaning menopause isn't identified as a cause of symptoms, worries about side effects of HRT, previous bad experiences with HRT (medical side effects or administrative issues), severity of symptoms, culture-related reasons, whether the patient is suitable to receive HRT treatment etc.

75. Overall, it is difficult to assess the weight of each of these potential barriers and the interaction between them, and thus it is uncertain to what extent a reduction in price will contribute to increasing the uptake of HRT.

76. Anecdotal evidence suggests that for some women the cost of HRT is indeed a barrier. The APPG Menopause Inquiry Concluding Report[2] states that "a survey carried out by Newson Health of over 1000 women found that 39% are paying between £51-£150 a year on HRT, while around 20% are paying over £150 a year, and some more than £300". Stakeholders have repeatedly cited these levels of charge as being a cause for concern. However, there is also some evidence that suggests that a low impact of menopause symptoms, worries about the risk of cancer or other illnesses and not knowing enough about HRT are the top three reasons for not trying HRT[3].

77. Uptake of HRT has already been rising following recent media campaigns to improve awareness of the benefits of HRT and patient confidence about suitability. Further rises are expected partly because of wider activity within the Women's Health Strategy to address other barriers, and also because uptake is still significantly below (about half the level of) historical highs.

[2] Challenging current policy in Parliament - Menopause APPG (menopause-appg.co.uk)

[3] Download.ashx (fawcettsociety.org.uk)

78. Nevertheless, costs have not been addressed and (as evidenced by stakeholder submissions) continue to be a barrier. Removing or reducing that barrier can be expected to increase demand over and above what could be achieved by non-financial measures alone.

79. The HRT PPC is designed to improve patient access by removing any financial barrier which might deter patients from starting or maintaining a course of treatment. It can increase uptake in two ways:
    a) patients who do not take HRT because of cost concerns, may start treatment; and
    b) patients who do take HRT but, because of cost concerns, limit their use to a level below their GP's recommendation, may increase their frequency or duration of use.

80. This context has implications for assessing the cost reduction (HRT PPC) element:
    a) cost reduction is an important element of the strategy, strongly supported and repeatedly cited by campaigners on both affordability and fairness grounds;
    b) it is difficult to isolate the precise effect on uptake of the HRT PPC on its own;
    c) the effect on individuals will vary – for some it may enable previously unaffordable treatment to be provided, for others it will make a difference only if combined with other interventions (such as improved diagnosis) and for some it may make no difference to their HRT decision; and
    d) the HRT PPC approach is new and bespoke – meaning it is tailored to suit the situation, but also that there is little in the way of firm evidence from similar interventions in the past

7.2.2. The price elasticity of demand

81. According to the law of demand, a reduction in the price of a product will usually lead to an increase in the consumption of that particular product. Therefore, the policy is expected to have some positive impact on HRT uptake. The sensitivity of demand with respect to changes in prices can be quantified through a price elasticity of demand (PED). The PED gives the percentage change in demand that can be expected from a one percentage change in price, holding everything else constant.

82. There is a lack of micro-data on HRT patients specifically, making a bespoke analysis for the purpose of this IA infeasible. Therefore, a more generic approach is taken, where the literature on the price elasticity of demand for prescribed medicines is reviewed. There is no officially agreed value for the PED for prescribed medicines in England as a whole. However, the body of research literature, some focusing on the UK, some on other countries, provides a useful starting point. A conservative approach with significant caveats is applied to the present HRT PPC situation.

7.2.3. Deciding on the value for the PED based on the literature review

83. The literature indicates variability in the specific size of the PED, but that demand for prescription medicines is price inelastic, i.e. a change in price translates into a less than proportionate change in demand. The PED might be different depending on the country analysed, population demographics or types/classes of medicines. Research also suggests that the response in demand to price increases and decreases may not be symmetrical. Studies tend to use individual level data and focus on the impact of a price change on either the out-of-pocket spending on prescription drugs or on the volume of

dispensed prescription drugs. A summary of the studies reviewed can be found in Annex A.

84. On average, the PED from the UK studies is approx. -0.32, the PED from meta-analyses is approx. -0.18, and that from papers focusing on other counties is approx. -0.15. An overall average of these values would lead to a PED of -0.2. However, given that the literature focusing on the UK is rather outdated, that no study specifically analyses HRT-related products, and that there may be asymmetry in people's responses to price increases versus decreases, the value of -0.2 is only considered for the high-end scenario. For the best-estimate scenario, a more conservative value for the PED is used, that of -0.15, i.e. a 10% increase in the price of HRT leads to a 1.5% reduction in demand. For the low-end scenario, the PED is set to an even lower value of -0.1. In the sensitivity analysis we further explore to what extent the overall NPV changes with the value of the PED.

85. Further assumptions employed:
    a) For the purpose of this analysis, demand is equivalent to the number of patients taking HRT. Therefore, a PED of -0.15 translates into: a 10% decrease in the price of HRT leads to a increase of 1.5% in the number of patients taking HRT.
    b) The PED remains constant over the 10-year period of the analysis
    c) The effect on uptake is immediate (i.e. uptake increases as dictated by the PED from the first year the policy is implemented)

86. Finally, in practice, the policy may increase uptake in two ways:
    a) Patients who do not take HRT because of cost concerns may start treatment; and
    b) Patients who do not take HRT but, because of cost concerns, limit their use to a level below their GP's recommendation, may increase their frequency or duration of use.

87. It is not possible to disentangle these two channels, therefore it is assumed that the increase in demand obtained by applying the PED of -0.15 accounts for ***new patients*** taking HRT as a result of the PPC reform. This represents one of the key assumptions in the present analysis and it also involves a high level of uncertainty.

88. Sensitivity analysis around the value of the PED is provided later on in the IA.

7.2.4. Estimating the increase in uptake as a result of the HRT PPC policy

89. To calculate the change in demand as a result of decreasing the price of HRT, the percentage change in the price of HRT must be determined. This is calculated as on overall weighted average between the percentage change in the price that patients purchasing single items only experience, and the change that patients using a PPC experience. The analysis assumes that people behave rationally and with perfect knowledge, such that they will always buy at the cheapest rate possible. In practice, this means that patients who currently pay more than they need to may save more than suggested. Those extra savings could be achieved now, though, so are excluded from the calculation (they are effectively included in option 1 – the status quo – and set to zero for appraisal purposes).

90. The percentage change in price for patients paying individual charges per different combination of HRT and non-HRT related items can be seen in the table below.

Table 9. Percentage change in price – patients paying individual charges[4]

H↓ N→	0	1	2	3	4	5	6	7	8	9
3	-33%	-25%	-20%	-17%	-14%	-13%	-11%	-10%	-9%	-5%
4	-50%	-40%	-33%	-29%	-25%	-22%	-20%	-18%	-14%	-5%
5	-60%	-50%	-43%	-38%	-33%	-30%	-27%	-22%	-14%	-5%
6	-67%	-57%	-50%	-44%	-40%	-36%	-31%	-22%	-14%	-5%
7	-71%	-63%	-56%	-50%	-45%	-39%	-31%	-22%	-14%	-5%
8	-75%	-67%	-60%	-55%	-48%	-39%	-31%	-22%	-14%	-5%
9	-78%	-70%	-64%	-57%	-48%	-39%	-31%	-22%	-14%	-5%
10	-80%	-73%	-65%	-57%	-48%	-39%	-31%	-22%	-14%	-5%
11	-82%	-74%	-65%	-57%	-48%	-39%	-31%	-22%	-14%	-5%
12 or more	-83%	-74%	-65%	-57%	-48%	-39%	-31%	-22%	-14%	-5%

91. Using the total number of patients that use each of these combinations, the weighted average percentage change in price for patients paying the single charge is -40%.

92. The percentage change in price for patients paying for an SPPC for different combinations of HRT and non-HRT related items can be seen in the table below.

Table 10. Percentage change in price – patients paying for a standard PPC

H↓ N→	0	1	2	3	4	5	6	7	8	9
3	-38%	-7%	0%	0%	0%	0%	0%	-7%	0%	-5%
4	-38%	-7%	0%	0%	-7%	0%	-18%	-7%	-14%	-5%
5	-38%	-7%	0%	-23%	-7%	-28%	-18%	-22%	-14%	-5%
6	-38%	-7%	-38%	-23%	-38%	-28%	-31%	-22%	-14%	-5%
7	-38%	-54%	-38%	-48%	-38%	-39%	-31%	-22%	-14%	-5%
8	-69%	-54%	-59%	-48%	-48%	-39%	-31%	-22%	-14%	-5%
9	-69%	-69%	-59%	-57%	-48%	-39%	-31%	-22%	-14%	-5%
10	-79%	-69%	-65%	-57%	-48%	-39%	-31%	-22%	-14%	-5%
11	-79%	-74%	-65%	-57%	-48%	-39%	-31%	-22%	-14%	-5%
12	-83%	-74%	-65%	-57%	-48%	-39%	-31%	-22%	-14%	-5%

93. Using the total number of patients that use each of these combinations, the weighted average percentage change in price for patients paying the SPPC is -22%.

94. Table 11 below summarises the overall weighted average percentage change in the price of HRT:

Table 11. Overall weighted average percentage change in price

	% change in price	Number of patients

[4] Adjusted to exclude any savings attainable without the HRT PPC being introduced, as explained in para 89.

Single Charge users	-40%	291,052
SPPC users	-22%	33,170
Overall weighted average percentage change in price		**-38%**

95. Given that the weighted average percentage change in the price of HRT is -38% and that the price elasticity of demand (PED) was set to -0.15, the change in demand as a result of introducing the policy is:

$$\%\ change\ in\ demand = \%\ change\ in\ price \times PED = (-38\%) \times (-0.15) = 5.7\%$$

96. This additional demand will comprise new patients starting HRT, existing patients increasing their usage, or possibly using HRT for longer, and possibly some patients being more willing to try a range of products to find the best ones for them. If all additional demand came from new patients (either brand new or those extending into additional years) then:

$$New\ patients = Existing\ patients \times \%\ change\ in\ demand = 1{,}700{,}000 \times 5.7\% = 100{,}000$$

7.2.5. Uncertainty around uptake impacts

Effect on uptake is highly uncertain

97. Firstly, we assume that the demand sensitivity to price changes for HRT is similar to that for prescription medicines in general. This may be different, particularly given the fact that HRT users represent a specific population, different than the average medicines user. In addition, patients on the lowest incomes already qualify for free prescriptions through benefit-related or age-based exemptions. The cohort most likely to be influenced by lower costs is those who do not qualify for such exemptions but who have relatively low income. It was not possible to get the characteristics of this targeted segment.

98. Secondly, there are limits on the quantity of HRT medication that it is safe and appropriate for an individual patient to take. It is unclear to what extent this limit is reflected in any estimate of price elasticity. Patients could certainly use HRT for longer, without increasing the quantity per month, but equally some will simply save money without increasing their own personal demand.

99. Thirdly, uptake of HRT is already on an upward trend, following substantial coverage in the media which has improved patient awareness and confidence. Any analysis of future impact should consider only the marginal gain relative to the status quo. However, it is possible that uptake has already risen slightly having been influenced by expectations about lower charges coming in. It is also possible that if expected reductions were withdrawn then uptake might suffer. While plausible, neither possibility is well-evidenced, and we have not made any adjustment for it. This may lead to a slight underestimate of overall impact. We do assume that any impact on uptake will be permanent and remain at the same level (which may not be true if circumstances such as the cost-of-living change markedly in the future).

7.3. Benefit B2 – health benefits

7.3.1. Quantifying health benefits – brief explanation of concepts

100. HRT is a treatment recommended by NICE and is proven to be effective in managing menopause symptoms such as hot flushes, mood swings or brain fog. It can also have wider health benefits, such as reducing the risk of developing heart disease, osteoporosis, diabetes, depression, and dementia.

101. The standard approach to quantify health benefits is to use Quality-Adjusted Life Years (QALYs). A QALY is two-dimensional, combining the effects on both the quality of life and longevity of a particular treatment or intervention[5].

102. Furthermore, it is also possible to assess the economic value of a health intervention compared to an alternative by using the incremental cost-effectiveness ratio (ICER). The ICER is a summary measure calculated by dividing the difference in total costs by the difference in the health outcome of effect, and thus it gives the extra cost per extra unit of health effect[6].

7.3.2. NICE menopause guidance

103. The health benefits associated with HRT usage are drawn from NICE's full guidance on menopause. The National Institute for Health and Care Excellence (NICE) clinical guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS. They use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions. The full guidance on menopause[7] was published in 2015, with a revised version being expected in early 2024. As part of this guidance, NICE include a review of published health economic literature, as well as their own health economic modelling. A summary of NICE's literature review, as well as details on their cost-effectiveness analysis for HRT are included in Annex B.

104. The results from NICE's analysis suggest that, for women with a uterus, the non-oral oestradiol and progestogen treatment has the highest level of QALY gain, while also having an ICER falling within the willingness to pay threshold (£20,000-£30,000 per QALY). For women without a uterus, non-oral oestradiol has the highest level of QALY gain and it is also the most cost-effective treatment.

7.3.3. QALY value used for the current cost-benefit analysis

105. Using the results provided by NICE, the starting point for quantifying the health benefits is the mean QALY figure associated with non-oral oestradiol and progestogen, 0.1856 for a period of treatment of 5 years, compared to having no treatment.

106. Given that a potential reason for women not trying HRT is not having severe symptoms, it may be that new patients with less severe symptoms that start taking HRT gain fewer health benefits than those patients who have already started. Therefore, the QALY gain would be smaller. Additionally, if a patient is already taking an alternative treatment and switches to HRT after the policy is introduced, the marginal QALY gain may be lower.

107. As such, for the purpose of this analysis, for the best-estimate scenario, only half of the NICE mean QALY gain per patient will be considered. The full QALY gain is

[5] Quality-Adjusted Life Year (QALY) - YHEC - York Health Economics Consortium

[6] Incremental Cost-Effectiveness Ratio (ICER) - YHEC - York Health Economics Consortium

[7] Overview | Menopause: diagnosis and management | Guidance | NICE

incorporated in the high-end scenario, while a third of the QALY gain value is used for the low-end one.

108. Therefore, for the central best estimate, the yearly mean QALY gained from taking HRT per patient is calculated as:

$$QALY\ gain\ per\ patient = \frac{0.1856}{5} \times 0.5 = 0.01856 \text{ per year}$$

109. The assumption is that this QALY gain is observed starting from the year the policy is introduced and remains constant across the 10-year period of the analysis.

110. The effect of changes in the value of the QALY gain is explored in the sensitivity analysis section.

7.3.4. Total QALY gain per year and monetary impact

111. In practice, health gains will be attributable to both new patients starting HRT and existing patients that may take HRT for longer due to the price reduction. Existing research on the health benefits of HRT mostly focus on women starting their treatment. As such, it is not possible to use two different values of the QALY gain for these two types of patients.

112. Additionally, literature on the price elasticity of demand usually gives the sensitivity of demand to changes in prices in terms of a volume of quantity response (for this policy, this would mean the increase in the number of dispensed HRT items). This further implies that it would be difficult to identify whether the quantity increases as a result of new patients starting HRT or existing patients consuming more.

113. As explained above, for the purpose of the current analysis, it is assumed that any increase in volume would translate into an equivalent increase in patient numbers. Therefore, to calculate the overall QALY gain, the number of new HRT patients will be multiplied by the QALY gain per patient. However, this is for mathematical convenience only, and it does not necessarily imply that it is only new patients that will see a health benefit.

$$QALY\ gain\ per\ year = New\ HRT\ patients \times QALY\ gain = 100{,}000 \times 0.01856 = 1{,}791$$

114. The monetary value of a QALY is currently set at £70,000, thus the monetised total health benefits are given by:

$$Health\ Benefits = QALY\ gain \times £70{,}000 = £125{,}390{,}000$$

7.4. Benefit B3 – reduction in sickness absence cost

115. Due to the many symptoms of the menopause, women's work activity and performance can be negatively impacted. Anecdotal evidence suggests that some women struggling with menopausal symptoms need to take leave, are less likely to go for a promotion or would consider leaving their roles before retirement[8]. One survey[9] suggests that 26% of women who had been employed at some time during the menopause had taken time off

[8] Challenging current policy in Parliament - Menopause APPG (menopause-appg.co.uk)

[9] Download.ashx (fawcettsociety.org.uk)

due to symptoms, with a fifth of women taking a month or more off over the whole of their menopause. Another[10] suggests that 59% of the respondents had taken time off due to symptoms, with 18% being absent for more than 8 weeks.

116. In 2017, the Government published a research paper on the effects of menopause transition on women's economic participation[11]. The paper represents an evidence review, covering 104 publications. The vast majority of these publications suggest a negative relationship between menopause transition and work. Negative impacts of symptoms on economic participation identified in the evidence base include lower productivity, reduced job satisfaction and problems with time management. The review quotes a total absence-related cost for the UK of approximately £7.3m per year. This is based on the results of a US study (Kleinman et al., 2013), where the additional cost of sickness absence for women who have menopause transition symptoms (compared to women who do not have severe symptoms) is estimated at $48 per women, the equivalent of £35.50 per woman (in 2010 prices).

117. To calculate this cost in 2022/23 price terms, the OBR's Average Earnings Index[12] has been used as follows:

$$\begin{aligned} &Sickness\ absence\ cost\ per\ woman_{2022/23} \\ &\quad = Sickness\ absence\ cost_{2010/11} \times \frac{Average\ Earnings\ Index_{2022/23}}{Average\ Earning\ Index_{2010/22}} \\ &\quad = £35.50 \times \frac{138.90}{100.89} = £48.87 \end{aligned}$$

118. Given they start using HRT, we can assume that symptoms severity will diminish for new HRT patients. Therefore, the sickness absence cost that can be recouped is:

$$\begin{aligned} Recouped\ Sickness\ Absence\ Cost &= New\ HRT\ patients \times Sickness\ Absence\ Cost\ per\ woman \\ &= £4{,}720{,}000\ per\ year \end{aligned}$$

119. Nevertheless, a range of caveats apply. Firstly, the experience of menopause transition at work for women in the US may be different than for women in the UK. Secondly, Kleinman et al. (2013) rely on the assumption that the treatment and control groups do not differ in terms of other underlying health conditions. Thirdly, the use of HRT is not explicitly mentioned or accounted for (it is not clear whether the treatment or control group take HRT and whether this has an impact on their symptoms). Then, the study's results are based on estimates for a non-representative sample of the US female labour force – women in employment having health insurance. Women in lower-skilled and potentially more physically demand roles may struggle more due to symptoms, and thus are likely take more leave, although this would be valued at a lower wage rate. Lastly, the assumptions that the cost per woman remains constant over the 10-year period of the analysis and that all new patients are employed may not hold.

120. As such, the above value for the recouped sickness absence cost could be an overestimate. Lower values are explored in the sensitivity analysis.

[10] balance - Menopause symptoms are killing women's careers, major survey reveals

[11] Menopause transition: effects on women's economic participation - GOV.UK (www.gov.uk)

[12] Economic and fiscal outlook - November 2022 - Office for Budget Responsibility (obr.uk) – Supplementary Economy Tables, Table 1.6

7.5. Benefit B4 – monetised QALYs gained from extra NHS revenue

121. All patients who start taking HRT as a result of the HRT PPC introduction are assumed to buy a PPC at the cost of £18.70. Therefore, the increase in NHS revenue each year will be:

$$Extra\ NHS\ Revenue\ =\ New\ patients \times HRT\ PPC\ price\ =\ 100{,}000 \times £18.70\ =\ £1{,}800{,}000$$

122. It is estimated that it costs the NHS £15,000 to deliver one full QALY valued at £70,000. Therefore, the monetised QALYs gained from this extra revenue from prescription charges can be calculated as follows:

$$Monetised\ QALYs\ gained\ from\ extra\ NHS\ revenue\ =\ Extra\ NHS\ revenue \times \frac{£70{,}000}{£15{,}000} =$$
$$=\ £8{,}420{,}000\ per\ year$$

7.6. Unquantified and unmonetised benefits

7.6.1. Benefit B5 – Savings for patients on unsuitable treatments

123. Some patients suffering from menopause symptoms may currently take a treatment that is not clinically suitable for them, such as antidepressants. If their clinician advises a change in treatment to HRT, then a reduction in price may encourage them to take up the HRT treatment so that they will no longer purchase the alternative forms of treatment, and thus, longer term could make a saving.

7.6.2. Benefit B6 – Decrease in other labour market costs

124. Experiencing menopause symptoms can have a range of negative impacts on women's economic participation. There is no sufficient evidence base to help quantify and monetise this beyond the sickness absence calculation in B3. However, a list of potential costs that could be alleviated by decreasing the price of HRT and thus incentivising uptake is as follows[13] :
    a) decreases in household income or costs borne by family members having to earn more income
    b) family members coping with mid-life women's symptoms at home and/ or supporting them concerning workplace challenges during transition
    c) symptom-related lateness to work
    d) lost productivity due to medical appointments during working hours
    e) women who reduce their working hours due to symptoms
    f) losing out on promotion opportunities

7.7. Cost C1 – Financial cost to new patients

125. As mentioned above, it is assumed that all new patients will purchase an HRT PPC at the cost of £18.70. Therefore:

[13] Menopause transition: effects on women's economic participation - GOV.UK (www.gov.uk)

$$Cost\ to\ New\ patients\ =\ New\ patients \times HRT\ PPC\ price\ =\ 100{,}000 \times £18.70$$
$$=\ £1{,}800{,}000\ per\ year$$

126. This is a maximum cost because in practice some increased demand may come from existing patients increasing their usage in the short term, who would already have been accounted for in estimating the need to buy HRT PPCs. However, that possibility is limited by clinical constraints on appropriate prescribing and is not expected to be a large proportion of the total.

7.8. Cost C2 – Opportunity cost

7.8.1. Lost revenue to the NHS in prescription charges

127. The total amount of savings that existing patients make translates into a loss in the NHS prescription charges revenue.

$$Lost\ revenue\ to\ the\ NHS\ in\ prescription\ charges\ =\ Savings\ for\ existing\ patients =$$
$$=\ £9{,}000{,}000\ per\ year$$

7.8.2. Cost to the NHS for providing extra HRT healthcare

128. The increase in uptake implies that the NHS will potentially have to spend more on HRT medicines. To estimate this additional cost, we use NHS BSA data on the Net Ingredient Cost for HRT items. This is the basic price of a drug, i.e. the price listed in Part II, Clause 8 of the Drug Tariff[14].

129. NHS BSA data for 2021/22 gives an average net ingredient cost for all HRT items dispensed of £101,581,135. Given that there are 1,700,000 existing HRT patients in 2021/22, the average net ingredient cost per patient is estimated at £60 per year. Therefore,

$$Cost\ to\ the\ NHS\ for\ providing\ extra\ HRT\ care\ each\ year =$$
$$=\ Average\ net\ ingredient\ cost\ per\ patient \times New\ patients\ =\ £5{,}790{,}000$$

130. This cost remains uncertain, subject to negotiation, and may change over the coming years. For analytical purposes, we have assumed the current level of NHS spending per patient is maintained.

7.8.3. Delivery and operating costs to the NHS Business Service Authority (BSA)

131. NHS BSA estimated their own delivery and operating costs, which are summarised in the table below. Operating costs were only provided up to 2027/28. For the remaining 5 years it was assumed these stay constant. To note, in 2022/23 NHS BSA already incurred delivery and operating costs totalling £1,269,000. These represent sunk costs[15] and are thus excluded from the cost-benefit analysis.

Table 12. Delivery and operating costs for NHS BSA

	2023/24	2024/25	2025/26	2026/27	2027/28
Delivery cost	-£112,000	-	-	-	-

[14] More information about cost can be found here: Prescription Cost Analysis – England – 2021/22 | NHSBSA

[15] Sunk costs are costs that have already been incurred, cannot be recouped, and thus should not contribute to the decision making.

Operating cost	-£2,064,000	-£902,000	-£1,003,000	-£1,070,000	-£1,070,000

	2028/29	**2029/30**	**2030/31**	**2031/32**	**2032/33**
Delivery cost	-	-	-	-	-
Operating cost	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000

132. Any appraisal carries a risk of optimism bias, where either the costs or benefits are viewed in an overly optimistic way. The HM Treasury's Green Book provides detailed guidance here. To account for the fact that NHS BSA may incur higher than anticipated delivery and operating costs, a 25% increase is applied each year. The final NHS BSA costs contributing to the opportunity cost are presented in the table below.

Table 13. Adjusted delivery and operating costs for NHS BSA

	2023/24	**2024/25**	**2025/26**	**2026/27**	**2027/28**
Adjusted NHS BSA costs	-£2,720,000	-£1,127,500	-£1,253,750	-£1,337,500	-£1,337,500

	2028/29	**2029/30**	**2030/31**	**2031/32**	**2032/33**
Adjusted NHS BSA costs	-£1,337,500	-£1,337,500	-£1,337,500	-£1,337,500	-£1,337,500

7.8.4. Calculating the opportunity cost

133. All the costs described above represent income that the NHS could use to generate additional QALYs. Given that it costs the NHS £15,000 to deliver one full QALY, which is then valued at £70,000, the opportunity cost of this policy is:

$$Opportunity\ cost = (Lost\ NHS\ revenue\ in\ prescription\ charges\ + Delivery\ and\ Operating\ costs\ for\ NHS\ BSA\ + Cost\ to\ the\ NHS\ in\ providing\ extra\ HRT\ healthcare) \times \frac{£70{,}000}{£15{,}000} = = £81{,}720{,}000 \text{ per year}$$

7.9. Cost C5 – Costs for pharmacists

134. Pharmacists are the main front-line providers of prescriptions and will help administer the new HRT PPC. Specifically, they will need to:
    a) Familiarise themselves with the new scheme and any associated system changes;
    b) Sell HRT PPCs to patients (if authorised to do so, and if the patient doesn't buy remotely by telephone or online);
    c) Check the validity of HRT PPC-funded prescriptions as they are issued; and
    d) Answer any queries from patients.

135. Currently 36% (2.5m) HRT prescriptions are "mixed" with non-HRT items. Only 7.7% (197k) of these mixed prescriptions attract charges, and of those not all patients will choose to buy an HRT PPC initially.

136. The new system will be supported by a range of IT arrangements. We have estimated the running costs to pharmacists to be in the region of £2,260,000 per year. In practice, the necessary IT systems may not be fully in place by April 2023, therefore, in the short-term, pharmacists may need to carry out some activities manually. The potential burdens for pharmacists are explained below:

a) Until new systems are fully embedded, problems may arise if a mix of HRT and non-HRT items are included on the same prescription form. Recording a single chargeable status may not be possible, requiring prescriptions to be reissued on separate forms with additional admin time for both pharmacists and GPs. Alternately patients may require one of the items urgently (HRT or non-HRT) from the mixed prescription. This would require a discussion with the patient and possibly advice from the pharmacist about whether the patient should choose to have the HRT or non-HRT items dispensed. The non-dispensed items would then need to be struck through on the prescription form as not dispensed. Assuming there are 197,000 mixed prescriptions for HRT each year that would attract prescription charges and that it takes 5 minutes of a pharmacists' time to contact the GP, this could add up to 16,500 hours to pharmacies' work at a cost of up to £387,000 per year (given an hourly pay of £23.56). GPs' time would be additional to that, but in practice this is expected to be a temporary issue that will diminish rapidly once all are familiar with the new system and clear guidance will be issued to GPs asking them to write separate prescriptions. We include costs of £387,000 as a worst-case scenario, but the true costs should be much lower even with GP time added on.
b) They will need to manually check the HRT PPC as Real Time Exemption Checking (RTEC) will not be able to check HRT PPC eligibility. RTEC saves 2 minutes per prescription[16]. There will be 300,000 existing patients and a further c.100,000 new patients benefiting from the HRT PPC. Assuming each gets 4 prescriptions per year, this equates to 1.6 million prescriptions. Therefore, 53,000 hours would be added to pharmacies' work at a cost of up to £1.25m per year.
c) They will need to manually check whether the HRT prescribed is on the list of eligible HRT medicines in the Drug Tariff as this will not be integrated in IT systems. Assuming this takes 1 minute for each of the 1.6 million prescriptions, this would add 2,600 hours to pharmacies' work at a cost of up to £623,000 per year.

137. Following the same approach as with the NHS BSA delivery and operating costs, a 25% increase in the costs to pharmacists is applied to account for any optimism in the initial cost estimates. Therefore, the cumulative burden on pharmacists used in the best-estimate scenario is valued at up £2,820,000 per year. The development of IT systems, and thus the burden on pharmacists will be monitored and is expected to reduce these costs once fully embedded.

7.10. Unquantified and unmonetised costs (C6)

138. In addition to the costs quantified and monetised above, pharmacists will also incur a one-off policy familiarisation cost, and spend a number of minutes on issuing the HRT PPCs.

139. One-off policy familiarisation costs will also be incurred by patients and GPs.

140. These costs are not monetised due to a lack of reliable estimates, but they are not expected to significantly increase the value calculated above.

[16] National expansion of Real Time Exemption Checking service for prescriptions | NHSBSA

141. For indicative purposes, in 2021 there were c.11,000 pharmacies, employing c.27,000 pharmacists, together with other staff. Not all of them are licensed to issue PPCs, however all of them will need to familiarise themselves with the rules, so that they can support patients appropriately. The average hourly wage for a pharmacist is £23.56, meaning that, indicatively, 10 minutes of familiarisation time would cost £4 per pharmacist (less for more junior staff).

7.11. Calculating the social net present value

142. Following the Green Book appraisal approach, health-related costs and benefits are discounted at 1.5%, while non-health related costs and benefits are discounted at 3.5%.

143. The standard Green Book recommendation for the timeline of such analysis is 10 years, which is appropriate in this case. Based on the calculations explained above, the sum of the discounted benefits over 10 years is approx. £1.3bn, while the sum of the discounted costs over 10 years is approx. £0.7bn. This gives a net present value of approx. £0.6bn.

144. The tables below provide step-by-step calculations for the best-estimate, higher-end and lower-end end scenarios respectively. Calculations may not add up due to rounding.

Table 14. Social Cost-Benefit Analysis for Option 2 – Best-Estimate

Year	1	2	3	4	5	6	7	8	9	10
	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	2031/32	2032/33
PATIENT NUMBERS										
Existing number of HRT Patients	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000
Existing patients making savings (18%)	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000
New Patients due to price reduction (change in demand = 5.7%)	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000
BENEFITS										
B1) Savings Benefits for Existing Patients (£30 per patient)	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000
QALYs due to HRT uptake (0.01856 per new patient)	1,791	1,791	1,791	1,791	1,791	1,791	1,791	1,791	1,791	1,791
B2) Monetised QALYs gained (£70,000 per QALY)	£125,390,000	£125,390,000	£125,390,000	£125,390,000	£125,390,000	£125,390,000	£125,390,000	£125,390,000	£125,390,000	£125,390,000
B3) Recouped sickness absence cost (£48.87 per patient)	£4,720,000	£4,720,000	£4,720,000	£4,720,000	£4,720,000	£4,720,000	£4,720,000	£4,720,000	£4,720,000	£4,720,000
NHS revenue gained from new patients (£18.70 per HRT PPC)	£1,800,000	£1,800,000	£1,800,000	£1,800,000	£1,800,000	£1,800,000	£1,800,000	£1,800,000	£1,800,000	£1,800,000
B4) Monetised QALYs gained from extra NHS revenue	£8,420,000	£8,420,000	£8,420,000	£8,420,000	£8,420,000	£8,420,000	£8,420,000	£8,420,000	£8,420,000	£8,420,000
Total Monetised Health Related Benefits (B2+B4)	£133,820,000	£133,820,000	£133,820,000	£133,820,000	£133,820,000	£133,820,000	£133,820,000	£133,820,000	£133,820,000	£133,820,000
Total Monetised Non-Health Related Benefits (B1+B3)	£13,720,000	£13,720,000	£13,720,000	£13,720,000	£13,720,000	£13,720,000	£13,720,000	£13,720,000	£13,720,000	£13,720,000
TOTAL BENEFITS	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**	**£147,530,000**
COSTS										
C1) Financial cost to new patients (£18.70 per HRT PPC)	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000	-£1,800,000
Lost revenue to the NHS in prescription charges	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000
Cost to the NHS in providing extra HRT healthcare	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000	-£5,790,000
Delivery cost to NHS BSA	-£110,000									
Operating cost to NHA BSA	-£2,060,000	-£900,000	-£1,000,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000
Optimism bias adjustment (25% increase in cost to NHS BSA)	-£540,000	-£230,000	-£250,000	-£270,000	-£270,000	-£270,000	-£270,000	-£270,000	-£270,000	-£270,000
Total financial cost to the NHS	-£17,510,000	-£15,920,000	-£16,040,000	-£16,130,000	-£16,130,000	-£16,130,000	-£16,130,000	-£16,130,000	-£16,130,000	-£16,130,000
C2) Opportunity cost (the value of the QALYs forgone due to lost NHS revenue)	-£81,720,000	-£74,290,000	-£74,880,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000
Cost to pharmacists contacting GP	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000
Cost to pharmacists performing manual checks	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000	-£1,870,000
Optimism bias adjustment (25% increase in costs to pharmacists)	-£560,000	-£560,000	-£560,000	-£560,000	-£560,000	-£560,000	-£560,000	-£560,000	-£560,000	-£560,000
C3) Total Cost for Pharmacists	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000	-£2,820,000
Total Monetised Health Related Costs (C2)	-£81,720,000	-£74,290,000	-£74,880,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000	-£75,270,000
Total Monetised Non-Health Related Costs (=C1+C3)	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000	-£4,620,000
TOTAL COSTS	-£86,340,000	-£78,910,000	-£79,500,000	-£79,890,000	-£79,890,000	-£79,890,000	-£79,890,000	-£79,890,000	-£79,890,000	-£79,890,000
NET BENEFITS	£61,190,000	£68,620,000	£68,030,000	£67,640,000	£67,640,000	£67,640,000	£67,640,000	£67,640,000	£67,640,000	£67,640,000
PRESENT VALUES (in 2022/23 terms)										
Discounted Health Related Benefits (@ 1.5%)	£131,840,000	£129,890,000	£127,970,000	£126,080,000	£124,220,000	£122,380,000	£120,570,000	£118,790,000	£117,030,000	£115,300,000
Discounted Non-Health Related Benefits (@ 3.5%)	£13,250,000	£12,810,000	£12,370,000	£11,950,000	£11,550,000	£11,160,000	£10,780,000	£10,420,000	£10,060,000	£9,720,000
Discounted Health Related Costs (@ 1.5%)	-£80,510,000	-£72,110,000	-£71,600,000	-£70,910,000	-£69,870,000	-£68,830,000	-£67,820,000	-£66,810,000	-£65,830,000	-£64,850,000
Discounted Non-Health Related Costs (@ 3.5%)	-£4,470,000	-£4,320,000	-£4,170,000	-£4,030,000	-£3,890,000	-£3,760,000	-£3,630,000	-£3,510,000	-£3,390,000	-£3,280,000
Total Discounted Benefits	£145,090,000	£142,690,000	£140,340,000	£138,030,000	£135,760,000	£133,540,000	£131,350,000	£129,210,000	£127,100,000	£125,030,000
Total Discounted Costs	-£84,980,000	-£76,420,000	-£75,770,000	-£74,940,000	-£73,760,000	-£72,600,000	-£71,450,000	-£70,330,000	-£69,220,000	-£68,130,000
NET PRESENT VALUE	£60,110,000	£66,270,000	£64,570,000	£63,090,000	£62,000,000	£60,940,000	£59,900,000	£58,880,000	£57,880,000	£56,900,000
									TOTAL NPV	£610,540,000

8. Risks

145. The policy effects are logical and expected, but uncertain in terms of size. In particular there are a number of risks that could lead to costs and/or benefits differing from the expected value. In most cases, the risk is two-way (i.e. the outturn could be higher or lower than expected), but optimism bias principles would suggest that the downside risk should receive particular consideration. The following table identifies the main risks in so far as they affect the cost/benefit analysis in this impact assessment.

Table 15. Summary of risks

Name of Risk	Description of Risk	Mitigation within the IA analysis
Patients do not achieve the expected cost savings even where available	The reform relies on people being aware of the new HRT PPC becoming available. It has attracted a lot of publicity but inevitably some patients may not take advantage, even if it would save them money.	Sensitivity analysis explores the effects of a lower number of patients benefiting from the reform (for whatever reason).
New patients are not incentivised to take up HRT	Cost is only one driver of behaviour out of many. Further, although the reform reduces costs, patients who do not currently use HRT could end up incurring costs for the first time. This may mean that the elasticity effects are optimistic.	Sensitivity analysis explores differing elasticity values.
Supply constraints	The IA assumes that the market will adapt to supply all patients with the HRT products they need (and indeed in the longer term that is reasonable). In the short-term any shortages might delay or limit the achievement of benefits.	Not analysed specifically, but the timing of benefit delivery could potentially be delayed.
Health effects	Evidence is strong for HRT to improve health for most women. However, those for whom the benefits are greatest (i.e. have the worst symptoms) may be less likely to be deterred by prescription costs. Hence the health gains for those who actually respond to the intervention may be lower than average.	Sensitivity analysis explores a range of values for the average health gain per patient.
Increased running costs	Outturn may be higher or lower than expected, not least because there is uncertainty over the number of HRT PPCs that will actually be issued. Such costs may affect both NHSBSA and pharmacists.	Costs are not significant and hence not material to the decision, but sensitivity analysis explores higher values
Increased implementation costs	Similar to running costs. System changes may not be fully operational until after the April 2023 launch, with interim measures potentially being required.	Costs are not significant and hence not material to the decision, but sensitivity analysis explores higher values

8.1. Effects of inflation

146. UK CPI inflation is currently 9.2% (ONS, year to December 2022)[1]. This is projected to return to the Bank of England target rate of 2% by 2024[2]. A combination of domestic and global macroeconomic factors creates uncertainty around the headline rate, with further uncertainty over how inflation will impact the NHS and the HRT PPC specifically.
    a) Growth in average earnings is currently below inflation and this has contributed to calls for lower costs for HRT to help with the cost of living.
    b) Prescription charges tend to increase in line with inflation (although they were frozen in 2022-23). The HRT PPC will be set at twice the standard single charge and so increase in tandem.
    c) Administrative costs (both within the NHS and for pharmacies) will tend to increase with wage or price inflation over time.
    d) The purchase cost of HRT medicines will tend to increase over time but may be heavily influenced by patents and by contractual agreements and NHS/industry pricing schemes.

8.1.1. Inflation effect on prescription charges and consequent patient behaviour

147. The status quo option (option 1) implicitly assumes that prescription charges will increase over time. Linking the cost of the HRT PPC to the standard single prescription charge means that the relative saving of switching from single charges to an HRT PPC will be maintained in real terms.

148. The attraction of that saving depends on wider cost of living pressures, such that if real incomes fall, the savings may become more attractive. Patients considering HRT for the first time would still have to pay more than they would if they avoided treatment altogether but will gain the most health.

149. To reflect these circumstances, the IA considers sensitivity analysis around the effects of price elasticity, and thus the number of patients likely to start treatment. This does not model a change in inflation directly, but instead recognises that inflation might affect uptake and therefore can be analysed indirectly.

8.1.2. Inflation effect on costs (and cost-related benefits)

150. Administrative costs are a combination of staff time (which might rise in line with average earnings) and equipment/overheads which might be more closely linked to CPI inflation. The IA assumes costs in future will remain at approximately their current real terms level. Sensitivity analysis then explores the effect of higher or lower rises in these costs.

151. The purchase cost of medicines is subject to contractual agreements and although known perfectly at the start, becomes more uncertain over time. Again, sensitivity analysis is used to explore the effect of changes in these costs.

8.1.3. Inflation effect on health

152. The value of a QALY is reviewed periodically and will take account of wider inflation and willingness to pay considerations at each review. The current value of £70,000 is

[1] Inflation and price indices - Office for National Statistics (ons.gov.uk) The Bank of England provided further commentary on 2-Feb-23: https://www.bankofengland.co.uk/monetary-policy-report/2023/february-2023

[2] Inflation - Office for Budget Responsibility (obr.uk)

assumed to hold true throughout the ten-year appraisal period, apart from normal discounting, in line with standard IA practice.

9. Sensitivity analysis

153. Any appraisal carries uncertainty and with it a risk of optimism bias, where either the costs or benefits are viewed in an overly optimistic way. The HM Treasury's Green Book provides detailed guidance: https://www.gov.uk/government/publications/green-book-supplementary-guidance-optimism-bias:

154. In the case of the HRT PPC, the two most significant parameters are the health gain per person and the elasticity of demand (uptake effect). The evidence for precise quantification of these is tentative, and that uncertainty is considered explicitly in the main high, medium and low scenarios. Although at face value the evidence points to higher values for both parameters, these values are only used in the upper scenario. More conservative assumptions are made for both central and lower cases.

155. Less influential variables, such as administrative operating costs, are assessed through sensitivity analysis alongside the main scenarios. This is a proportionate approach which avoids undue complexity. The effect of any individual parameter is shown in the main sensitivity analysis table below.

156. The sensitivity analysis does not reflect every factor that might affect the NPV, not least because some factors are subjective and unquantified. Examples include some patients being unwilling or unable to use HRT PPCs even if they could save money, some pharmacies not being registered to issue PPCs and thus hindering some patients' possibility to purchase an HRT PPC, or supply issues hampering access to HRT products themselves. These are unlikely to make a huge difference to the NPV, but should be borne in mind.

157. The analysis also explores the extent to which the key inputs of the cost-benefit analysis can vary in order for the policy to still retain a positive NPV>0.

Table 16. Impact of varying individual inputs

Rationale and uncertainties	Range of values*	Total NPV	% change in NPV
Price elasticity of demand			
The PED drives the value of the increase in uptake that the policy will generate. Not only this influences the cost to new patients and the revenue loss for the NHS, but it also stands at the basis of calculating the total health gained, which is one of the largest components in the cost-benefit analysis. The current value of the PED is based on a literature review, however no paper included specifically analysed the consumption of HRT or the specific population that would use this type of treatment. Moreover, studies focused on the UK are relatively outdated.	**-0.15***	**£610,540,000**	
	-0.20	£945,320,000	55%
	-0.10	£275,760,000	-55%
	-0.06	£0	-100%
QALY gain per patient			
The monetised health gains for patients, as well as the opportunity cost to the NHS are the two largest components of the cost-benefits analysis. If a large number of women will start using HRT as a result of the policy do not, in fact, struggle with severe symptoms, it may be the case the QALY gain per patient is much lower.	**0.01856***	**£610,540,000**	
	0.03712	£1,766,940,000	189%
	0.01237	£225,080,000	-63%
	0.00876	£0	-100%

It is also not possible to distinguish between the QALY gain for a patient who starts using HRT from that of a patient who decides to use HRT for longer. Moreover, given that a patient would only gain a marginal benefit if they were already taking an alternative treatment and then switch to HRT, the best-estimate scenario assumes that a patient will benefit from half the QALY gain identified by NICE. A full QALY gain, as well as lower values are explored.			
Sickness absence cost per woman			
The original estimate stems from a US study. It is likely that the population analysed in the study and the population targeted by the HRT PPC policy are not as similar. Furthermore, we assume that all new patients are employed, and will stop taking sick leave as a result of taking HRT, which could inflate the overall value of this benefit. Thus, it is possible that the value used in the 10-year cost-benefit is an overestimate, and lower sickness absence costs per woman are tested.	**£48.87***	**£610,540,000**	
	£24.44	£590,930,000	-3%
	£0.00	£571,310,000	-6%
Saving amount per existing patient			
The savings amount per existing patient were estimated based on the assumption that patients are rational and always take the optimal payment option. However, this may not hold in reality, therefore different values were used in the NPV calculations.	**£30***	**£610,540,000**	
	£20	£714,700,000	17%
	£40	£506,380,000	-17%
Number of existing patients making savings			
Given that i) not all existing patients are currently choosing the optimal payment option for prescription charges, ii) the policy has already received publicity, and iii) some patients will have to wait for their current SPPC to expire before making use of an HRT PPC, it is possible that there are fewer existing patients that will make a saving as a result of the policy. The overall effect of these factors is uncertain, but we have modelled the effect of halving the number of people making savings. This is judged to be a plausible conservative case. To note, fewer exiting patients making savings will lead to an increase in the NPV, due to having a lower loss in the NHS revenue, and thus a lower opportunity cost.	**300,000***	**£610,540,000**	
	150,000	£617,890,000	1%
Delivery and operating costs to NHS BSA			
The best-estimate scenario includes an optimism bias assumption to account for the possibility that NHS BSA would encounter difficulties in delivering and operating this scheme. A 25% increase in costs was applied just for those prescriptions involving an HRT PPC. This table shows what the NPV would be without the optimism bias assumption.	Without optimism bias	£623,060,000	
	With optimism bias*	**£610,540,000**	-2%
Cost to pharmacists			
Given the uncertainty around specific IT systems being in place, and the total number of patients that will use the new HRT PPC, an optimism bias assumption was employed in the best-estimate scenario. An increase of 25% in costs to pharmacists was applied, again just for those prescriptions involving an HRT PPC. This table shows what the NPV would be without the optimism bias assumption.	Without optimism bias	£615,230,000	
	With optimism bias*	**£610,540,000**	-1%
Net ingredient cost per patient			
As previously mentioned, the purchasing costs of HRT medicines are subject to negotiations and contractual agreements. However, to test the sensitivity of the NPV to this input, an indicative increase of 25% was applied to the net ingredient cost per patient.	**£60***	**£610,540,000**	
	£75	£548,240,000	-10%
Speed of impact			
In the original 10-year analysis, it is assumed that uptake fully increases in the first year of the implementation of the policy	**as per Table 14***	£610,540,000	

and that patient benefit from the full QALY gain from the year they start using HRT. To account for the possibility of there being a delay both in terms of uptake and in terms of acquiring the QALY gain, the following have been explored: • Assume the demand increase is only half in the first year and at the full extent from the second year onwards • Assume that in any year t, patients get half of the QALY gain in year t, and half in the following year, year t+1	1 year delay	£495,490,000	-19%
* *Starred values are the ones used in the best-estimate scenario 10-year analysis, as shown in Table 14*			

158. The results presented above show that, when tested in isolation, the NPV remains positive even when using more extreme values of the key inputs. Although it is important to acknowledge uncertainties with regards to all parameters, the analysis shows that the NPV is most sensitive with regards to the values of the PED and the QALY gain per patient. The break-even values for the PED and QALY gain per patient respectively suggest that there would have to be barely any increase in uptake and barely any health gain in order for the NPV to be zero. Neither of these two separate scenarios are plausible.

159. It is possible that both the PED and the QALY gain per patient used in the best-estimate scenario are over/underestimated. To account for this, a range of combinations were tested, which are then used as the low-end and high-end NPV scenarios. The main differences in inputs between the three scenarios, as well as their associated NPV are presented in the table below. As above, these scenarios show that the NPV is highly sensitive to changes in the PED and the QALY gain per patient. Nevertheless, the NPV remains positive even when using more pessimistic values of these two parameters.

160. Detailed calculations for the social cost-benefit analysis for the low-end and high-end scenarios are included in Annex C and D respectively.

Table 17. NPV scenarios

	Low	Best-estimate	High
PED	-0.1	-0.15	-0.2
% change in demand	3.80%	5.70%	7.60%
New patients	60,000	100,000	130,000
QALY gain	0.01237 *a third*	0.01856 *half*	0.03712 *full*
Optimism bias adjustment	25%	25%	25%
10-year NPV	£18,790,000	£610,540,000	£2,487,180,000

10. Direct and indirect costs and benefits to business calculations

161. The main business impacts of the policy are:
    a) One-off familiarisation costs for businesses (pharmacies) involved in issuing HRT PPCs and/or dispensing prescriptions;
    b) Ongoing changes in administrative costs for the same firms;
    c) Increased demand for HRT products – affecting those involved in the supply chain; and
    d) Reduced staffing costs for all businesses, associated with the health gains and reduced staff absence arising from better menopause healthcare.

162. All these impacts are a direct result of the intervention, although it is true that the last two may also be affected by wider factors affecting HRT demand.

163. One indirect benefit for business arises from patients spending the money saved on other products and services (not necessarily health-related). This utility benefit to patients - and revenue benefit for businesses - is not quantified but may be significant at an aggregate level.

164. Other indirect costs and benefits to business are not expected to be significant, but could arise if, for example, the policy exacerbated shortages of certain medicines or if a switch to HRT led to a fall in demand for other products (such as anti-depressants).

165. In all cases, the business impacts are out-of-scope of the Business Impact Target, the main measure of administrative burden. This is because the reform relates to the tariff charged for medical services, and taxes, tariffs and levies are exempted from inclusion in the measure.

11. Impact on small and micro businesses

166. This policy predominantly affects pharmacies who will need to sell PPCs to patients, answer queries and process prescriptions. Much of this already takes place, and the effect of the change is expected to be relatively small. Small businesses are not being treated any differently from larger ones and that is appropriate given the nature of the reform. It would not make sense to exempt smaller firms in some way because that would distort demand for prescriptions and potentially lead to a shift of business away from smaller to larger firms. Equally, there is little need or opportunity to vary the requirements or the level of support to suit small firms specifically.

167. The main impact for small businesses will be some familiarisation time when the policy first takes effect, and potentially extended service times as patients ask queries and seek guidance. Longer term processing of prescriptions is not expected to change significantly from the status quo.

168. The only small or micro businesses (SMBs) who are expected to be impacted are independent pharmacies and possibly GPs. In the initial phase of implementing the HRT PPC it will require pharmacies to manually check whether patients have purchased an HRT PPC and whether the product they wish to purchase is on the list of applicable products. This may require additional staff training and may reduce the efficiency of these purchases.

169. This system will be adopted to allow for a quicker implementation of the HRT PPC, despite the increased administrative burden in the short term. After this initial phase, prescribing systems are expected to be updated to facilitate automated checks for HRT PPCs and applicable HRT products, eliminating this inefficiency. Impacts on these SMBs are expected to be marginal after this point.

170. Guidance will be made available throughout, explaining the new rules and prices.

171. As mentioned above, in 2021 there were c.11,000 pharmacies, employing c.27,000 pharmacists, together with other staff. Not all of them are licensed to issue PPCs, however all of them will need to familiarise themselves with the rules, so that they can support patients appropriately. The average hourly wage for a pharmacist is £23.56,

meaning that, indicatively, 10 minutes of familiarisation time would cost £4 per pharmacist (less for more junior staff).

12. Exemption from Regulatory Policy Committee (RPC) assessment

172. Most reforms with significant effects on business benefit from RPC scrutiny of the proposals, to help ensure that any regulation is justified, any costs to business are minimised, and in particular that small and micro businesses are not disadvantaged. However, some reforms are exempt.

173. There is a statutory exemption related to reforms which set tariffs and taxes for government services. Prescription charges fall within this exemption.

174. To a lesser extent, the reform also falls within a further exemption for reforms affecting procurements, because the HRT PPC proposal has implications for future demand (i.e. the need to procure) HRT medication. But the tariff-setting exemption alone excludes this IA from the RPC process.

175. Nevertheless, the IA continues to set out the main business impacts together with the available evidence and quantification where possible.

13. Wider impacts

176. All women, with the exception of those who have undergone certain medical treatments, will be affected by menopause at some point in their life; irrespective of socio-economic factors or other protected characteristics. Prescription exemptions already exist for those on low-income levels. The suggested intervention will further reduce the cost of treatment for all patients not currently exempt.

177. Under the BAU, those not exempt are charged the same for prescriptions regardless of income levels. The proposed intervention would reduce the cost for all non-exempt patients by the same amount. However, the law of diminishing returns would indicate that on a lower income would derive a greater benefit from these additional savings[3].

178. Due to the expected increased demand for HRT products, we expect the aggregate impact on business to be positive and therefore have either a negligible and or positive impact on innovation. As higher sales are more likely to increase profits and incentivise innovation.

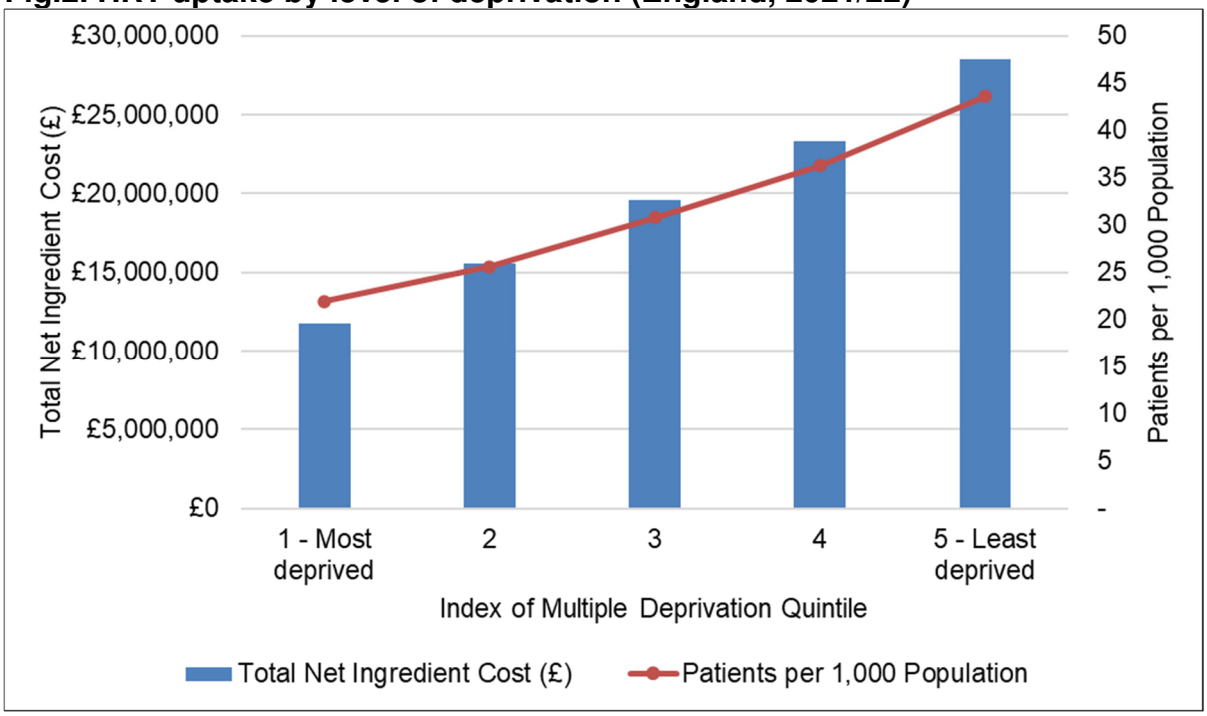
179. The environmental and competition impacts have not been extensively explored. These impacts are expected to be marginal.

13.1. Demographics and distributional impacts

180. Uptake of HRT increases in line with affluence as shown by the line in the graph below. People going through the menopause are twice as likely to take HRT if they are in the least deprived quintile than if they are in the most deprived. There are many reasons for this, including differences in culture, attitudes, awareness and levels of interaction with health services.

[3] Those on a lower income level will value an additional pound of saving more than those on a higher income

Fig.2. HRT uptake by level of deprivation (England, 2021/22)



181. The cost of HRT is also a factor, but the effect is more subtle. Those on very low incomes and in receipt of benefits qualify for free prescriptions within the current system – so the poorest will only benefit from the HRT PPC if their income rises. However, those with variable sources of income, inconsistent employment or seasonal income, would benefit from lower costs in the long run. We assume more affluent patients are more likely to be using HRT already and thus to benefit from savings, but they are also less likely to change their behaviour in response to those savings.

182. The result is twofold:
    a) financial savings among existing patients will be greater amongst the more affluent, because they are more likely to be using HRT (and paying for it); but
    b) increases in HRT uptake, and by extension the greatest health gains, are likely to come from people for whom money is an issue, but who are outside the most deprived groups.

183. We expect a positive narrowing of health inequalities because the health gains will disproportionately affect people on lower incomes, and by value they far exceed the financial savings made by the better off. It is true that the very poorest will not benefit financially because they already qualify for free medication. This reinforces the importance of other interventions (such as education) being used alongside costs to overcome as many barriers to uptake as possible.

184. Wider social benefits may be greater for those in (or seeking) employment, for those with caring responsibilities, and for those with less family and friend support. It is not possible to assess these effects in detail, but the basic message is that the greater the adverse impacts of menopausal symptoms, the greater the benefits for those taking HRT.

185. An equality impact assessment is being published separately and provides fuller detail on those characteristics protected in law. Obviously, age and gender are the primary characteristics determining who experiences the menopause, but anyone may be impacted indirectly.

14. Monitoring and evaluation

14.1. Overview

186. How an intervention produces its desired outcomes depends on:
    a) the inputs or resources required to develop, implement and operate the intervention;
    b) the successful delivery of outputs (short-term and enabling effects);
    c) the delivery of outcomes (long-term and eventual effects);
    d) the wider context, including relationships between this intervention (HRT PPC) and other factors affecting HRT use.

187. These factors may also produce unwanted side effects, and those effects may be expected or unexpected, short-term or long-term.

188. Evaluation and monitoring provide a systematic assessment of an intervention's design, implementation and outcomes. In this particular case, these components are summarised in the table below. Throughout, the HRT PPC should be seen within the wider context of improvements in women's menopausal health being delivered through a number of complementary interventions over time.

Table 19: Monitoring and evaluation summary

Category	Description	Measurement
Inputs & resources	• NHSBSA investment to build the HRT PPC system • Rollout of that system to pharmacies • Training and familiarisation for all users • Operating costs form NHSBSA • Operating costs for pharmacies • Education / publicity and support to explain and engage the public with the new rules.	• One-off financial investment and operating costs have been estimated by NHSBSA. Management data will be collected and will allow some tracking, supported if needed by additional qualitative assessment of opportunity costs and wider impacts. • The experience of pharmacists is expected to be tracked relatively easily, but informally, through existing feedback mechanisms and industry engagement. • Public awareness could be tracked through bespoke engagement or survey-type work, or indirectly by proxy through the numbers of HRT PPCs being used. The need for a bespoke survey will be determined based on the emerging statistics and feedback.
Outputs	• HRT PPC available for purchase through all expected channels (phone, online, face-to-face) • Patients buying them.	• Routine monitoring of sales and use will be completed through statistical monitoring within the system.

	• PPC sales and issuing of prescriptions both operating without problems. • Supply of HRT remains sufficient to meet demand. • No other adverse impacts.	• Alongside anecdotal feedback this should enable any local difficulties to be identified and addressed. • HRT availability of supply is tracked centrally and regular liaison with suppliers will identify any shortages or other issues. Serious Shortage Protocols (SSPs) may be used to alleviate any short-term issues and their use will also be monitored as part of overall process evaluation.
Outcomes	• New patients coming forward to get HRT, using the new PPC. • HRT uptake rising. • (In medium to longer term) health improving and socio-economic benefits being achieved.	• NHSBSA and other NHS systems will track prescribing and dispensing behaviour, including numbers of patients, new patients and duration of treatment. • Uptake rates in terms of absolute numbers can be tracked and monitored. Percentage uptake rates are more difficult to measure because the eligible population may not be precisely known. • Uptake will also be affected by other external factors (see next row) so establishing causation robustly will be challenging. • Longer-term effects will take time to fully bed in. Anecdotal or bespoke research might be used to explore how effective additional HRT use has been in alleviating symptoms, alongside the existing evidence base for effectiveness.
Wider context & other factors	• Success does depend on patients being aware of the new charges, and reacting to them, even if they do not currently engage with health services. • Demand for HRT may rise or fall as a result of non-cost-related factors (e.g. media coverage, perceived medical benefit etc.). • The current trend is upwards, but current demand remains only about half of the past historical peak. • Even if a patient starts using HRT it may not be clear what contribution, if any, lower charges may have made to their decision.	• Activity to publicise the new charges will take place and can be monitored. • Other interventions will have their own impact analysis, and if implemented after the HRT PCC should, in principle, avoid double-counting effects. Evidence will be assessed on a joined-up basis wherever possible. • The price elasticity approach adopted for this HRT PPC appraisal should, in principle, estimate only the effect of a price change, with other things being held equal. • Uncertainty remains and is tackled in this IA primarily through sensitivity analysis. • Individual patient motivations can be explored through bespoke research, with some attempt at gauging the significance of cost in their behaviour. Independent research could be conducted to explore how motivations/behaviours/attitudes have changed, and in particular

		whether new HRT patients have reacted to the lower costs. • Some demographic information about patients (age, deprivation) is collected routinely.

189. The above summary does not identify every detail but should help set the scene for any evaluation of the reform's effect. Additional variables may be included, as necessary, to ensure a range of perspectives are considered to best evaluate the intervention.

14.2. How will the impact of the new arrangements be monitored in practice?

190. Prescription charges, including the cost of PPCs, are typically reviewed and revised annually.

191. Although the HRT PPC is being introduced for the first time, its price has been set with reference to the standard prescription charge, (two standard prescription charges) and its relative attractiveness (and hence impact) will depend on wider movements in prescription charges. As such, the monitoring and evaluation plan for the HRT PPC needs to combine with wider prescription charge monitoring as efficiently as possible. It will be led by DHSC and comprise:
    a) Short-term management monitoring of the development and implementation phase, to confirm that HRT PPCs are successfully being publicised, issued, used and reconciled.
    b) Regular collection and monitoring of HRT PPC statistics (numbers issued, total value, usage).
    c) Regular annual consideration of the HRT PPC charge rate, as part of the normal prescription charges review process.
    d) Additional review (either DHSC-led or independent) to determine whether the policy objectives have been met, within five years of implementation (this timeframe may be shortened if expedient depending on early feedback, wider events and other influences).
    e) The status of the review will be non-statutory, and the results will inform the ongoing design of the HRT PPC system and any resultant implications.

192. The following questions and answers elaborate further on the rationale supporting the proposed evaluation and monitoring plan.

14.3 What are the main external factors that will have an impact on the success of the intervention?

193. Successful implementation relies on patients taking up the HRT PPC, so the main external factor is patient behaviour. That entails people being made aware of, understanding, being willing and having the opportunity to use HRT PPCs. This will happen through a combination of general publicity, media coverage and through individual interaction when patients collect their prescriptions – assuming pharmacists are supported in becoming familiar with the new rules. The exception is those patients who are currently deterred from seeking medical help at least in part because of cost concerns and/or who do not realise that costs have fallen. They will need to be reached, particularly if they do not have any immediate need for contact with their GP.

14.4. How will you assess whether the original objectives have been met, or whether the intervention should be amended?

194. There are three objectives to be considered for the intervention, these are below alongside a brief account of how they will be assessed:

    a) The first is to reduce the cost of HRT treatment. This happens automatically once the new system is in place.
    b) Secondly, we want to improve access to treatment. This will be measured by monitoring the number of patients who receive HRT prescriptions. These data are routinely recorded within the NHS and can be analysed routinely and as part of any wider evaluation review work.
    c) The third objective is to ensure that NHS revenue is maintained at a sustainable and appropriate level. That level has been assessed as being commensurate with a charge for the HRT PPC of £18.70 and will therefore be achieved automatically once the policy is in place.

195. Given the nature of this intervention, there is a challenge in determining whether any change in uptake has been caused purely by the reduction in costs afforded by the intervention, or whether other factors are influencing uptake. For example, such other factors, including promoting HRT therapies to women and improving awareness by reducing stigma, may be more significant than the cost issue. This would be consistent with what some stakeholders and lobby groups have been saying to date (including in parliamentary debates and public statements). Assessing the relative effect of different factors will be difficult and dependent on the evidence available.

14.5. What are the current monitoring and evaluation provisions in place for the current system, and how can they maintain the appropriate flexibility?

196. Current data monitoring comprises of regular collation of patient statistics which show how many patients have paid for prescriptions and the total revenue collected. These statistics can also identify new patients who have come forward for the first time and will indicate whether such patients are coming forward in larger numbers then they normally do. They will also capture a range of demographic data to aid our understanding. The data monitored can also be expanded to include other routine monitoring data as required to ensure appropriate flexibility.

197. Some system changes may be required to record purchases of and use of the HRT PPC specifically. These changes form parts of the overall implementation and are essential to ensure its effective operation.

14.6. Will you need to collect extra data that is not already being collected to assess whether the policy has been successful?

198. The main gap, as explained above, is understanding the motivations and behaviour of patients, and changes therein. There are no plans to explore these aspects, in advance of implementation, beyond the existing evidence put forward by campaigners on behalf of the patients concerned. It follows that any review of the intervention could be enhanced, where proportionate, by additional qualitative analysis of these factors.

14.7. What circumstances / changes in the market or sector would require the policy to be reviewed sooner or later?

199. The policy is expected to take effect from April 2023 and to have an immediate effect on the prices charged to patients. Incentivising additional patients to come forward may take longer as the word spreads, patients decide to talk to their GPs, prescriptions are issued and monies paid. A further delay to seeing the full effects of the intervention may occur as patients using standard annual PPCs may need to wait for up to a year before their certificates expire and they can switch to the cheaper HRT PPC version.

200. We expect therefore that the new rules would take time to bed in, but that the main effects of the policy should start to emerge in the monitoring data after about 6 to 12 months. It would seem sensible therefore for review activity to include statistical monitoring throughout the rest of 2023. Decisions on charges from April 2024 would normally take place in or around November 2023. We do not expect to have sufficient data on the effect of the HRT PPC by November 2023 to complete an assessment then. Instead, we expect a fuller review would take place in or around November 2024 to inform charges from April 2025. More general monitoring however will take place continuously from April 2023 onwards.

201. These timeframes could be adjusted if necessary. A review could take place earlier if, for example, the emerging statistics suggested that there was a problem with the HRT PPC, or indeed if patients raised concerns. A review could be delayed if it was felt that a longer period of time would usefully provide more data. For example, assessing the health impacts of additional patients coming forward would take significantly more time.

202. Additional questions that could be considered alongside the review and evaluation of the intervention include:
    a) what do pharmacists and other professionals think about the new rules. We expect to receive feedback through trade body and other representatives as part of normal liaison procedures, but views could be examined further.
    b) is the intervention working for different groups of patients, for example those who are less well-off and more likely to benefit from the lower charges? Some socio-economic analysis can be done using the monitoring statistics, for example more deprived areas can be analysed separately.
    c) where can the policy be improved? This will include the question of the “correct” price for the HRT PPC, which as stated will be considered annually in November. It also includes questions of administrative efficiency and whether the issuance, processing payment for and monitoring of prescriptions and HRT PPC documentation could be improved. These questions would need to be addressed in discussion with those who are directly affected such as GPs and pharmacists.
    d) does the policy provide value for money? This is not a leading issue in this case because the main effect of the policy is a financial transfer rather than a decision to invest differently within the NHS. It is not practical or intended to assess what patients do with the money saved. We may review the use of official money spent on implementation and operation of the new system and identify any learning points or improvements that might emerge.
    e) Has the change in approach to charging HRT influenced changes in patient behaviour, for example, have patients who are already using the treatment, continue to do so for longer than they would have done, if the price hadn’t been reduced.
    f) Have there been any unintended consequences of the policy intervention?

14.8. Summary

203. This reform is relatively straightforward and many of the intended outputs and outcomes will be monitored and fully analysed through routine statistics collected within the NHS. There are some elements relating to patient behaviour that will require additional qualitative research with patients and other users of the system.

204. Aligning evaluation and monitoring with the annual prescription charge review cycle will ensure that the continuing effectiveness and desirability of the HRT PPC is reflected in decisions. This will be supplemented by a fuller review, possibly in November 2024, that considers the feedback and views expressed from stakeholders alongside the statistical analysis.

205. This combination approach is intended to provide a proportionate review of the policy. It will help assess the uptake of the HRT PPC and the administrative impacts, but is unlikely to be able to assess the long-term health impacts because they may take years to manifest themselves. The evidence is already very strong that HRT therapy provides significant benefits to those that use it. As such, the earlier review, without a consideration of longer-term health, will be sufficient.

14.9. Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

206. This reform is primarily a price change that results in a financial transfer from the NHS to patients. It does not involve radical change and it will cost DHSC and its arm's length bodies less than £10 million annually in administrative costs.

207. The main impact by value is the health gain arising from better HRT treatment being accessed by patients. This is expected to outweigh the opportunity cost to the NHS of any reduction in prescription charging revenue. It is also expected to accrue relatively quickly because many of the symptoms alleviated will lead to improved health now, as well as potentially improving health in the future.

208. As such, it is judged that it is proportionate to complete a full impact assessment of the effects, more so than would be required for a more routine simple price change.

209. The main risks involved are (1) not implementing reform and thus failing to improve women's healthcare, and (2) implementing reform in a way which damages the NHS. The latter is mitigated by the retention of a modest charge to preserve some revenue, and by the strong evidence base suggesting that HRT delivers significant health gains.

210. Although the precise value of benefits is uncertain, the prospect of achieving a positive NPV is very good, and a break-even analysis demonstrates that even very conservative assumptions would offset the system costs involved.

211. The level of analysis conducted is therefore considered sufficient to support the intervention.

Annex A. Literature Review on the Price Elasticity of Demand for Prescribed Medicines

This annex sets out the evidence used to inform the elasticity modelling used in this impact assessment.

There is little bespoke evidence for the price elasticity of demand for prescription charges for HRT specifically. There is, however, a body of research looking at prescription charges more generally (which includes HRT as one component). Research spans the UK and other countries. Some evidence is quite old but remains the best available.

UK

Studies conducted for the UK were published in the 80s-90s and look at the effect of introducing drug co-payments in the NHS or subsequent increases in charges on the utilisation of NHS prescribed drugs (dispensation). The PED values range from -0.09 to -0.64, i.e. a 10% increase in charges leads to a reduction in utilisation/dispensation of NHS drugs ranging from 0.9% to 6.4%. The table below summarises the PED values for the UK studies.

Table A.1. Summary of UK studies

Study	Price Elasticity of Demand
Hughes and McGuire (1995)	[-0.37, -0.32]
Lavers (1989)	-0.22
O'Brien (1989)	-0.23 for the initial period of 1969-1977 -0.64 later on for 1978-1986
Ryan and Birch (1991)	-0.11 for the short-run -0.09 for the long-run
Smith and Watson (1990)	-0.58

Wales

In Wales, prescription charges were abolished in April 2007. Cohen et al. (2010) look at the effect of this on rates of dispensing. General practice-level monthly dispensing data were compared before and after the abolition between Wales and Northeast England, where the charges were retained. The analysis included the 14 medicines that had the most items dispensed subject to charge before abolition. For the period analysed, dispensing increased significantly in both areas. However, results show that the Welsh policy was associated only with a modest increase in dispensing (16%) relative to that in Northeast East England (37%). The smaller relative increase in total dispensing rates in Wales suggests that the overall impact of the abolition was minimal.

This study provides a useful insight for the current HRT PPC policy in that the responsiveness of the demand for medicines to changes in prescription charges may not be symmetrical. Reductions in charges may have less impact on dispensing than the equivalent rises in charges to patients.

Other countries & Meta-analyses

A summary of relevant studies for other countries can be found in the table below

Table A.2. Summary of other countries and meta-analyses studies

Study	Country	Price Elasticity of Demand
Gemmill (2008)	Meta-analysis (studies from America and Canada)	PED for general population: [-0.58, -0.02] PED for the low-income population: [-0.20, -0.05] Adjusted PED: -0.16 (but not statistically significant)
Gemmill, Thomson and Mossialos (2008)	Meta-analysis (173 studies from 15 high-income countries)	[-0.56, -0.02] based on non-aggregate data [-0.08, -0.06] based on aggregated data
Simonsen, Skipper and Skipper (2010)	Denmark	[-0.25, -0.08]
Cantonyannis et al. (2005)	Canada (Quebec)	[-0.16, -0.12]
Fiorio and Siciliani (2010)	Italy	An increase in the co-payment by one Euro reduces the per capita number of prescriptions by 4% A reduction in the co-payment by one Euro increases the per capita number of prescriptions by 3.4%
Soni (2019)	US	-0.9 for Opioids
Gatwood et al. (2014)	US	-0.015 for Opioids -0.018 for Antiplatelets -0.032 for Thyroid hormone -0.051 for Anticonvulsants -0.064 for Statins -0.066 for Bisphosphonates -0.087 for Proton Pump Inhibitors -0.157 for Smoking deterrents

Annex B. Information on NICE's review and analysis on the cost effectiveness of HRT

NICE's Literature Review

The literature review includes 9 published studies. The economic evaluations considered various hormone replacement therapies (combined oestrogen and progestogen or oestrogen alone) and tibolone. All studies include a cost-utility analysis and used a Markov model except one (Ylikangas, 2005), which was a trial-based economic evaluation:

- Two US studies (Botteman, 2004; Lekander, 2005)
- Two UK studies (Lekander, 2009; Swift, 2005)
- One Swedish study (Zethraeus, 2005)
- Three Canadian studies (Coyle, 2003; Brown, 2006; Diaby, 2007)
- One Finish trial-based economic evaluation (Ylikangas, 2005)

The relevant incremental costs, benefits and ICER values from these studies are summarized in the table below.

Table B.1. NICE's Literature Review Summary

Study	Country	Study info	Costs	Main effects	ICER
Botteman (2004)	US	Study used a Markov decision-analytic model with a 1-year time horizon	NA/EE vs no therapy = $680.84 CEE/MPA vs no therapy = $847.93	NA/EE vs no therapy = 0.110 QALYs CEE/MPA vs no therapy = 0.104 QALYs	NA/EE dominates CEE/MPA NA/EE vs no therapy = $6,200 per QALY CEE/MPA vs no therapy = $8,200 per QALY
Brown (2006)	Canada	Study employed a Markov decision-analytic model with a 5-year time horizon	Patch vs oral = $296 Patch vs no therapy = $654-665	Patch vs oral = 0.00 QALYs Patch vs no therapy = 0.02-0.08 QALYs	Oral dominates patch Patch compared to no therapy for moderate (32,300 CAD per QALY) and severe (8,300 CAD per QALY)
Coyle (2003)	Canada	Study employed a Markov decision-analytic model with a 5-year time horizon	1st line: CEE/MPA vs no therapy = 100 CAD NA/EE vs CEE/MPA = 600 CAD 2nd line: CEE/MPA vs no therapy = 0 CAD NA/EE vs CEE/MPA = 400 CAD	1st line: CEE/MPA vs no therapy = 0.30 QALYs NA/EE vs CEE/MPA = 0.03 QALYs 2nd line: CEE/MPA vs no therapy = 0.37 QALYs NA/EE vs CEE/MPA = 0.02 QALYs	1st line: CEE/MPA vs no therapy = 333 CAD per QALY NA/EE vs CEE/MPA = 20,300 CAD per QALY 2nd line: CEE/MPA vs no therapy CEE/MPA dominates NA/EE vs CEE/MPA = 16,400 CAD per QALY

Lekander (2009a)	UK	Study employed a Markov decision analytic model with a lifetime horizon	Women with an intact uterus: HRT vs No therapy = 677 GBP Hysterectomised women: HRT vs No therapy = 252 GBP	Women with an intact uterus: HRT vs No therapy = 1.17 QALYs Hysterectomised women: HRT vs No therapy = 1.23 QALYs	Women with an intact uterus: HRT v no therapy = 580 GBP per QALY Hysterectomised women: HRT vs No therapy = 205 GBP per QALY
Lekander (2009b)	US	Study employed a Markov decision analytic model with a lifetime horizon	Women with an intact uterus: HRT vs No therapy = 3224 USD Hysterectomised women: HRT vs No therapy = 358 USD		Women with an intact uterus: HRT v no therapy = 2803 USD per QALY Hysterectomised women: HRT vs No therapy = 295 USD per QALY
Swift (2005)	UK	Study developed an economic model over a one-year time horizon	Low-dose vs high dose CE/MPA = -£1,443	Low-dose vs high dose CE/MPA = 0.62-1.49 QALYs	Low dose dominates high dose CE/MPA
Yilkangas (2007)	Finland	Study conducted a trial-based economic evaluation over a 9-year time horizon	ccHRT vs gen population = €101	ccHRT vs gen population = 0.022 QALYs The improvement in quality weight: 0.44 per annum for years 1-6 0.041 per annum for years 7-9 Average QALY gained per treated year (discounted at 3%) = 0.037 for ccHRT and 0.015 for controls	ccHRT vs gen population: Up to 9 years: €4613 per QALY Up to 5 years: €2996 per QALY Up to 1 year: €171 per QALY
Zethraeus (2005)	Sweden	Study employed a Markov decision analytic model with a lifetime horizon	Intact uterus HRT vs No HRT = SEK 15,242 Hysterectomised HRT vs No HRT = SEK 10,107	Intact uterus HRT vs No HRT = 1.19 QALYs Hysterectomised HRT vs No HRT = 1.22 QALYs	Intact uterus HRT vs No HRT = SEK 12,807 per QALY Hysterectomised HRT vs No HRT = SEK 8,266 per QALY HRT would remain cost-effective provided the quality of life scores > 0.013

NA/EE – norethindrone acetate / ethinyl oestradiol
CEE/MPA – conjugated oestrogens / medroxyprogesterone

NICE's own de Novo model

General Information

To also address more alternative treatments, NICE performed their own semi-Markov decision analytic model to assess the cost effectiveness of 5 years of use of HRT, non-HRT drugs, herbal preparations and other interventions given to menopausal women with vasomotor symptoms starting treatment at 50 years of age, the average age at which women typically start the menopause.

The model was run for three populations:

- Women with a uterus
- Women without a uterus
- Women who have had breast cancer or are at high risk of breast cancer

The clinical outcomes included in the health economic model are:

- Vasomotor symptoms
- Vaginal bleeding (not included as an outcome for women without a uterus)
- Discontinuation of treatment
- Breast cancer (not included as an outcome for women with breast cancer)
- Venous thromboembolism (VTE)

The treatment alternatives for each of the three different populations are listed below:

Table B.2. Treatment alternatives

Intervention	Women with Uterus	Women without Uterus	Women with breast cancer or high risk of breast cancer
No treatment	✓	✓	✓
Acupuncture	✓	✓	
Chinese herbal medicine	✓	✓	
Gabapentin	✓	✓	✓
Isoflavones / Genisten / Soy	✓	✓	✓
Multibotanicals	✓	✓	
Oestradiol + progestogen non-oral	✓	✓	
Oestradiol + progestogen oral	✓	✓	
Black cohosh	✓	✓	
Valerian root	✓	✓	
SSRI/SNRIs	✓	✓	✓
Tibolone	✓	✓	
St John's Wort			✓

Costs and benefits

For each intervention above, including the no treatment option, the costs and the benefits, measured in QALYs, are calculated based on the probabilities of various events and outcomes reflecting the comparative risks and benefits of the treatment alternatives derived from the evidence.

Costs are based on an NHS and Personal Social Services perspective as outlines in the NICE reference case (The guidelines manual, NICE November 2012). Costs are expressed in 2015 prices and since the analysis spans over 5 years, future costs are discounted at a rate of 3.5%. The costs taken into account include the actual treatment cost (e.g. the price of an oestrogen only patch), as well as the costs of an initial GP appointment, a gynaecologist appointment, and costs of resource use and those related to diagnosis (e.g. transvaginal ultrasound with biopsy, Doppler ultrasound, or a full blood count).

The health states utilities used in the model are shown in the table below. The model assumes that the decision maker has a willingness to pay for a QALY.

Table B.3. Health states utility decrement

Event	Health State utility decrement
Death	0.82
Hot flush	0.021
Bleeding	0.01
Breast Cancer	0.28
Venous thromboembolism	0.007

Results

The results from NICE's analysis are summarized in the table below. These suggest that, for women with a uterus, the non-oral oestradiol and progestogen treatment has the highest level of QALY gain, while also having an ICER falling within the willingness to pay threshold (£20,000-£30,000 per QALY). For women without a uterus, non-oral oestradiol has the highest level of QALY gain and it is also the most cost-effective treatment.

The net mean benefit is calculated as follows:

$$\text{Net Mean Benefit} = \text{Mean QALY} \times £20{,}000 - \text{Mean Cost}$$

The mean QALY is multiplied by £20,000 since this represent the decision maker's willingness to pay for a QALY gain of that specific magnitude. The mean cost and the mean QALY values are based on the cost and the QALY generated for each treatment in over 10,000 simulations.

The probability that each treatment is cost-effective reflects the degree of uncertainty in the results and is calculated from the number of times that a particular intervention is the most cost-effective over all individual simulations.

The ICERs are calculated relative to the next best non-dominated treatment alternative. Treatments that are marked as "dominated" have unambiguously preferred treatment alternatives offering a higher mean QALY and lower mean costs.

Table B.4. NICE's own analysis results

Treatment	Mean Cost	Mean QALY	Net Mean Benefit	Probability Cost-Effective	ICER
Women with a uterus					
No treatment	£0	0.0000	£0	2.2%	n/a
SSRIs/SMRIs	£33	0.0446	£860	18.6%	£735
Gabapentin	£53	0.0523	£994	15.0%	£2,580
Isoflavones/Genistein/Soy	£311	0.1094	£1,878	2.1%	Extended dominance
Oestradiol + Progestogen oral	£383	0.1034	£1,685	2.0%	Dominated
Valerian root	£435	0.0001	-£434	0.0%	Dominated
Black cohosh	£448	0.1613	£2,778	25.8%	£3,628
Multibotanicals	£481	0.0524	£566	5.3%	Dominated
Acupuncture	£545	0.1047	£1,549	7.5%	Dominated
Tibolone	£615	0.0974	£1,333	3.1%	Dominated
Oestradiol + Progestogen non-oral	£887	0.1856*	£2,825	18.4%	£18,083
Chinese herbal medicine	£2,030	0.0010	£2,009	0.0%	Dominated
Women without a uterus					
No treatment	£0	0.0000	£0	13.6%	n/a
SSRIs/SMRIs	£57	0.0406	£754	6.6%	Extended dominance
Gabapentin	£61	0.0601	£1,142	10.3%	£1,007
Oestradiol oral	£210	0.0897	£1,576	2.2%	Extended dominance
Isoflavones/Genistein/Soy	£314	0.1112	£1,911	1.5%	Extended dominance
Oestradiol non-oral	£357	0.1981	£3,606	39.1%	£2,149
Valerian root	£438	0.0001	-£437	0.0%	Dominated
Black cohosh	£450	0.1674	£2,899	19.4%	Dominated
Multibotanicals	£486	0.0589	£692	3.5%	Dominated
Acupuncture	£545	0.1083	£1,621	3.9%	Dominated
Chinese herbal medicine	£2,033	-0.0019	£2,072	0.0%	Dominated
Women with breast cancer					
No treatment	£545	0.0000	£0	9.3%	n/a
Gabapentin	£28	0.0598	£1,168	52.9%	£474
SSRIs/SMRIs	£33	-0.1662	-£3,358	2.8%	Dominated
Isoflavones/Genistein/Soy	£263	-0.0337	-£938	2.3%	Dominated
St John's Wort	£459	0.0919	£1,379	32.7%	£13,435

** value chosen for the cost-benefit analysis*

Sensitivity analysis conducted by NICE shows that, for women with a uterus, non-oral oestradiol and progestogen remains cost-effective even when varying the following:

- Symptom severity
- The costs and QALY losses from breast cancer
- The costs and QALY losses from VTE

- Treatment costs
- Discontinuation assumptions
- Health state utility losses from hot flushes
- QALY loss from bleeding

Additionally, for women without a uterus, non-oral oestradiol remains cost-effective even when varying the following:

- Symptom severity
- The costs and QALY losses from breast cancer
- Health state utility losses from hot flushes

Annex C. Social Cost Benefit Analysis for Option 2 – Low-end Scenario

Year	1	2	3	4	5	6	7	8	9	10
	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	2031/32	2032/33
PATIENT NUMBERS										
Existing number of HRT Patients	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000
Existing patients making savings (18%)	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000
New Patients due to price reduction (change in demand = 3.8%)	60,000	60,000	60,000	60,000	60,000	60,000	60,000	60,000	60,000	60,000
BENEFITS										
B1) Savings Benefits for Existing Patients (£30 per patient)	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000
QALYs due to HRT uptake (0.01237 per new patient)	796	796	796	796	796	796	796	796	796	796
B2) Monetised QALYs gained (£70,000 per QALY)	£55,730,000	£55,730,000	£55,730,000	£55,730,000	£55,730,000	£55,730,000	£55,730,000	£55,730,000	£55,730,000	£55,730,000
B3) Recouped sickness absence cost (£48.87 per patient)	£3,140,000	£3,140,000	£3,140,000	£3,140,000	£3,140,000	£3,140,000	£3,140,000	£3,140,000	£3,140,000	£3,140,000
NHS revenue gained from new patients (£18.70 per HRT PPC)	£1,200,000	£1,200,000	£1,200,000	£1,200,000	£1,200,000	£1,200,000	£1,200,000	£1,200,000	£1,200,000	£1,200,000
B4) Monetised QALYs gained from extra NHS revenue	£5,620,000	£5,620,000	£5,620,000	£5,620,000	£5,620,000	£5,620,000	£5,620,000	£5,620,000	£5,620,000	£5,620,000
Total Monetised Health Related Benefits (B2+B4)	£61,350,000	£61,350,000	£61,350,000	£61,350,000	£61,350,000	£61,350,000	£61,350,000	£61,350,000	£61,350,000	£61,350,000
Total Monetised Non-Health Related Benefits (B1+B3)	£12,140,000	£12,140,000	£12,140,000	£12,140,000	£12,140,000	£12,140,000	£12,140,000	£12,140,000	£12,140,000	£12,140,000
TOTAL BENEFITS	£73,490,000	£73,490,000	£73,490,000	£73,490,000	£73,490,000	£73,490,000	£73,490,000	£73,490,000	£73,490,000	£73,490,000
COSTS										
C1) Financial cost to new patients (£18.70 per HRT PPC)	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000	-£1,200,000
Lost revenue to the NHS in prescription charges	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000
Cost to the NHS in providing extra HRT healthcare	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000	-£3,860,000
Delivery cost to NHS BSA	-£110,000									
Operating cost to NHA BSA	-£2,060,000	-£900,000	-£1,000,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000
Optimism bias adjustment (25% increase in cost to NHS BSA)	-£540,000	-£230,000	-£250,000	-£270,000	-£270,000	-£270,000	-£270,000	-£270,000	-£270,000	-£270,000
Total financial cost to the NHS	-£15,580,000	-£13,990,000	-£14,110,000	-£14,200,000	-£14,200,000	-£14,200,000	-£14,200,000	-£14,200,000	-£14,200,000	-£14,200,000
C2) Opportunity cost (the value of the QALYs forgone due to lost NHS revenue)	-£72,710,000	-£65,280,000	-£65,870,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000
Cost to pharmacists contacting GP	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000
Cost to pharmacists performing manual checks	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000	-£1,720,000
Optimism bias adjustment (25% increase in costs to pharmacists)	-£530,000	-£530,000	-£530,000	-£530,000	-£530,000	-£530,000	-£530,000	-£530,000	-£530,000	-£530,000
C3) Total Cost for Pharmacists	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000	-£2,630,000
Total Monetised Health Related Costs (C2)	-£72,710,000	-£65,280,000	-£65,870,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000	-£66,260,000
Total Monetised Non-Health Related Costs (=C1+C3)	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000	-£3,830,000
TOTAL COSTS	-£76,540,000	-£69,110,000	-£69,700,000	-£70,090,000	-£70,090,000	-£70,090,000	-£70,090,000	-£70,090,000	-£70,090,000	-£70,090,000
NET BENEFITS	-£3,050,000	£4,380,000	£3,790,000	£3,400,000	£3,400,000	£3,400,000	£3,400,000	£3,400,000	£3,400,000	£3,400,000
PRESENT VALUES (in 2022/23 terms)										
Discounted Health Related Benefits (@ 1.5%)	£60,440,000	£59,550,000	£58,670,000	£57,800,000	£56,940,000	£56,100,000	£55,270,000	£54,460,000	£53,650,000	£52,860,000
Discounted Non-Health Related Benefits (@ 3.5%)	£11,730,000	£11,340,000	£10,950,000	£10,580,000	£10,230,000	£9,880,000	£9,550,000	£9,220,000	£8,910,000	£8,610,000
Discounted Health Related Costs (@ 1.5%)	-£71,630,000	-£63,360,000	-£62,990,000	-£62,430,000	-£61,500,000	-£60,600,000	-£59,700,000	-£58,820,000	-£57,950,000	-£57,090,000
Discounted Non-Health Related Costs (@ 3.5%)	-£3,700,000	-£3,580,000	-£3,460,000	-£3,340,000	-£3,230,000	-£3,120,000	-£3,010,000	-£2,910,000	-£2,810,000	-£2,720,000
Total Discounted Benefits	£72,170,000	£70,880,000	£69,620,000	£68,380,000	£67,170,000	£65,980,000	£64,820,000	£63,680,000	£62,560,000	£61,470,000
Total Discounted Costs	-£75,340,000	-£66,940,000	-£66,450,000	-£65,770,000	-£64,730,000	-£63,710,000	-£62,710,000	-£61,730,000	-£60,760,000	-£59,810,000
NET PRESENT VALUE	-£3,170,000	£3,940,000	£3,170,000	£2,610,000	£2,440,000	£2,270,000	£2,110,000	£1,950,000	£1,800,000	£1,660,000
									TOTAL NPV	£18,790,000

Annex D. Social Cost-Benefit Analysis for Option 2 – High-end Scenario

Year	1	2	3	4	5	6	7	8	9	10
	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29	2029/30	2030/31	2031/32	2032/33
PATIENT NUMBERS										
Existing number of HRT Patients	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000	1,700,000
Existing patients making savings (18%)	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000	300,000
New Patients due to price reduction (change in demand = 5.7%)	130,000	130,000	130,000	130,000	130,000	130,000	130,000	130,000	130,000	130,000
BENEFITS										
B1) Savings Benefits for Existing Patients (£30 per patient)	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000	£9,000,000
QALYs due to HRT uptake (0.01856 per new patient)	4,777	4,777	4,777	4,777	4,777	4,777	4,777	4,777	4,777	4,777
B2) Monetised QALYs gained (£70,000 per QALY)	£334,380,000	£334,380,000	£334,380,000	£334,380,000	£334,380,000	£334,380,000	£334,380,000	£334,380,000	£334,380,000	£334,380,000
B3) Recouped sickness absence cost (£48.87 per patient)	£6,290,000	£6,290,000	£6,290,000	£6,290,000	£6,290,000	£6,290,000	£6,290,000	£6,290,000	£6,290,000	£6,290,000
NHS revenue gained from new patients (£18.70 per HRT PPC)	£2,410,000	£2,410,000	£2,410,000	£2,410,000	£2,410,000	£2,410,000	£2,410,000	£2,410,000	£2,410,000	£2,410,000
B4) Monetised QALYs gained from extra NHS revenue	£11,230,000	£11,230,000	£11,230,000	£11,230,000	£11,230,000	£11,230,000	£11,230,000	£11,230,000	£11,230,000	£11,230,000
Total Monetised Health Related Benefits (B2+B4)	£345,610,000	£345,610,000	£345,610,000	£345,610,000	£345,610,000	£345,610,000	£345,610,000	£345,610,000	£345,610,000	£345,610,000
Total Monetised Non-Health Related Benefits (B1+B3)	£15,290,000	£15,290,000	£15,290,000	£15,290,000	£15,290,000	£15,290,000	£15,290,000	£15,290,000	£15,290,000	£15,290,000
TOTAL BENEFITS	£360,900,000	£360,900,000	£360,900,000	£360,900,000	£360,900,000	£360,900,000	£360,900,000	£360,900,000	£360,900,000	£360,900,000
COSTS										
C1) Financial cost to new patients (£18.70 per HRT PPC)	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000	-£2,410,000
Lost revenue to the NHS in prescription charges	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000	-£9,000,000
Cost to the NHS in providing extra HRT healthcare	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000	-£7,720,000
Delivery cost to NHS BSA	-£110,000									
Operating cost to NHA BSA	-£2,060,000	-£900,000	-£1,000,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000	-£1,070,000
Optimism bias adjustment (25% increase in cost to NHS BSA)	-£540,000	-£1,130,000	-£1,250,000	-£1,340,000	-£1,340,000	-£1,340,000	-£1,340,000	-£1,340,000	-£1,340,000	-£1,340,000
Total financial cost to the NHS	-£19,440,000	-£18,750,000	-£18,980,000	-£19,130,000	-£19,130,000	-£19,130,000	-£19,130,000	-£19,130,000	-£19,130,000	-£19,130,000
C2) Opportunity cost (the value of the QALYs forgone due to lost NHS revenue)	-£90,730,000	-£87,500,000	-£88,560,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000
Cost to pharmacists contacting GP	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000	-£390,000
Cost to pharmacists performing manual checks	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000	-£2,020,000
Optimism bias adjustment (25% increase in costs to pharmacists)	-£600,000	-£600,000	-£600,000	-£600,000	-£600,000	-£600,000	-£600,000	-£600,000	-£600,000	-£600,000
C3) Total Cost for Pharmacists	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000	-£3,010,000
Total Monetised Health Related Costs (C2)	-£90,730,000	-£87,500,000	-£88,560,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000	-£89,270,000
Total Monetised Non-Health Related Costs (=C1+C3)	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000	-£5,420,000
TOTAL COSTS	-£96,140,000	-£92,920,000	-£93,980,000	-£94,680,000	-£94,680,000	-£94,680,000	-£94,680,000	-£94,680,000	-£94,680,000	-£94,680,000
NET BENEFITS	£264,760,000	£267,980,000	£266,920,000	£266,220,000	£266,220,000	£266,220,000	£266,220,000	£266,220,000	£266,220,000	£266,220,000
PRESENT VALUES (in 2022/23 terms)										
Discounted Health Related Benefits (@ 1.5%)	£340,500,000	£335,470,000	£330,510,000	£325,630,000	£320,820,000	£316,070,000	£311,400,000	£306,800,000	£302,270,000	£297,800,000
Discounted Non-Health Related Benefits (@ 3.5%)	£14,770,000	£14,270,000	£13,790,000	£13,320,000	£12,870,000	£12,440,000	£12,020,000	£11,610,000	£11,220,000	£10,840,000
Discounted Health Related Costs (@ 1.5%)	-£89,380,000	-£84,940,000	-£84,700,000	-£84,110,000	-£82,860,000	-£81,640,000	-£80,430,000	-£79,240,000	-£78,070,000	-£76,920,000
Discounted Non-Health Related Costs (@ 3.5%)	-£5,230,000	-£5,060,000	-£4,880,000	-£4,720,000	-£4,560,000	-£4,410,000	-£4,260,000	-£4,110,000	-£3,970,000	-£3,840,000
Total Discounted Benefits	£355,270,000	£349,740,000	£344,300,000	£338,950,000	£333,690,000	£328,510,000	£323,420,000	£318,410,000	£313,490,000	£308,640,000
Total Discounted Costs	-£94,620,000	-£89,990,000	-£89,580,000	-£88,830,000	-£87,420,000	-£86,040,000	-£84,690,000	-£83,360,000	-£82,050,000	-£80,760,000
NET PRESENT VALUE	£260,660,000	£259,750,000	£254,720,000	£250,130,000	£246,270,000	£242,470,000	£238,730,000	£235,060,000	£231,440,000	£227,880,000
									TOTAL NPV	£2,447,110,000

Annex E. Bibliography

Botteman, M. F., Shah, N. P., Lian, J., Pashos, C. L., & Simon, J. A. (2004). A cost-effectiveness evaluation of two continuous-combined hormone therapies for the management of moderate-to-severe vasomotor symptoms. *Menopause*, *11*(3), 343-355.

Brown, A., Coyle, D., Chen, S., Cumming, D., & Mensinkai, S. (2006). Transdermal hormone replacement therapy patches for women with postmenopausal symptoms: Economic analysis of short-term use. *CCOHTA. Technology Report*, (61).

Cohen, D., Alam, M. F., Dunstan, F. D., Myles, S., Hughes, D. A., & Routledge, P. A. (2010). Abolition of prescription copayments in Wales: an observational study on dispensing rates. *Value in Health*, *13*(5), 675-680.

Contoyannis, P., Hurley, J., Grootendorst, P., Jeon, S. H., & Tamblyn, R. (2005). Estimating the price elasticity of expenditure for prescription drugs in the presence of non-linear price schedules: an illustration from Quebec, Canada. *Health economics*, *14*(9), 909-923.

Coyle, D., Cranney, A., & Tugwell, P. (2003). Economic evaluation of norethisterone acetate/ethinylestradiol (FemHRT®) for women with menopausal symptoms. *Pharmacoeconomics*, *21*(9), 661-669.

Fiorio, C. V., & Siciliani, L. (2010). Co-payments and the demand for pharmaceuticals: evidence from Italy. *Economic Modelling*, *27*(4), 835-841.

Gatwood, J., Gibson, T. B., Chernew, M. E., Farr, A. M., Vogtmann, E., & Fendrick, A. M. (2014). Price elasticity and medication use: cost sharing across multiple clinical conditions. *Journal of Managed Care Pharmacy*, *20*(11), 1102-1107.

Gemmil, M. (2008). *The price elasticity of demand for prescription drugs: An exploration of demand in different settings*. London School of Economics and Political Science (United Kingdom).

Gemmill, M. C., Thomson, S., & Mossialos, E. (2008). What impact do prescription drug charges have on efficiency and equity? Evidence from high-income countries. *International journal for equity in health*, *7*(1), 1-22.

Hughes, D., & McGuire, A. (1995). Patient charges and the utilisation of NHS prescription medicines: some estimates using a cointegration procedure. *Health Economics*, *4*(3), 213-220.

Kleinman, N. L., Rohrbacker, N. J., Bushmakin, A. G., Whiteley, J., Lynch, W. D., & Shah, S. N. (2013). Direct and indirect costs of women diagnosed with menopause symptoms. *Journal of occupational and environmental medicine*, *55*(4), 465-470.

Lavers, R. J. (1989). Prescription charges, the demand for prescriptions and morbidity. *Applied economics*, *21*(8), 1043-52.

Lekander, I., Borgström, F., Ström, O., Zethraeus, N., & Kanis, J. A. (2009). Cost-effectiveness of hormone replacement therapy for menopausal symptoms in the UK. *Menopause international*, *15*(1), 19-25.

Lekander, I., Borgström, F., Ström, O., Zethraeus, N., & Kanis, J. A. (2009). Cost-effectiveness of hormone therapy in the United States. *Journal of Women's Health*, *18*(10), 1669-1677.

O'Brien, B. (1989). The effect of patient charges on the utilisation of prescription medicines. *Journal of Health Economics*, *8*(1), 109-132.

Ryan, M., & Birch, S. (1991). Charging for health care: evidence on the utilisation of NHS prescribed drugs. *Social Science & Medicine*, *33*(6), 681-687.

Simonsen, M., Skipper, L., & Skipper, N. (2016). Price sensitivity of demand for prescription drugs: exploiting a regression kink design. *Journal of Applied Econometrics*, *31*(2), 320-337.

Smith, S., & Watson, S. (1990). Modelling the effect of prescription charge rises. *Fiscal Studies*, *11*(1), 75-95.

Soni, A. (2019). Health insurance, price changes, and the demand for pain relief drugs: evidence from Medicare Part D. *Kelley School of Business Research Paper*, (19-4).

Swift, J. A., Conway, P., & Purdie, D. W. (2005). A cost-utility analysis of low-dose hormone replacement therapy in postmenopausal women with an intact uterus. *Current medical research and opinion*, *21*(12), 2051-2061.

Ylikangas, S., Bäckström, T., & Heikkinen, J. (2007). Cost-effectiveness of continuous combined hormone replacement therapy in long-term use: economic evaluation based on a 9-year study in Finland. *Current medical research and opinion*, *23*(1), 57-64.

Zethraeus, N., Borgström, F., Jönsson, B., & Kanis, J. (2005). Reassessment of the cost-effectiveness of hormone replacement therapy in Sweden: results based on the Women's Health Initiative randomized controlled trial. *International journal of technology assessment in health care*, *21*(4), 433-441.

Zethraeus, N., Johannesson, M., & Jönsson, B. (1999). A computer model to analyze the cost-effectiveness of hormone replacement therapy. *International journal of technology assessment in health care*, *15*(2), 352-365.