

## EXPLANATORY MEMORANDUM TO

### THE NATIONAL HEALTH SERVICE (AMENDMENTS RELATING TO PRE-PAYMENT CERTIFICATES, HORMONE REPLACEMENT THERAPY TREATMENTS AND MEDICINE SHORTAGES) REGULATIONS 2023

2023 No. 171

#### 1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of His Majesty.

#### 2. Purpose of the instrument

- 2.1 The National Health Service (Amendments relating to Pre-Payment Certificates, Hormone Replacement Therapy Treatments and Medicine Shortages) Regulations 2023 amend four sets of Regulations. They will allow for the introduction of a dedicated Pre-payment Certificate (PPC) to reduce costs for patients who are prescribed Hormone Replacement Therapy (HRT) treatments, where these treatments are on a list published in the Drug Tariff. They will also facilitate changes to GP prescribing software in relation to shortages of medicines and to make a minor amendment in relation to charges for products supplied under a Serious Shortage Protocol (SSP). SSPs allow for alternatives to be supplied where prescription items are in serious shortage.
- 2.2 The Regulations amended by this instrument are:
- 2.3 (i) the National Health Service (Charges for Drugs and Appliances) Regulations 2015 (S.I. 2015/570, as amended), (the ‘Charges Regulations’) which will be amended to provide for the sale and use of a bespoke HRT only PPC and set the charge for it as £18.70 for 12 months, valid from the date of purchase, and which will enable the free supply of listed HRT medicines or appliances to holders of a valid HRT only PPC. The Charges Regulations will also be amended to ensure that where items need to be supplied under a SSP that might incur an additional charge (for example, a spacer device for a substituted inhaler), an additional prescription charge is not payable.
- 2.4 (ii) the National Health Service (General Medical Services) Regulations 2015 (S.I. 2015/1862, as amended) (the ‘GMS Regulations’) and the National Health Service (Personal Medical Services Agreements) Regulations 2015 (S.I. 2015/18879, as amended) (the ‘PMS Regulations’) will be amended to: require prescribers in GP practices to prescribe listed HRT items on a separate prescription; and to facilitate changes to GP prescribing software to provide GP practices with up-to-date information on shortages of any NHS medicines.
- 2.5 (iii) the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended) (the ‘PLPS Regulations’) will be amended to allow pharmacists to refuse to dispense items on mixed prescriptions that include listed HRT items and at least one other item, if a patient is claiming exemption from prescription charges for the listed HRT items on the basis of holding a valid HRT only PPC.
- 2.6 The main policy intention behind this instrument is to significantly reduce the cost of HRT prescriptions to treat menopause symptoms, and by doing so to ensure that these

treatments are more accessible for all who require them – and to seek compliance with regard to single item prescribing and dispensing of these items to ensure correct charges to patients and reimbursement for pharmaceutical and local pharmaceutical services contractors when dispensing a HRT prescription against a HRT only PPC.

- 2.7 The cost of the HRT only PPC will be twice the cost of an applicable prescription charge, which is currently £9.35 per item. Prescription charges are usually subject to inflationary annual uplifts that are applied from April of each year. If there is an inflationary uplift applied to prescription charges from 1st April 2023, the cost of the HRT only PPC will be uplifted to reflect that. This means that the charge specified for the HRT only PPC set out in this instrument is subject to potential change before this instrument comes into force, which will be made in line with the prescription charges uplift regulations, if made.

### **3. Matters of special interest to Parliament**

*Matters of special interest to the Joint Committee on Statutory Instruments*

- 3.1 None.

### **4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument is England and Wales.  
4.2 The territorial application of this instrument is England.

### **5. European Convention on Human Rights**

- 5.1 The instrument is subject to the negative resolution procedure and does not amend primary legislation, so no statement is required.

### **6. Legislative Context**

- 6.1 The Charges Regulations set the prescription charge payable for medicines and appliances supplied by the National Health Service in England. Patients requiring multiple prescriptions throughout the year can save money by purchasing a pre-payment certificate of either three or 12 months at a cost (as at the date of the making of these Regulations) of £30.25 or £108.10, respectively.
- 6.2 Although the charges levied under the Charges Regulations are generally for supplies against prescriptions, the Charges Regulations also provide for the prescription charge to be levied in some other circumstances. In particular, where a product is supplied against a SSP, a prescription charge is also generally payable – although there is a current exemption where the supply under the SSP is of a smaller quantity than the quantity specified in the prescription that the supply under the SSP replaces. SSPs are protocols issued, in England, by the Secretary of State that enable dispensers to supply an alternative product or products to a product ordered on a prescription, where the prescription item is or may become in serious shortage, without breaching either the PLPS Regulations or the Human Medicines Regulations 2012 (S.I. 2012/1916, as amended).
- 6.3 The GMS Regulations and the PMS Regulations set out the framework for general medical services (GMS) contracts and personal medical services (PMS) agreements respectively for general practice – and they include the statutory terms of service that apply to GPs providing general medical services under GMS contracts and PMS

agreements. These statutory terms of service include terms of service relating to prescribing.

- 6.4 The PLPS govern the arrangements in England, under Part 7 of the National Health Service Act 2006 for the provision of pharmaceutical and local pharmaceutical services. The core pharmaceutical or local pharmaceutical service is the dispensing of NHS prescriptions – and there are different statutory terms of service that cover the dispensing by the different types of pharmaceutical or local pharmaceutical services providers. The providers that are able to dispense medicines are community pharmacies that either are on an approved list of providers known as a pharmaceutical list or are commissioned to provide services under a local pharmaceutical services contracts – or they are dispensing doctors on an approved list of such doctors, which covers GP practices in some rural areas.

## **7. Background**

### *What is being done and why?*

- 7.1 As is noted above, the main policy intention behind this instrument is to significantly reduce the costs to patients of HRT prescriptions. The operational solution to deliver this reduction is to introduce a bespoke pre-payment certificate to enable a patient to reduce their annual HRT prescription costs through the purchase of an annual HRT only PPC for a one-off annual fee of (at the date of the making of this instrument) £18.70. This means they can obtain all of their NHS HRT items without paying any further charges for the duration of the validity of their HRT only PPC, provided those items are on a list published in the Drug Tariff, which is a monthly publication, now published exclusively online, compiled by the NHS Business Services Authority (BSA) and which is used as the essential basis for remunerating providers of pharmaceutical and local pharmaceutical services.

### *Explanations*

#### What did any law do before the changes to be made by this instrument?

- 7.2 The Charges Regulations allow patients to purchase a PPC for either a three or 12-month period, at a cost of £30.25 (3 months) or £108.10 (12 months) respectively. The existing PPC is aimed at patients accessing a wide range of prescription items for a single fee, which could include their current HRT prescriptions. The 12-month PPC can be paid for by monthly instalments and offers good value for money if a patient is not exempt from prescription charges and needs 12 or more prescription items a year. There was no provision for a bespoke HRT only PPC.
- 7.3 The policy context for the changes relating to SSPs and suppliers of prescribing software for GP practices is given below

#### Why is it being changed?

- 7.4 As noted above, the main policy intention is to reduce the costs of HRT prescriptions for patients whose primary medical need is HRT treatment with eligible medicines. However, it is important that we do so in a way that ensures, where possible, correct patient charging at the point of dispensing and that is consistent with our pharmacy reimbursement and recovery of charges processes following the dispensing of a HRT item against a HRT only PPC. This is what is behind the changes to ensure single item prescribing of the affected products and a discretion for providers of pharmaceutical

and local pharmaceutical services to refuse to dispense where this new rule is not followed.

- 7.5 Because there have been shortages of HRT products in the United Kingdom, the Department also looked at whether there were other changes that could be made to support the fair and effective management of shortages of medicines generally. This has led to the opportunity being taken to fix two further practical problems, one to do with prescription charging for items supplied under SSPs and the other to do with GP practice access to up-to-date information on supply shortages of medications (so that they can take mitigations e.g. prescribe suitable alternative medications of which there is not a shortage).

*What will it now do?*

*HRT only PPC introduction*

- 7.6 The principal change to the Charges Regulations will allow for the introduction of a dedicated HRT only PPC (whilst retaining the existing general PPCs) that is targeted at patients whose primary need is HRT for the treatment of menopause symptoms, although other patients prescribed with the same treatments for other purposes could also benefit. The change means that patients accessing only HRT treatments will pay significantly less, particularly if they are currently using either a 3 month or 12 month PPC to cover the cost of their HRT medicines. The HRT only PPC will be charged as two standard prescription charges, which are currently (at the time of the making of this instrument) £9.35 each, totalling £18.70 per 12 months (subject to any inflationary increases in the prescription charge).
- 7.7 The new HRT only PPC can be used to access a specific list of HRT prescription items. The current list is of products in scope, in Annex A, will be limited to licensed versions of those products, and as noted above, it will be published in the on-line Drug Tariff, which will enable patients, prescribers and pharmacists to view the list. The list of eligible HRT products will also be published on the HRT only PPC application website to ensure that the patient can check that they will be able to benefit from the HRT only PPC before purchasing a certificate.
- 7.8 The HRT only PPC has been developed in response to criticism in relation to access to HRT treatments for patients in England. The menopause will affect fifty percent of the population at some point in their lives and can have negative effects on their quality of life and ability to continue working.
- 7.9 Under the new legislation, a patient will be able to purchase a HRT only PPC from the NHS BSA's website, over the telephone or direct from a pharmacist who is authorised to sell existing general PPCs.
- 7.10 When a patient collects a prescription for an HRT treatment on the approved Drug Tariff list and presents a valid HRT only PPC, the pharmacist will not be required to charge them the applicable prescription charge for that prescription item.

*Prescription charges associated with SSP supplies*

- 7.11 As indicated above, the amendments also make a minor change to the Charges Regulations in relation SSPs. SSPs allow the Secretary of State to put in place alternative arrangements for supply where a drug or appliance is ordered on prescription but there is, or may in the future be, a serious shortage of the drug or appliance. Most commonly, this will mean the supply of a different prescription only

medicine, or a different quantity of a prescription only medicine, to that ordered by a prescriber. However, there may be circumstances where one product has to be replaced by two or more products – for example, where an inhaler medicine is self-administered by a bespoke spacer device, and the alternative product requires the supply of a new device as well as the inhaler. As a consequence of the amendment, in these circumstances, if the patient is a patient who pays prescription charges, they will still only pay one charge, even though they are being supplied with two products instead of one to manage the shortage. Similarly, if there were circumstances where the a product that being supplied free of charge to patients who would ordinarily pay prescription charges is replaced, under the SSP, by a product for which a charge would be levied, then the SSP supply will be free because the supply on prescription would have been free.

- 7.12 This issue came to light with a SSP for an inhaler product (Combisal).

*Changes to GP and community pharmacy terms of service to support the introduction of HRT only PPCs*

- 7.13 The amendments to the GMS Regulations and PMS Regulations will require a GP to prescribe listed HRT medications on a separate prescription form to avoid charged items and items that will be supplied free of charge under the HRT only PPC being prescribed on the same prescription. This is required as the NHS BSA's processes for calculating payments to pharmacists and the prescription checking procedures that are carried out as part of our recovery procedures are based on either all items on the prescription being supplied free of charge where the patient has an exemption under one of the various grounds, or holds a general PPC, or the applicable charge being collected by the pharmacy. Prescription charges collected under these arrangements are deducted from pharmacist contractors' payments. Where an exemption from charges is claimed by a patient, this may be checked by the NHS BSA to verify the patient's exemption. Where this cannot be done, this triggers the recovery processes which may lead to a patient being issued with a penalty charge notice. To ensure that pharmacies are correctly paid when supplying HRT medicines to a holder of a HRT only PPC, and to avoid the recovery procedures being inadvertently triggered, GPs are being required to prescribe HRT medicines on separate prescriptions. If they breach their obligations, the pharmacy will have a discretion to refuse to supply any or all of the items on the prescription.

*Changes to GP terms of service to support handling of medicines supply shortages*

- 7.14 The Department's Medicines Supply Team responds to shortages of medicines in a variety of ways and using a number of levers, but a key part of its strategy is the acquisition of information under the Health Service Products (Provision and Disclosure of Information) Regulations 2018 (S.I. 2018/677). There are however statutory limits to the uses to which the information that they gather can be put – and on the disclosure of that information.
- 7.15 A practical difficulty that has come to light is that while the Department can disclose information directly to GP practices about shortages and discontinuation of supplies of medicines, it is unable to do so via intermediaries who are not on the relevant statutory list of those who are entitled to receive that information. This means that, before now, information could not be supplied to the primary care IT system suppliers that supply the prescribing software that GP practices use, so that they could update

that software about medicines shortages in a way that will help support prescribing decisions in GP practices.

- 7.16 These Regulations provide a solution to that difficulty, but only where the GP practice wants to receive this type of information via its prescribing software and their IT system supplier has a programme available to support that function. In these circumstances, the GP practice's contract with their NHS commissioner will include a requirement that the GP contractor's contract with their IT system supplier will need to include appropriate provision to facilitate the necessary data flows, and the new data flows will then be subject to the same confidentiality requirements as would be in place if the information was supplied directly to the GP practice rather than indirectly via the IT systems supplier.
- 7.17 The IT system supplier will then be able access the Department's medicine supply portal and use the information within it in line with the Department's shortage standard when providing the information to the GP practice via the prescribing software. This will provide prescribers with up-to-date information about medicine supply shortages which they can consider when prescribing impacted medicines.
- 7.18 This will enable them to take mitigating steps, if this is possible, such as prescribing an alternative medicine or a smaller quantity of a medicine. This is intended to assist in helping to manage supply shortages, and to help reduce the number of prescriptions needing to be returned to GPs for a new prescription, which it is hoped will reduce potential pressure on pharmacies, the GP sector and patients.

## **8. European Union Withdrawal and Future Relationship**

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

## **9. Consolidation**

- 9.1 There are no plans to consolidate the Regulations impacted by these changes.

## **10. Consultation outcome**

- 10.1 The Department of Health & Social Care is not required to consult on the Charges Regulations. However, the following linked consultations took place on the wider changes and on the introduction of the HRT only PPC.
- 10.2 Customarily, DHSC seeks the views of the General Practitioners Committee of the British Medical Association (BMA) on changes to the GMS and PMS Regulations, and the Pharmaceutical Services Negotiating Committee (PSNC) on changes to the PLPS Regulations. DHSC has met with both representative bodies to discuss the policy changes and draft instrument, and responded to their comments, making changes to this instrument where appropriate.

## **11. Guidance**

- 11.1 Patients will be provided with information about the new HRT only PPC in time for its implementation on 1st April 2023 via targeted communications delivered through their GP practice, pharmacist, other NHS healthcare providers, and online through social media and relevant professional websites, most prominently the NHS BSA website.

- 11.2 Information about eligibility for help with health costs (including free NHS prescription items) and an online exemption checker tool to enable patients to check their eligibility for free prescriptions before they purchase either a general or HRT only PPC or pay the prescription charge before their items are dispensed, is available on the NHS BSA website. This will be updated to include information on whether the general PPC or the HRT only PPC is the most appropriate choice for each patient.
- 11.3 From 1st April 2023, patients will be able to purchase the HRT only PPC online through the NHS BSA website, over the phone or in-person at selected pharmacies (those who sell the general PPCs).
- 11.4 Professionals involved in the roll-out of the HRT only PPC, specifically GPs and pharmacists, will be provided with guidance by 1st April 2023 on how to prescribe and dispense items covered by the HRT only PPC.
- 11.5 The HRT items in scope for a reduced payment via the HRT only PPC will be added to the on-line Drug Tariff in the Notes on Charges section for the April 2023 published Drug Tariff and be presented on the NHS BSA's HRT only PPC application site to ensure the patient makes an informed choice.
- 11.6 The list of HRT items in scope for the HRT only PPC is attached in **Annex A**. This list, which will be limited to licensed versions of the products, will be published in the on-line Drug Tariff for April 2023 for pharmacists and prescribers, and as part of the NHS BSA application webpages for the HRT only PPC. This will enable patients to make an informed choice regarding the value for money aspects of an HRT only PPC and a general 3 or 12 month PPC.

## **12. Impact**

- 12.1 The impact on business, charities or voluntary bodies extends primarily to pharmacists who will be subject to different dispensing regulations in respect of HRT when the patient presents an HRT only PPC as opposed to paying the single charge per item.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An impact assessment in relation to the measures in these Regulations that relate to prepayment certificates for hormone replacement therapy treatments is being submitted with this memorandum and published alongside the Explanatory Memorandum on the [legislation.gov.uk](https://www.legislation.gov.uk) website.

## **13. Regulating small business**

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses.
- 13.3 As the PLPS Regulations concern the provision of NHS services in England on the basis of nationally determined terms of service, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed nation-wide standards and practices in the provision of such services as part of the nationally determined contractual framework.

## **14. Monitoring & review**

- 14.1 The approach to monitoring of this legislation is the same as it is for monitoring the annual prescription charging uplift. The cost of the HRT only PPC will be reviewed annually alongside the standard prescription charge and, if deemed necessary, will be

increased in April of each year. Any price uplift will be communicated widely in advance of the change being made.

- 14.2 The Department monitors the implementation and efficient operation of the GMS, PMS and PLPS Regulations, and has regular discussions with interested parties including the BMA and PSNC as mentioned in paragraph 10.2 above on any problems identified.

**15. Contact**

- 15.1 Carol Walker at the Department of Health and Social Care Telephone: 0113 2546384 or email: carol.walker@dhsc.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Kathryn Glover, Deputy Director for Medicines Regulation and Prescribing at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Neil O'Brien, Parliamentary Under Secretary of State for Primary Care and Public Health at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.



# Annex A

## A-Z list of HRT items in scope for the HRT only PPC

Product name	Ingredient
Bedol	(Estradiol 2mg)
Bijuve/Bijuva	(Estradiol 1mg; Micronised Progesterone 100mg)
Blissel	(Estriol 50mcg)
Climanor	(Medroxyprogesterone 5mg)
Clinorette	(Estradiol 2mg; Norethisterone 1mg)
Elleste Duet	(Estradiol 1mg and 2mg; Norethisterone 1mg)
Elleste Duet Conti	(Estradiol 2mg; Norethisterone 1mg)
Elleste Solo	(Estradiol 1mg and 2 mg)
Estraderm MX	(Estradiol 25mcg, 50mcg, 75mcg and 100mcg)
Estradot	(Estradiol 25mcg, 37.5mcg, 50mcg, 75mcg and 100mcg)
Estring (90-day preparation)	(Estradiol 7.5mcg/24 hours)
Estriol	(Estriol 0.01%)
Ethinylestradiol 10mcg	(Ethinylestradiol 10mcg)
Evorel	(Estradiol 25mcg, 50mcg, 75mcg and 100mcg)
Evorel Conti	(Estradiol 50mcg; Norethisterone 170mcg)
Evorel Sequi	(Estradiol 50mcg; Norethisterone 170mcg)
Femoston	Estradiol 1mg and 2mg; Dydrogesterone 10mg)
Femoston Conti	(Estradiol 500mcg and 1mg; Dydrogesterone 2.5mg and 5mg)
Femseven	(Estradiol 50mcg, 75mcg)
Femseven Conti	(Estradiol 50mcg; Levonorgestrel 7mcg)
FemSeven Sequi	(Estradiol 50mcg; Levonorgestrel 10mcg)
Gina	(Estradiol 10mcg)
Imvaggis	(Estriol 30mcg)
Indivina	(Estradiol 1mg and 2mg; Medroxyprogesterone 2.5mg and 5mg)
Kliofem	(Estradiol 2mg; Norethisterone 1mg)
Kliovance	(Estradiol 1mg; Norethisterone 500mcg)
Lenzetto	(Estradiol 1.53mg)
Livial	(Tibolone 2.5mg)
Mirena	(Levonorgestrel 20mcg/24 hours)
Novofem	(Estradiol 1mg; Norethisterone 1mg)
Oestrogel/dose	(Estradiol 0.06%)
Ovestin	(Estriol 1mg)
Premarin	(Conjugated oestrogen 300mcg, 625mcg and 1.25mg)
Premique low dose	(Conjugated oestrogen 300mcg; Medroxyprogesterone 1.5mg)
Progynova	(Estradiol 1mg and 2mg)
Progynova TS	(Estradiol 50mcg and 100mcg)

Sandrena	(Estradiol 500mcg and 1mg)
Tridestra	(Estradiol 2mg; Medroxyprogesterone 20mg)
Trisequens	(Estradiol 2mg/2mg/1mg; Norethisterone 1mg)
Utrogestan	(Micronised Progesterone 100mg and 200mg)
Vagifem	(Estradiol 10mcg)
Vagirux	(Estradiol 10mcg)
Zumenon	(Estradiol 1mg and 2mg)